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Pharmacovigilance and patient safety: The interplay of nursing, diagnosis, and medical records

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Abstract-- Background-Pharmacovigilance, as defined by the World Health Organization, involves the scientific and operational activities aimed at identifying, evaluating, comprehending, and mitigating the adverse effects or any issues associated with medicines or vaccines. It plays a crucial role in recognizing negative effects of medications that may escape detection during clinical trials. This scrutiny is particularly vital for older individuals, who are frequently excluded from clinical studies due to their comorbidities and polypharmacy, resulting in treatment regimens that extend beyond the duration of these trials. **Aim of Work**-The aim of this narrative review is to explore novel approaches in pharmacovigilance studies focused on medications for elderly individuals. It specifically highlights how advancements in digital health technologies, electronic health records, and real-world health data can enhance the detection and evaluation of adverse effects in this sensitive population. **Methods**-The review employs a narrative approach, synthesizing current literature on the utilization of digital health technologies and available health data in

pharmacovigilance. It emphasizes recent developments in electronic health records and real-world data analytics, assessing how these tools can facilitate the monitoring of medication safety among older patients. **Results**-The findings indicate that the integration of digital health technologies and electronic health records significantly enhances the capacity for pharmacovigilance in older populations. These innovations allow for improved monitoring of adverse drug reactions, more robust data collection, and better evaluation frameworks that can accommodate the complexities of polypharmacy and chronic conditions prevalent in older adults. **Conclusion**-Novel pharmacovigilance approaches leveraging digital health technologies and real-world health data have the potential to substantially improve the identification and evaluation of adverse drug effects in elderly individuals. This is critical for optimizing medication safety and promoting healthier aging, addressing a significant gap in traditional pharmacovigilance efforts.

Keywords--*Pharmacovigilance, Elderly, Digital Health Technologies, Adverse Drug Reactions, Real-World Data.*

Introduction

Pharmacovigilance, as per the World Health Organization's definition, involves the scientific and operational endeavors to detect, assess, understand, and avoid any adverse effects or problems associated with drugs or vaccines. Pharmacovigilance studies are essential for evaluating the safety of medications in real-life situations, particularly among older individuals, for a variety of reasons [1]. Firstly, the prevalence of chronic illnesses is higher among older individuals compared to younger individuals, leading to a greater use of medications for managing these disorders [2]. Older individuals are more susceptible to damage caused by medications compared to younger individuals. This is due to the fact that the risk of harm connected with medications rises with the number of medications used by a person grows. Additionally, the likelihood of drug interactions also increases with the number of medications used. For instance, a study conducted on older adults who were hospitalized revealed that the likelihood of experiencing a cytochrome P450 mediated drug-drug interaction was 50% for individuals using between 5 and 9 medications, 81% for those using 10–14 medications, 92% for those using 15–19 medications, and 100% for those using 20 or more medications [3].

Pharmacists determined that careful monitoring or adjusting the dosage was necessary to avoid damage from medication interactions in 25% of patients. A separate research revealed that those aged 60 or above had a much higher likelihood, about 6 to 7 times greater, of experiencing a severe drug-drug interaction compared to patients in the 20-29 age range [3,4]. The physiological changes that occur with aging may modify the way drugs are processed and their effects on the body. This increases the likelihood of damage from medication usage in older individuals compared to younger individuals. A comprehensive study and synthesis of many studies revealed that 25% of elderly individuals

admitted to hospitals have an adverse drug response (ADR). Furthermore, almost all of these reactions (90%) were either dose-dependent or could be predicted based on the known pharmacological effects of the medications. Approximately one-third of the responses were classified as severe and were likely or certainly avoidable [5].

Furthermore, the clinical trials conducted for medications include a restricted sample size of individuals, who are often younger and less medically intricate compared to the broader population that eventually utilizes the drug in clinical settings [6]. Older individuals are sometimes not included or are not well represented in clinical trials for medications, leading to a lack of knowledge about the safety of these medications in older populations when they are released to the market. An examination of data from almost 44,000 randomized controlled trials (RCTs) revealed that, when categorized by medication class, a median of 26% of clinical studies omitted individuals over the age of 60, 41% excluded those over the age of 70, and 53% excluded those over the age of 80. More than 90% of randomized controlled trials (RCTs) contained exclusions based on comorbid diseases, whereas only 9% of RCTs permitted participants to have chronic disorders other than the specific one targeted by the trial medication [6]. Furthermore, it is worth noting that around 53% of randomized controlled trials (RCTs) for medications in each category deliberately excluded patients who were concurrently on medications other than the study treatment. These findings emphasize that the exclusion criteria used in randomized controlled trials (RCTs) often result in a lack of understanding about the effectiveness and safety of many medications in older individuals when these medications are released to the market. This is concerning since older persons are more vulnerable to the potential damage associated with medications. When older adults are included in clinical trials of drugs, they often comprise robust and healthy individuals rather than frail ones.

