

Prototype of information system for adverse drug reaction monitoring in hospitals

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Abstract

Adverse Drug Reaction Monitoring (ADRM) is one of the responsibilities of pharmacists in hospitals. However, practitioners experience problems documenting monitoring results due to the limited support for digital-based information systems. Our article presents a prototype information system for pharmacists to store data on the results of ADRM activities. The prototype includes a flowchart and user interface design of the system's operations. The preparation of flowcharts uses the draw.io application, which is confirmed by the design of the user interface developed with the Microsoft PowerPoint application. Our prototype shows a series of menus beginning with user login, a three-step ADRM data input process, and two steps for displaying patient data. Furthermore, the development of prototypes in the form of software applications will present a digital-based transformation of the role of pharmacists, which certainly optimizes performance in ADRM documentation. The proposed data analysis approach, as well as system performance, has been tested. The results show that this system can potentially increase the spontaneous reporting rate of suspected adverse drug reactions.

Keywords

Adverse drug reaction monitoring, Digital-based information systems, Prototype

Introduction

In order to ensure the safety of national drug use, adverse drug effect monitoring (ADRM) is one part of clinical pharmacy services in hospitals [1][2]. This activity encourages pharmacists to monitor each patient's response after taking the drug [3][4]. Unusual events that are not caused by drug use are the subject of ADRM's activity report to the national drug control regulator [5]. After a decade of ADRM implementation, pharmacists have experienced problems optimizing the documentation of monitoring activities [6][7]. The limited number of facilitated personnel and the system of manually

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documenting notes on paper [8] are a combination of obstacles to the successful provision of ADRM result reports [9].

Digitalization of the national pharmaceutical system is a strategic solution to problems arising from manual-based documentation of reports [10–12]. A few transformations have taken place for priority programs, such as the supervising of therapeutic activities for tuberculosis patients [13]. Information system-based reports make it easier for pharmacists to quickly capture and access essential data [14]. In other pharmacy service lines, drug administration monitoring of each patient in the ward has been developed so that pharmacists can monitor in real-time without face-to-face interaction [15–17]. The digital transformation of pharmaceutical service operations results from the success of monitoring patient health based on medical records [18].

Based on the presentation above, the author concludes that the era of digitalization in the pharmaceutical service space is starting to develop and has become a primary need for optimizing the pharmacists' performance. Nonetheless, not all lines have been transformed in the information system scheme, but the only line monitoring drug side effects on patients has. Our article presents a *prototype* of the information system for pharmacists to store data on the results of ADRM activities. Our presentation is on the basis of software development so that the performance of documenting monitoring results is more optimal.

Methods

The researchers initiated the analysis of ADRM scale digitization needs with literature observations that revealed various obstacles in the documentation of monitoring results. We conclude the workflow of pharmacists in ADRM activities based on our observations.

ADRM's operational workflow is the basis for the preparation of the business processes that we pour into compiling flowcharts using draw.io applications that are available online free of charge to confirm the feasibility of the flowchart, the researcher confirmed it by compiling a user interface design as a prototype blueprint that we produced. We compiled the user interface design and navigation structure using the Microsoft PowerPoint application. The prototype results have been presented in a scientific discussion forum for pharmacy students and reviews and feedback have been received from them.

Results and Discussion

We present the information system workflow for ADRM on two sides (Figure 1). The left side shows officers in the data input process on the side effect monitoring results form. The right side shows the flow of the ADRM data search process or the process of obtaining the presentation of the results of the ADRM recapitulation. Supervisory-level pharmacists who handle pharmaceutical policy services typically use the right side.

User interface design for data input officers, beginning with the main page to allow access to the option of logging in as a user or supervisor and assisting service providers with problem resolution (Figure 2). Access to enter using two usernames and passwords owned by each officer (Figure 3). After completing the form, the officer enters several pieces of data, including the patient's basic characteristics (Figure 4), manifestations of side effects experienced by the patient (Figure 5), and details of drugs taken prior to experiencing side effects (Figure 6). After successfully entering the entire dataset, the system will confirm to the officer that the dataset has been saved (Figure 7).

The user interface display for supervisor access begins with the main page for selecting the role status in the login (Figure 8), then continues with filling in the username and password (Figure 9). Supervisors have the right to access ADRM result information based on the patient's identity or the type of manifestation of side effects (Figure 10). After a successful search, the supervisor obtained a display of the patient's identity, manifestations of side effects, and a history of drugs suspected of triggering those side effects (Figure 11).