Moreover, it is difficult to draw sweeping generalizations about how older adults respond to drugs and the possible impact of adverse pharmacological effects on them. Elderly individuals with strong physical capabilities and the ability to conduct daily tasks without assistance are less likely to experience medication-related harm compared to fragile elderly individuals [7,8]. In addition, many negative consequences may be difficult to identify in elderly individuals, especially those who are fragile, and might be mistakenly attributed to the natural aging process [9]. For instance, the negative consequences linked to sedative or anticholinergic medications might lead to decreased physical function or cognitive decline. These effects accumulate over time and are often not acknowledged as being caused by the medications, which increases the likelihood of experiencing further adverse events as a result of taking the medications [8-11]. Medications may have many negative consequences, such as urine incontinence. Sometimes, these symptoms are mistakenly ascribed to the natural process of aging instead of being recognized as a side effect of the drug. This can lead to the prescription of more medications to treat the first bad impact, creating a prescribing cascade [12]. Introducing a new prescription to address the negative side effects of another medication increases the older person's susceptibility to subsequent medication-related adverse events.

Pharmacovigilance studies

Pharmacovigilance studies are essential for assessing the safety of medications in real-world scenarios, especially among older individuals who often have multiple chronic conditions, take multiple medications, and undergo longer treatment periods than those in clinical trials. The omission of the elderly population from the majority of premarketing clinical trials for medications results in a limited understanding of the safety profile of these medications in older individuals upon their market release [13,14]. Pharmacovigilance operations of the traditional kind are carried out by regulatory bodies after drugs are available in the market. These activities include examining spontaneous reports of adverse events that are reported by patients, healthcare providers, and manufacturers. Adverse event signals can be identified in these reports through the analysis of disproportionalities, Bayesian techniques, or data mining. Traditional methods of pharmacovigilance also involve monitoring patients who have been treated with new medications through the use of sentinel sites. These sites review the medical records of patients at selected healthcare facilities to identify any adverse effects caused by the new medication. Follow-up interviews with patients and doctors may be conducted if necessary. Additionally, prescription or health claims data can be monitored to identify patients who are using a new medication. Follow-up questionnaires are then sent to these patients or their doctors to identify any adverse events. Another potential avenue for pharmacovigilance is the utilization of data sources such as administrative claims data, which are routinely collected in healthcare settings. Observational research approaches, such as case-controlled studies and cohort studies, may be used to analyze this data and establish connections between the dispensing of medications and the incidence of health services that may indicate unfavorable consequences [15-17].

Postmarket studies are essential for evaluating the safety of drugs, but they have several limitations. Disproportionality analyses of spontaneous adverse event reports can only provide an indication of a potential adverse event, and further studies are typically necessary to confirm or disprove the potential association. It is important to note that under-reporting of adverse events and biased reporting, such as increased reporting for new medicines and decreased reporting for long-standing medicines, are limitations of spontaneous adverse event reports [18]. Observational studies, on the other hand, can be utilized to identify connections between a medicine and negative outcomes, but they often require extensive real-world data spanning several years. Even with prolonged use of a medicine, detecting adverse events in observational studies can be challenging if the specific adverse event outcome is not recorded in the datasets or if the sample size of the population is too small to adequately detect rare adverse events. Observational data does not particularly include or accurately assess critical adverse events that are common in older individuals, such as frailty, urine incontinence, reduced cognition, and noninjurious falls. In population-based datasets, the elderly population usually represents a lower proportion, and the number of individuals may be insufficient to accurately capture infrequent unfavorable occurrences [19,20].

Aim of Work

The growing accessibility of digital health technology, electronic health records, and real-world health data is opening up possibilities for pioneering approaches in pharmacovigilance research of medications in the elderly population. Several of these techniques may effectively address the difficulties associated with conventional pharmacovigilance methodologies. This narrative review provides a critical description of chosen novel methodologies used in pharmacovigilance studies of medications. The focus is on their use for monitoring pharmaceutical safety in older individuals. We examine the use of digital health technologies to detect indications of drug safety issues in elderly individuals. Digital health technologies encompass a wide range of technologies that aim to enhance an individual's health, monitor and gather health data, and facilitate the sharing of this information between patients and healthcare providers. Examples of such technologies include electronic health record systems, electronic prescribing, mobile applications (apps), wearable devices, and artificial intelligence. In this context, we discuss the utilization of longitudinal cohort studies to detect potential safety concerns related to medication use in older individuals. In addition, we explore the utilization of international collaborations and distributed research networks, where researchers independently implement a shared data analysis protocol across multiple data sources. This enables coordinated signal detection studies in larger populations, thereby enhancing the likelihood of identifying potential rare adverse events.