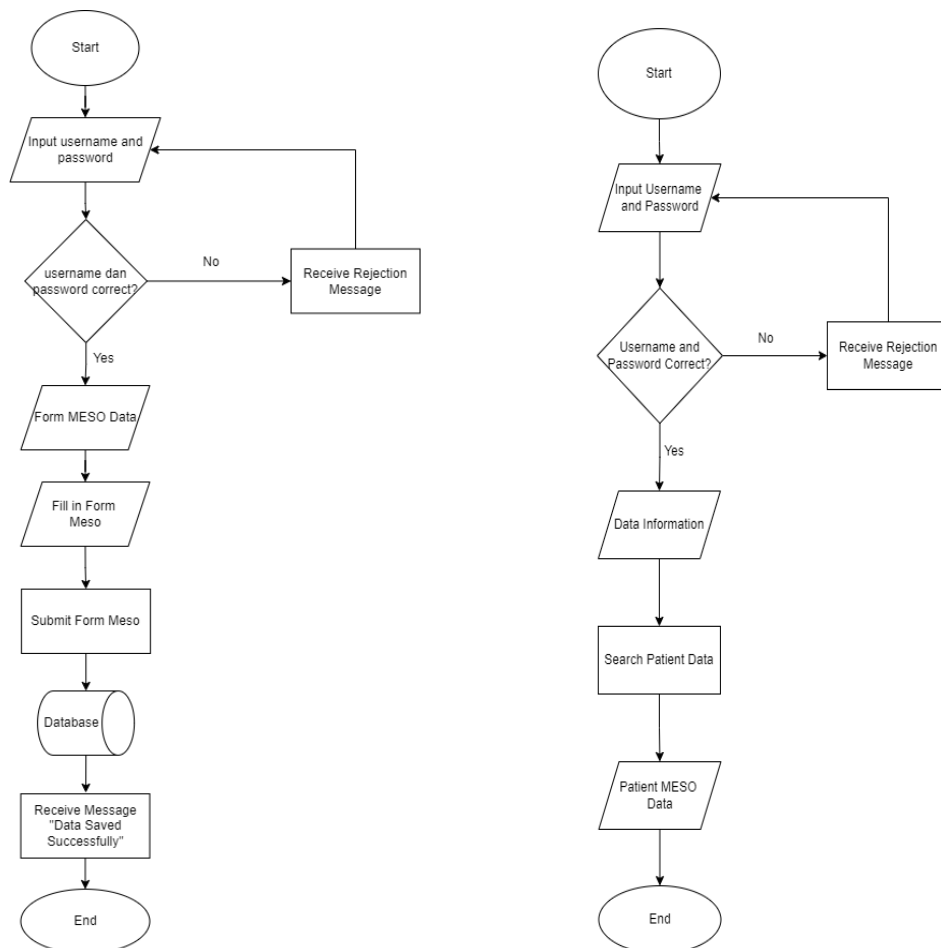


Figure 1. Flowchart operational business process monitoring side effects in hospital pharmacy installations

The purposes of making this application include: making it easier to recap ADRM result data and making it easier for pharmacists to collect patient information data and all incoming ADRM data so that it becomes a source of policy-making data, minimizing the

risk of recurrence and incidence of unwanted drug reactions [19][20]. This is because Adverse Drug Reactions are unintended consequences of drug therapy that can result in hospitalizations or even deaths [21][22]. Reporting ADR to regulatory supervisors on time is critical for research, drug monitoring, and patient safety maintenance [23]. Adverse drug reactions documentations that are incomplete or incorrect can limit prescribing options, resulting in inadequate pharmaceutical care [12][24].

The application we developed was intended to support the acceleration of the realization of the national e-health system launched by the government. This application is included in the classification of "E-Kesehatan Care Application," where this application supports the care and maintenance of health services [25]. The treatment and handling of health services in question take the form of monitoring the side effects of patient drugs. In addition, based on government regulation number 46 the year 2014, information data collection is carried out through medical record collection activities including electronic medical records and non-electronic medical records [26].

Identifying ADRs directly from free-text electronic health record (EHR) notes could solve the issue of underreporting in a structured format by healthcare professionals [27]. With the growing use of technology as well as the standardization of electronic health records (EHR), data can be stored permanently and more readily accessible at the time of therapy initiation, for instance during hospital admission [28].

With the growing use of technology as well as the standardization of electronic health records (EHR), data can be stored permanently and more readily accessible at the time of therapy initiation, for instance during hospital admission [26][28]. Though it may be challenging to fully turn to automated process, but as constant effort to the implementation of going online for the data inputting process, it becomes critical to implement more carefully designed computing algorithms to aid the cause - and - effect reasoning process, which may substitute some manual procedures in the evaluation. There are two primary approaches to achieving this goal. To begin, it is critical to comprehend and document well-designed reasoning processes in current practice. A good reasoning process reduces evaluation variations and incoherence [28]. Lastly, in the reasoning process, integrating information from various sources is critical for reaching conclusive results.

ADR monitoring applications offer several benefits. First, they improve patient safety by identifying potential ADRs early. This allows healthcare providers to act before the ADR becomes more severe. Second, ADR monitoring applications can help healthcare providers make more informed prescribing decisions. By providing real-time data on ADRs, healthcare providers can make better decisions about which drugs to prescribe. Finally, ADR monitoring applications can help regulatory agencies identify safety issues associated with drugs and medications. This information can then be used to inform regulatory decisions and improve patient safety. Apart from observation, during the data collection stage for analysis needs, no supporting questionnaires or interviews were held with pharmacists [29-31].

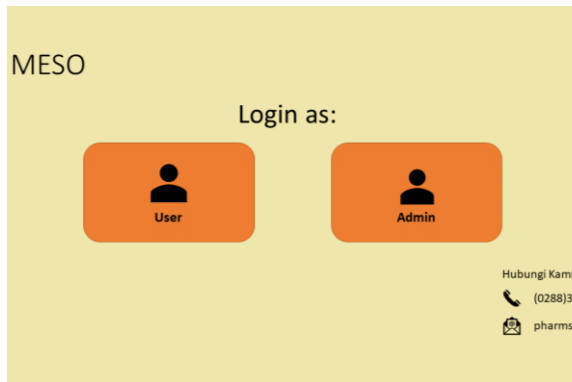


Figure 2. Main page view

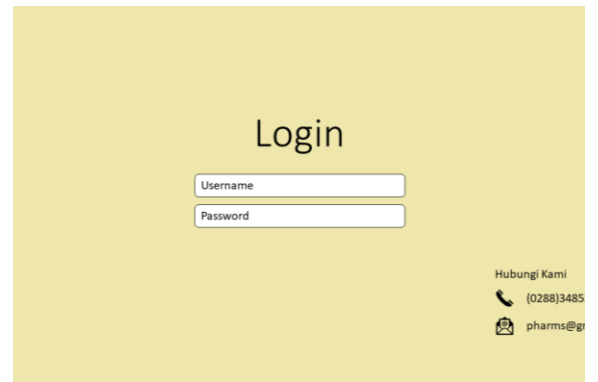


Figure 3. Log in User page view

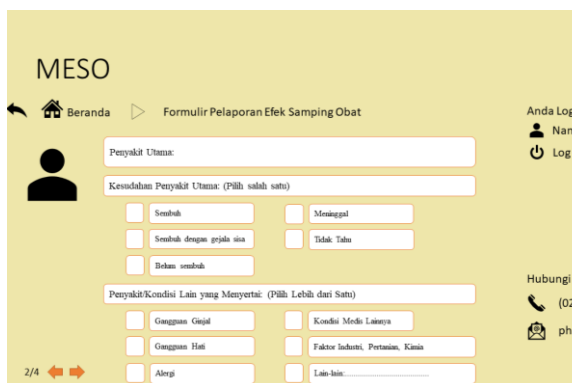


Figure 4. The display of the patient's basic characteristics data input page on the form

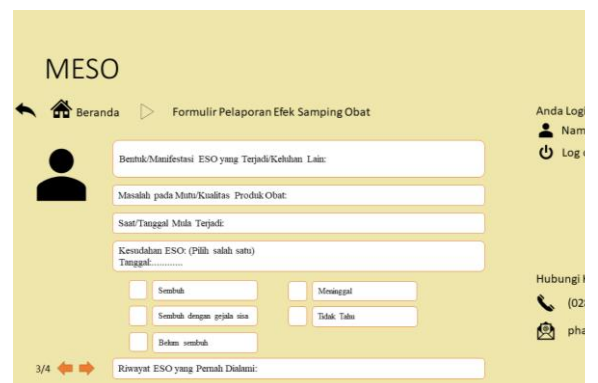


Figure 5. The display of the page inputs the manifestation of side effects on the form