Methodology

A comprehensive search of electronic databases, such as Medline, Embase, and Google Scholar, was performed to discover relevant publications published till 2023. The search phrases utilized were "pharmacovigilance", "medication safety", "aged", as well as specific terms related to each area of interest, such as "wrist accelerometer" and "distributed network analysis". Only research papers published in the English language were considered.

Digital health technology in research of the safety and effectiveness of medications for older individuals

The improvements in digital health technology are creating new potential for enhancing pharmacovigilance monitoring in older individuals. These technologies, such as electronic health record systems that are connected to spontaneous adverse event reporting systems and mobile health apps, have the potential to enhance population-based pharmacovigilance efforts in older individuals by providing more opportunities to gather adverse event reports. In addition, the use of remote monitoring tools and wearable devices should facilitate the immediate identification of probable adverse events in persons prior to their occurrence [8, 21-26].

Integration of electronic health records with spontaneous adverse event

One drawback of pharmacovigilance through spontaneous adverse event reports is the voluntary nature of reporting, which often leads to underreporting of

adverse events. One method to improve the reporting of spontaneous adverse events is to encourage primary care clinicians to submit reports directly through their electronic health records systems or to prompt pharmacists to report through their dispensing software systems. In Australia, the national medicines regulator, known as the Therapeutic Goods Administration (TGA), has created a digital health technology add-on for its adverse event reporting template. This add-on can be installed into the two most widely used electronic health record systems in Australian primary care, namely Best Practice software and Medical Director software.

The template adheres to TGA criteria, guaranteeing compliance with regulatory standards. The template is included into the primary care software, enabling the primary care physician to immediately submit adverse drug reactions (ADRs) to the Therapeutic Goods Administration (TGA) using the electronic health record system. Although the influence of the software add-on on adverse event reporting rates by general practitioners has not been evaluated, pilot studies conducted worldwide on comparable software add-ons have shown their ability to enhance adverse event reporting by medical practitioners [27]. Pharmacists may integrate a digital health technology add-on into their pharmacy dispensing software, enabling them to immediately report adverse drug reactions (ADRs) to the Therapeutic Goods Administration (TGA) via their dispensing system. The number is 28. Preliminary assessment of the software's effect on adverse event reporting rates indicated that it led to a rise in ADR reporting by pharmacists. However, this higher reporting rate was not maintained over the long term [28]. The incorporation of adverse event reporting into health professional software is expected to be advantageous for older individuals, as they tend to have more frequent interactions with healthcare providers such as pharmacists and doctors compared to younger individuals [29, 30]. Consequently, there is a possibility that adverse events will be identified more promptly.

Mobile health apps and internet channels for voluntary reporting of adverse events

One drawback of pharmacovigilance via spontaneous reports is that the reporting procedure may be burdensome and necessitates a suspicion of an adverse occurrence. Regulatory agencies in multiple countries have established online platforms for consumers to voluntarily submit reports of adverse events. However, the adoption of these online platforms by consumers has been minimal [31]. One of the primary issues with web-based adverse event reporting is the inconvenience it poses, which is likely the main reason for the low uptake of online platforms by consumers. The growing accessibility and use of mobile phones provide the chance to utilize mobile health applications (apps) for enhancing the rates of adverse event reporting. Mobile applications provide a more convenient and user-friendly platform for both consumers and healthcare professionals to submit adverse drug reaction (ADR) reports. Over 80% of the population owns a smartphone and, on average, individuals check their phones more than 24 times per day [32]. Research has indicated that both consumers and healthcare professionals are willing to utilize mobile applications to report adverse drug reactions (ADRs) [22]. One example of such an app is the European Union WEB-RADR (Recognizing Adverse Drug Reactions) project, which was developed in