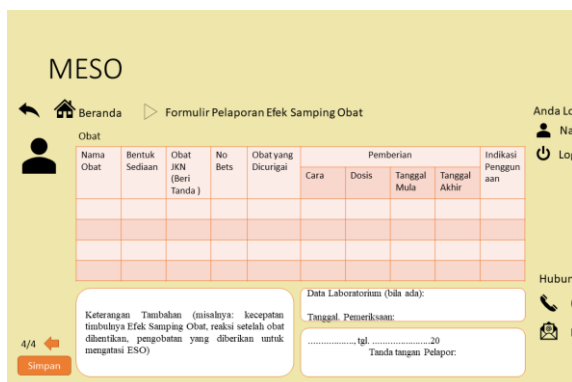


Figure 6. Display of the drug details input page on the form

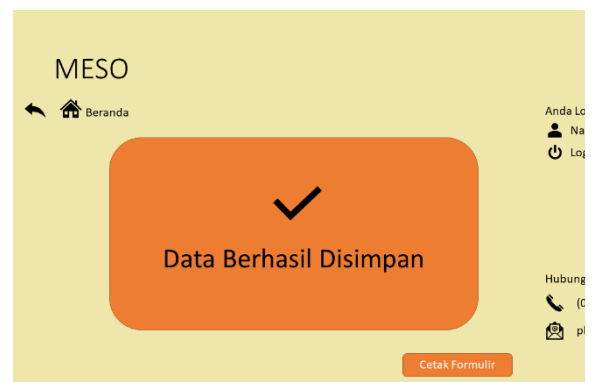


Figure 7. Display after successful data input on the form

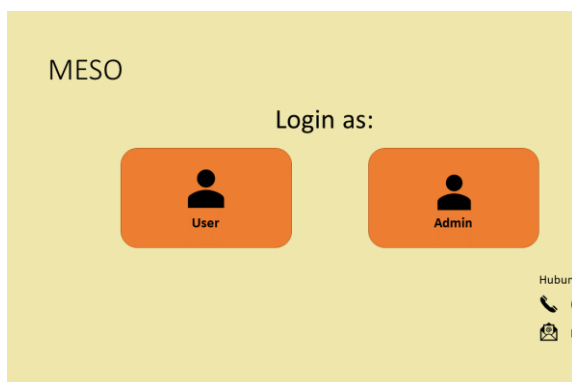


Figure 8. Main page view

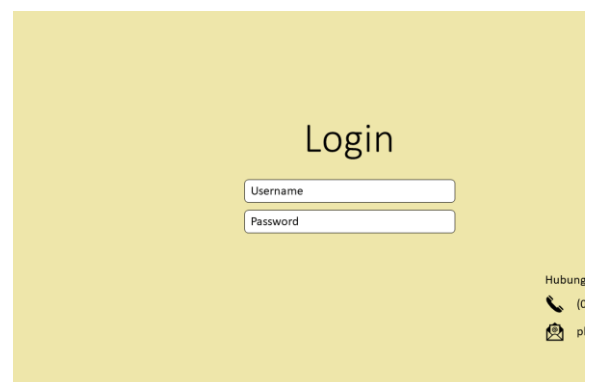


Figure 9. Log in Supervisor page view

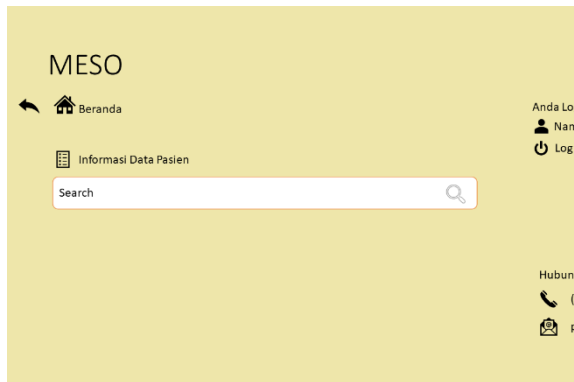


Figure 10. Page view of the disbursement of the patient's identity or the type of side effect desired

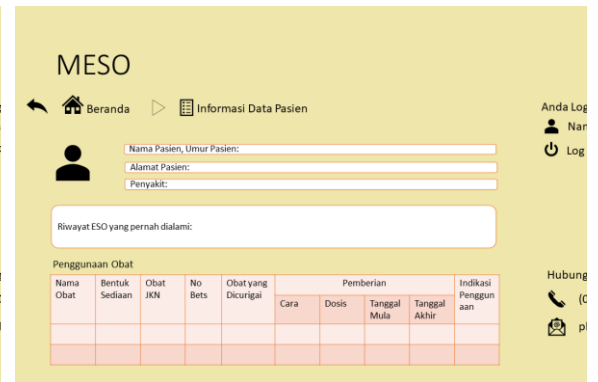


Figure 11. A page display of the input of the manifestation of side effects along with a history of suspected therapy

Conclusion

Further research can develop an adverse drug reaction monitoring information system that is equipped with more comprehensive predisposing factors. This paper's ADRM information system prototype displays a list of menus starting with the user login, three steps of the ADRM data input process, and two steps of displaying patient data. The continuation of prototype development in the form of software applications will lead to the transformation of the role of digital-based pharmacists, which optimizes ADRM documentation performance.

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References

- [1] BPOM RI, *Pedoman Monitoring Efek Samping Obat (MESO) Bagi Tenaga Kesehatan*. Jakarta: Direktorat Pengawasan Distribusi Produk Terapetik dan PKRT Badan POM RI, 2012.
- [2] 'Panduan Monitoring Efek Samping Obat RSUD Dr. Saiful Anwar Malang'. Rumah Sakit Muji Rahayu Surabaya, 2017.
- [3] S. B. Santoso, H. Lutfiyati, U. H. Afifi, and S. Ratnafuri, 'Quality of Life Profile Based on Controlled First-line Antiretroviral Treatment in Patients with HIV Infection', in *Proceedings of the 2nd Borobudur International Symposium on Humanities and Social Sciences, BIS-HSS 2020, 18 November 2020, Magelang, Central Java, Indonesia, Magelang, Indonesia, Sep. 2021*. doi: 10.4108/eai.18-11-2020.2311628.
- [4] S. B. Santoso, H. Lutfiyati, R. I. Prasadha, S. Ratnafuri, and K. A. Azzahra, 'What Do Patients with Hiv-Infection Perceive and Know Regarding to Antiretrovirals? An Exploration Among Participants Undergoing Controlled-Therapy', *Technology Report Kansai University*, vol. 62, no. 04, p. 8, Apr. 2020.
- [5] *Peraturan Menteri Kesehatan Nomor 72 Tahun 2016 Standar Pelayanan Kefarmasian di Rumah Sakit*. 2016.
- [6] H. Lutfiyati, P. Pribadi, and S. B. Santoso, 'Kesiapan Apoteker dalam Memberikan Layanan Medication Therapy Management', *CERATA Jurnal Ilmu Farmasi*, vol. 10, no. 1, p. 5, Jul. 2019.
- [7] H. Lutfiyati, B. Mintarsih, S. B. Santoso, and D. K. Dewi, 'Evaluasi Sumber Daya Apoteker Berdasarkan Standar Pelayanan Kefarmasian Terkait Sumber Daya Manusia di Apotek Kabupaten Temanggung', in *Challenges & Opportunities of Pharmapreneurship 4.0 in Universal Health Coverage (UHC) Era*, Surakarta, Indonesia, 2020.