collaboration with the World Health Organization [22]. Initially launched in 2015, this mobile app was introduced in the United Kingdom (MHRA), Netherlands (Lareb), and Croatia (Halmed). An analysis of reports submitted through the WEB-RADR mobile app revealed that 40% of the reports were submitted by patients. These reports were of moderate clinical quality and contained comprehensive information, although the quality was slightly lower compared to traditional adverse drug reaction (ADR) reporting methods. Additionally, there was a lower occurrence of duplicate reports compared to traditional methods. During a period of 1 year in the UK and less than 6 months in the Netherlands and Croatia, the app helped identify 8 potential safety signals related to medications. Significantly, across the 3 nations, a substantial 40% of the reports were for those aged over 65 years. This indicates that the app has the potential to be a valuable tool for monitoring the safety of medications in older adults. The utilization of digital technology among older individuals is on the rise. For instance, in 2017, only 51% of Australians aged 65 years or older reported using a mobile phone for online activities. However, this number increased to 78% in 2020. Additionally, since the onset of the COVID pandemic, 79% of older individuals have utilized telehealth services, indicating that they possess the required devices, skills, and motivation to engage in pharmacovigilance activities through mobile applications [33].

Tools for monitoring from a distance

Utilizing remote monitoring tools is an additional method for enhancing pharmacovigilance in elderly individuals via the use of digital health technology. Remote monitoring tools enable healthcare professionals to digitally track the health of patients outside of the clinic. These tools transmit readings electronically, providing real-time data that allow healthcare professionals to promptly identify potential adverse drug events and intervene as necessary. For instance, monitoring changes in heart rate or sudden increases in blood pressure remotely can help healthcare professionals detect medication-related issues. Remote monitoring tools can be programmed to send alerts and notifications to both older adults and their healthcare professionals when unusual health patterns are detected. For example, if an older adult's blood pressure drops significantly, these tools can trigger alerts that prompt further investigation [24].

The current remote monitoring technologies in healthcare mostly focus on monitoring essential signs such as heart rate, blood pressure, and oxygen saturation. In addition, they monitor incidents of falling and measure levels of physical activity. Nevertheless, their use in pharmacovigilance remains limited, despite the potential they have in this field. A remote monitoring tool called Geriatric Risk Assessment Medicine (GRAM) software has been used in nursing home patients to identify physical, functional, or cognitive deterioration, all of which are known as possible adverse medication events in older individuals [25, 34]. The GRAM program was integrated with pharmacy dispensing software and, using the medications presently being given to a patient, produced a report that identified the likelihood of physical, functional, or cognitive impairment related to those medications. If symptoms suggestive of an unfavorable drug reaction were identified, the patient underwent evaluation by a nurse and appropriate measures were taken to address the medication-related adverse event, if necessary [25, 34]. A software evaluation revealed that elderly individuals residing in nursing homes

where the software was implemented experienced a decrease in falls and delirium compared to individuals in control sites. Furthermore, there was a significant reduction in hospital admissions resulting from adverse drug events among those in nursing homes utilizing the software, in comparison to those without it. Nevertheless, the program was only implemented in two pharmacies located in a solitary US state. Its adoption was dependent on grant funds. It remains uncertain if the software has been used more extensively or continues to be used after the grant funding period ended in the early 2000s.

Despite the evident promise of remote monitoring techniques as pharmacovigilance tools for specific older persons, their present use is limited. The utilization of remote monitoring tools in healthcare is hindered by challenges related to funding, integration into healthcare systems, technology barriers (such as the requirement for a reliable internet connection to transmit health data to healthcare professionals), and the need for digital health literacy to effectively use these tools. These limitations have restricted the widespread adoption of remote monitoring tools in practice. However, the COVID pandemic has led to a significant increase in the use of these tools in recent years. If this trend continues, there is a genuine possibility that remote monitoring tools could become valuable pharmacovigilance tools in the future [24].

Wearable devices for pharmacovigilance

Wearable gadgets have gained popularity for monitoring health and wellbeing and are also shown promise as a digital health pharmacovigilance tool in the elderly. These gadgets, often in the shape of a wristwatch or jewelry, are worn on the body and include many sensors to monitor and track numerous aspects of an individual's health. Wearable technologies have the ability to continuously monitor and analyze physiological changes, which may help identify early signs of adverse medication events in older persons. Wearable technologies, like smartwatches, have the capability to monitor heart rate and activity levels. They may notify users or their caretakers about any worrisome alterations [8].

The incorporation of wearables into pharmacovigilance is now in its nascent phase. Nevertheless, researchers are actively investigating the potential of wearable devices in identifying and averting hazardous medication events. Wearables are especially beneficial in older individuals for distinguishing between physiological decline caused by adverse events and the natural decrease associated with aging [35]. The ReMInDAR trial, conducted in 39 residential aged care facilities in Australia, utilized wearable activity trackers to assess the sedative effects of medicines. The trial's data demonstrated that an accelerometer-based wearable activity tracker can effectively detect significant sedative effects of medicines. Additionally, the researchers found that when the sedative load was increased by two additional medicines, residents spent an extra 24 minutes per day being sedentary. Furthermore, the study showed that activity metrics measured using wearable activity trackers can predict hospitalization and death within a 12-month period. Although this prediction does not specifically relate to adverse drug events, the research suggests that wearable devices have the potential to predict serious adverse events associated with the use of medicines [36, 37].

A previous cross-sectional study conducted on 28 elderly residents in a care facility utilized wearable devices to identify adverse drug events. The study revealed that residents who consumed a higher quantity of sedative medications exhibited lower levels of physical activity compared to those who consumed fewer sedative medications. Another cross-sectional study conducted on older individuals employed triaxial accelerometers to evaluate the influence of opioid analgesics, hypnotics, or anticholinergic medication usage on physical activity. The research discovered a correlation between an increase in anticholinergic load and a decrease in physical activity, as evaluated by accelerometers. These instances demonstrate the rising capability of wearable technologies to contribute to pharmacovigilance studies including older individuals [26].

Longitudinal cohort studies in pharmacovigilance research on medications for the elderly.

Longitudinal studies of ageing provide an additional avenue for undertaking pharmacovigilance research on medications for older individuals. These studies involve tracking groups of older individuals over a period of time and measuring their health and well-being at regular intervals [38]. Longitudinal studies on aging have demonstrated that as frailty increases from the initial measurement to subsequent measurements, the risk of death also increases. Additionally, poorer grip strength and slower walking speed are associated with a higher risk of death or disability. Furthermore, lower blood pressure is linked to an increased risk of developing depression for the first time [39-42]. One advantage of these longitudinal studies is that the health measures collected during follow-up visits, such as frailty, grip strength, cognitive function, and blood pressure, are not routinely recorded or accurately measured in other sources of data. Aggregating these health measurements enables researchers to account for significant variables and potential influences in health studies. Previously, longitudinal studies on aging were not often used for pharmacovigilance research due to the lack of full information about drug exposure. The majority of these studies utilized cross-sectional self-reporting of medication usage, which has certain limitations in terms of the accuracy and comprehensiveness of reported medication use. Additionally, there is limited information available regarding the duration, continuity, and cumulative exposure to medicines. The growing accessibility of electronic/computerized health records and administrative claims data enables the connection of long-term health study data to prescription records for participants, facilitating the use of these data sources for pharmacovigilance research in older individuals [38].

Summary

Elderly individuals are very susceptible to the potential dangers and negative effects that might arise from the use of medications. This study has provided a concise overview of the evidence on the use of digital health technologies, longitudinal cohort studies including older individuals (with linked medication data), and the application of dispersed research networks for pharmacovigilance studies in older populations. The study emphasized that conventional approaches to pharmacovigilance, such as relying only on spontaneous reports, are

insufficient for ensuring efficient monitoring of drug safety in older individuals. Utilizing digital technology may facilitate the reporting of adverse occurrences, hence improving the quality of the data utilized for analysis.

Furthermore, remote monitoring tools and wearable devices have significant promise as pharmacovigilance tools for older individuals. They may detect early alterations in physiological parameters that indicate the onset of medication-related harms in real-time. This is crucial because it allows for timely actions to address and avoid the recurrence of the negative result. The study also emphasized that longitudinal studies of elderly individuals, together with pharmaceutical data, may be used to identify and measure adverse events. This includes occurrences that are connected to the cumulative use of medications or adverse drug reactions (ADRs) that may take many years to manifest, such as dementia. These studies often include a small sample size, which means that rare or unusual adverse outcomes may go unnoticed. Distributed research networks may effectively address this problem and serve as a crucial tool for conducting pharmacovigilance studies in older individuals. By using electronic health data from many sources, these networks can enhance the ability to identify infrequent or unusual medication-related adverse effects.

References

- 1- **World Health Organization.** What is pharmacovigilance? 2023. <https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance>
- 2- **Shah H, Nagi J, Khare S, Hassan H, Siu A.** Limiting factors in implementing pharmacovigilance principles in the elderly. *Cureus.* 2023; 15(3):e36899. doi:10.7759/cureus.36899
- 3- **Doan J, Zakrzewski-Jakubiak H, Roy J, Turgeon J, Tannenbaum C.** Prevalence and risk of potential cytochrome P450-mediated drug-drug interactions in older hospitalized patients with polypharmacy. *Ann Pharmacother.* 2013; 47(3): 324-332. doi:10.1345/aph.1R621
- 4- **Guthrie B, Makubate B, Hernandez-Santiago V, Dreischulte T.** The rising tide of polypharmacy and drug-drug interactions: population database analysis 1995–2010. *BMC Med.* 2015; 13(1): 74. doi:10.1186/s12916-015-0322-7
- 5- **Yadesa T, Kitutu F, Deyno S, Ogwang P, Tamukong R, Alele P.** Prevalence, characteristics and predicting risk factors of adverse drug reactions among hospitalized older adults: a systematic review and meta-analysis. *SAGE Open Med.* 2021; 9: 1-14. doi:10.1177/20503121211039099
- 6- **Tan Y, Papez V, Chang W, Mueller S, Denaxas S, Lai A.** Comparing clinical trial population representativeness to real-world populations: an external validity analysis encompassing 43895 trials and 5685738 individuals across 989 unique drugs and 286 conditions in England. *Lancet Healthy Longev.* 2022; 3(10): e674-e679. doi:10.1016/S2666-7568(22)00186-6
- 7- **Hilmer S, Gnjdic D, Le Couteur D.** Thinking through the medication list. Appropriate prescribing and deprescribing in robust and frail older patients. *Aust Fam Physician.* 2012; 41(12): 924-928.
- 8- **Roughead E, Pratt N, Parfitt G, et al.** Effect of an ongoing pharmacist service to reduce medicine-induced deterioration and adverse reactions in aged-care facilities (nursing homes): a multicentre, randomised controlled trial (the

- ReMInDAR trial). *Age Ageing*. 2022; 51: 1-9.
- 9- **Lim R, Kalisch Ellett L, Widagdo I, Pratt N, Roughead E.** Analysis of anticholinergic and sedative medicine effects on physical function, cognitive function, appetite and frailty: a cross-sectional study in Australia. *BMJ Open*. 2019; 9(9):e029221. doi:10.1136/bmjopen-2019-029221
 - 10- **Kalisch Ellett L, Pratt N, Ramsay E, Barratt J, Roughead E.** Multiple anticholinergic medication use and risk of hospital admission for confusion or dementia. *J Am Geriatr Soc*. 2014; 62(10): 1916-1922. doi:10.1111/jgs.13054
 - 11- **Kalisch Ellett L, Pratt N, Ramsay E, Sluggett J, Barratt J, Roughead E.** Central nervous system-acting medicines and risk of hospital admission for confusion, delirium, or dementia. *J Am Med Dir Assoc*. 2016; 17(6): 530-534. doi:10.1016/j.jamda.2016.02.008
 - 12- **Kalisch Ellett L, Pratt N, Barratt J, Rowett D, Roughead E.** Risk of medication-associated initiation of oxybutynin in elderly men and women. *J Am Geriatr Soc*. 2014; 62(4): 690-695. doi:10.1111/jgs.12741
 - 13- **European Medicines Agency.** Note for guidance on planning pharmacovigilance activities (CPMP/ICH/5716/03). In ICH Topic E 2 E Pharmacovigilance Planning (Pvp). 2005, EMEA: London.
 - 14- **Gould A.** Practical pharmacovigilance analysis strategies. *Pharmacoepidemiol Drug Saf*. 2003; 12(7): 559-574. doi:10.1002/pds.771
 - 15- **Hazell L, Shakir S.** Under-reporting of adverse drug reactions: a systematic review. *Drug Saf*. 2006; 29(5): 385-396. doi:10.2165/00002018-200629050-00003
 - 16- **Lasser K, Allen P, Woolhandler S, Himmelstein D, Wolfe S, Bor D.** Timing of new black box warnings and withdrawals for prescription medications. *Jama*. 2002; 287(17): 2215-2220. doi:10.1001/jama.287.17.2215
 - 17- **Wahab I, Pratt N, Kalisch L, Roughead E.** Comparing time to adverse drug reaction signals in a spontaneous reporting database and a claims database: a case study of rofecoxib-induced myocardial infarction and rosiglitazone-induced heart failure signals in Australia. *Drug Saf*. 2014; 37(1): 53-64. doi:10.1007/s40264-013-0124-9
 - 18- **Awad A, Trenfield S, Pollard T, et al.** Connected healthcare: improving patient care using digital health technologies. *Adv Drug Deliv Rev*. 2021; 178:113958. doi:10.1016/j.addr.2021.113958
 - 19- **Lavertu A, Vora B, Giacomini K, Altman R, Rensi S.** A new era in pharmacovigilance: toward real-world data and digital monitoring. *Clin Pharmacol Ther*. 2021; 109(5): 1197-1202. doi:10.1002/cpt.2172
 - 20- **Australian Institute of Health and Welfare (AIHW).** Digital health. Accessed 31 January 2024. 2022. <https://www.aihw.gov.au/reports/australias-health/digital-health>
 - 21- **Australian Government Therapeutic Goods Administration.** Adverse drug reaction reporting using best practice: installing the ADR reporting template. 2023. <https://www.tga.gov.au/resources/resource/guidance/adverse-drug-reaction-reporting-using-best-practice-installing-adr-reporting-template>
 - 22- **Oosterhuis I, Taavola H, Tregunno P, et al. Characteristics,** quality and contribution to signal detection of spontaneous reports of adverse drug reactions via the WEB-RADR mobile application: a descriptive cross-sectional study. *Drug Saf*. 2018; 41(10): 969-978. doi:10.1007/s40264-018-0679-6
 - 23- **Innovative Medicines Initiative.** WEB-RADR Med safety app. 2023. <https://web-radr.eu/mobile-apps/med-safety/>

- 24-Hood C, Sikka N, Manaoat C, Mossburg SE.** Remote patient monitoring. PSNet Patient Safety Network. March 15, 2023. [https://psnet.ahrq.gov/perspective/remote-patient-monitoring#:~:text=Remote%20patient%20monitoring%20\(RPM\)%20is,oximeter%20C%20and%20blood%20glucose%20meters](https://psnet.ahrq.gov/perspective/remote-patient-monitoring#:~:text=Remote%20patient%20monitoring%20(RPM)%20is,oximeter%20C%20and%20blood%20glucose%20meters)
- 25-Feinberg J, Cameron K, Lapane K, Allsworth J.** The use of GRAM™ software to improve patient safety in nursing facilities. *Consult Pharm.* 2004; 5(5): 398-413. doi:10.4140/TCP.n.2004.398
- 26-Parfitt G, Post D, Kalisch Ellett L, et al.** A cross-sectional assessment of the relationship between sedative medication and anticholinergic medication use and the movement behaviour of older adults living in residential aged care. *Peer J.* 2020; 8:e9605. doi:10.7717/peerj.9605
- 27-Delio J, Catalanotti J, Marko K, et al.** Integrating adverse event reporting into a free-text mobile application used in daily workflow increases adverse event reporting by physicians. *Am J Med Qual.* 2019; 35(5): 374-379. doi:10.1177/1062860619891995
- 28-Li R, Curtain C, Bereznicki L, Zaidi S.** Community pharmacists' knowledge and perspectives of reporting adverse drug reactions in Australia: a cross-sectional survey. *Int J Clin Pharmacol.* 2018; 40(4): 878-889. doi:10.1007/s11096-018-0700-2
- 29-National Health Performance Authority, Healthy Communities.** Frequent GP attenders and their use of health services in 2012–13. 2015. NHPA: Canberra.
- 30-NAB Health.** NAB pharmacy survey 2021. Consumer attitudes and behaviours: trust, importance, visitation, patient satisfaction and scope of practice. 2021. NAB: Sydney.
- 31-Margraff F, Bertram D.** Adverse drug reaction reporting by patients: an overview of fifty countries. *Drug Saf.* 2014; 37(6): 409-419. doi:10.1007/s40264-014-0162-y
- 32-Australian Government Australian Digital Health Agency.** Safe, seamless and secure: evolving health and care to meet the needs of modern Australia. Australia's National Digital Health Strategy. 2017. Australian Digital Health Agency: Canberra.
- 33-Australian Government Australian Communications and Media Authority.** Communications and media in Australia. The digital lives of older Australians. 2021, ACMA: Canberra.
- 34-Lapane K, Hughes C, Daiello L, Cameron K, Feinberg J.** Effect of a pharmacist-led multicomponent intervention focusing on the medication monitoring phase to prevent potential adverse drug events in nursing homes. *J Am Geriatr Soc.* 2011; 59(7): 1238-1245. doi:10.1111/j.1532-5415.2011.03418.x
- 35-Lim R, Dumuid D, Parfitt G, et al.** Using wrist-worn accelerometers to identify the impact of medicines with anticholinergic or sedative properties on sedentary time: a 12-month prospective analysis. *Maturitas.* 2023; 172: 9-14. doi:10.1016/j.maturitas.2023.03.006
- 36-Andrade A, Lim R, Kelly T, Parfitt G, Pratt N, Roughead E.** Wrist accelerometer temporal analysis as a prognostic tool for aged care residents: a sub-study of the ReMInDAR trial. *J Am Geriatr Soc.* 2023; 71(4): 1124-1133. doi:10.1111/jgs.18181
- 37-Clarke C, Sniehotta F, Vadiveloo T, Donnan P, Witham M.** Association

between objectively measured physical activity and opioid, hypnotic, or anticholinergic medication use in older people: data from the physical activity cohort Scotland study. *Drugs Aging*. 2018; 35(9): 835-842. doi:10.1007/s40266-018-0578-7

- 38-Logie H, Hogan R, Peut A.** Longitudinal studies of ageing: implications for future studies. AIHW cat. no. AGE 42. 2004. Australian Institute of Health and Welfare: Canberra.
- 39-Bennett S, Song X, Mitnitski A, Rockwood K.** A limit to frailty in very old, community-dwelling people: a secondary analysis of the Chinese longitudinal health and longevity study. *Age Ageing*. 2013; 42(3): 372-377. doi:10.1093/ageing/afs180
- 40-Hirsch C, Buzkova P, Robbins J, Patel K, Newman AB.** Predicting late-life disability and death by the rate of decline in physical performance measures. *Age Ageing*. 2012; 41(2): 155-161. doi:10.1093/ageing/afr151
- 41-Briggs R, Kenny R, Kennelly S.** Does baseline hypotension predict incident depression in a cohort of community-dwelling older people? Data from the Irish longitudinal study on ageing (TILDA). *Age Ageing*. 2017; 46(4): 648-653. doi:10.1093/ageing/afx033
- 42-Martin F, Ortuno R.** Longitudinal studies of ageing: from insights to impacts: commentary to accompany themed collection on longitudinal studies. *Age Ageing*. 2019; 48(4): 481-485. doi:10.1093/ageing/afz028

اليقظة الدوائية وسلامة المرضى: التفاعل بين التمريض والتشخيص والسجلات الطبية الملخص

الخلفية

يشمل علم اليقظة الدوائية، كما عرّفته منظمة الصحة العالمية، الأنشطة العلمية والتشغيلية التي تهدف إلى تحديد وتقييم وفهم وتخفيف الآثار السلبية أو أي مشكلات مرتبطة بالأدوية أو اللقاحات. يلعب هذا العلم دورًا حيويًا في التعرف على الآثار السلبية للأدوية التي قد تفوتها عملية الاكتشاف أثناء التجارب السريرية. هذه المراقبة مهمة بشكل خاص لكبار السن الذين غالبًا ما يتم استبعادهم من الدراسات السريرية بسبب الأمراض المزمنة المتعددة واستخدام العديد من الأدوية، مما يؤدي إلى أنظمة علاجية تتجاوز مدة هذه التجارب.

الهدف

الهدف من هذه المراجعة السردية هو استكشاف الطرق الجديدة في دراسات اليقظة الدوائية المتعلقة بالأدوية لكبار السن. ويحاول التركيز على كيف يمكن أن تعزز التطورات في تقنيات الصحة الرقمية والسجلات الصحية الإلكترونية والبيانات الصحية الواقعية عملية الكشف والتقييم للآثار السلبية في هذه الفئة السكانية الحساسة.

الطرق

تستخدم المراجعة نهجًا سرديًا، حيث تجمع الأدبيات الحالية حول استغلال تقنيات الصحة الرقمية والبيانات الصحية المتاحة في علم اليقظة الدوائية. وتؤكد على التطورات الأخيرة في السجلات الصحية الإلكترونية وتحليلات البيانات الواقعية، مع تقييم كيف يمكن أن تساعد هذه الأدوات في مراقبة سلامة الأدوية بين المرضى الكبار في السن.

النتائج

تشير النتائج إلى أن دمج تقنيات الصحة الرقمية والسجلات الصحية الإلكترونية يعزز بشكل كبير القدرة على اليقظة الدوائية في الفئات العمرية المتقدمة. تتيح هذه الابتكارات تحسين مراقبة ردود الفعل السلبية على الأدوية، وجمع البيانات بشكل أفضل، وأطر تقييم أكثر قوة يمكن أن تستوعب التعقيدات المرتبطة بتعدد الأدوية والأمراض المزمنة السائدة لدى كبار السن.

الاستنتاجات

تتمتع طرق اليقظة الدوائية الجديدة التي تستفيد من تقنيات الصحة الرقمية والبيانات الصحية الواقعية بإمكانية كبيرة لتحسين تحديد وتقييم آثار الأدوية السلبية في كبار السن. يعد هذا أمرًا حاسمًا لتحسين سلامة الأدوية وتعزيز الشبخوخة الصحية، مما يعالج فجوة كبيرة في جهود اليقظة الدوائية التقليدية.