- [8] D. Pandiangan, 'Kajian Kinerja Kefarmasian Di RUMAH SAKIT Dr. Ferdinand Lumbantobing Sibolga Tahun 2020', *Jurnal Inovasi Kesehatan Masyarakat*, vol. 2, no. 2, 2021.
- [9] H. Tika, 'Evaluasi Tingkat Pengetahuan, Sikap dan Praktik Apoteker Rumah Sakit Tentang Pelaporan Monitoring Efek Samping Obat Di Kota Bengkulu'. Universitas Andalas, 2021.
- [10] N. U. Salamah, N. R. Majid, A. F. Makarim, P. Pribadi, and S. B. Santoso, 'Website-based Scientific Traditional Medicine Information Prototype', in *Peran Perguruan Tinggi dalam Menjaga Stabilitas Nasional pasca Pandemi Covid-19*, Universitas Muhammadiyah Gombong, Mar. 2022.
- [11] P. D. Savita, D. Miftahuda, W. A. Safi, and S. B. Santoso, 'Online Home Pharmacy Care Prototype', in *Peran Perguruan Tinggi dalam Menjaga Stabilitas Nasional pasca Pandemi Covid-19*, Universitas Muhammadiyah Gombong, Mar. 2022, p. 8.
- [12] S. L. Anggitha, N. Rahayu, P. Pribadi, and S. B. Santoso, 'Telegram-Bot Applications in Drug Information Services and Pharmaceutical Counseling', in *Peran Perguruan Tinggi dalam Menjaga Stabilitas Nasional pasca Pandemi Covid-19*, Universitas Muhammadiyah Gombong, Mar. 2022, p. 8.
- [13] H. Hayurani and F. D. Hartanti, 'Sistem Monitoring Dan Controlling Pasien Tuberkulosis (Tb)', *Jurnal Teknologi Informasi YARSI*, vol. 3, no. 1, pp. 8–17, 2016.
- [14] E. Yulianti, A. A. K. O. Sudana, N. Made, and I. Marini, 'Perancangan Sistem Informasi Manajemen Rumah Sakit Modul Farmasi', *Perancangan Sistem Informasi Manajemen Rumah Sakit Modul Farmasi*, vol. 6, no. 2, pp. 96–107, 2015, doi: 10.24843/LKJITI.6.2.16704.
- [15] R. Agussalim, A. Adnan, and M. Niswar, 'Monitoring Cairan Infus Berdasarkan Indikator Kondisi Dan Laju Cairan Infus Menggunakan Jaringan Wifi', *ILKOM Jurnal Ilmiah*, vol. 8, no. 3, pp. 145–152, 2016, doi: 10.33096/ilkom.v8i3.69.145-152.
- [16] S. B. Santoso, M. H. N. Majid, A. A. Suryaningtyas, R. Faizah, and I. M. P. Wibowo, 'Interaction Exchange in Dispensaries: An Observation on the Chronic Disease Management Program', in *Proceedings of the 2nd Borobudur International Symposium on Humanities and Social Sciences, BIS-HSS 2020, 18 November 2020, Magelang, Central Java, Indonesia, Magelang, Indonesia, Sep. 2021*. doi: 10.4108/eai.18-11-2020.2311623.
- [17] A. A. Suryaningtyas, A. N. Vianto, M. B. Octaviano, and S. B. Santoso, 'The Pharmacist-Patient Communication Model in the Chronic Disease Management Program', in *Proceedings of the 2nd Borobudur International Symposium on Humanities and Social Sciences, BIS-HSS 2020, 18 November 2020, Magelang, Central Java, Indonesia, Magelang, Indonesia, Sep. 2021*. doi: 10.4108/eai.18-11-2020.2311746.
- [18] A. R. Pratama, D. A. Hutagalung, W. Siregar, and H. Sihombing, 'Monitoring patient health based on medical records using fuzzy logic method', *Sinkron*, vol. 3, no. 2, p. 20, 2019, doi: 10.33395/sinkron.v3i2.10014.
- [19] J. Fossouo Tagne, R. A. Yakob, T. H. Dang, R. Mcdonald, and N. Wickramasinghe, 'Reporting, Monitoring, and Handling of Adverse Drug Reactions in Australia: Scoping Review', *JMIR Public Health Surveill*, vol. 9, p. e40080, Jan. 2023, doi: 10.2196/40080.
- [20] C. Foreman, W. B. Smith, G. E. Caughey, and S. Shakib, 'Categorization of Adverse Drug Reactions in Electronic Health Records', *Pharmacol Res Perspect*, vol. 8, no. 2, Apr. 2020, doi: 10.1002/prp2.550.
- [21] S. B. Santoso, P. U. Chabibah, and P. Pribadi, 'Resiko Hepatotoksik Populasi Indonesia Akibat Polimorfisme Enzim NAT2 dan CYP2E1 dalam Metabolisme Isoniazid', *UJAS*, vol. 1, no. 1, pp. 9–16, Apr. 2021, doi: 10.53017/ujas.11.
- [22] D. Brandariz-Nãã, 'Prevalence of adverse drug reactions associated with emergency department visits and risk factors for hospitalization', *Farmacia Hospitalaria*, 2023.
- [23] S. Wardani, S. H. P. Nugroho, and S. B. Santoso, 'An evaluation of Dehydration Assessment and Zinc Administration in Children with Acute Diarrhea in Hospitals', in *Proceedings of the 2nd Borobudur International Symposium on Humanities and Social Sciences, BIS-HSS 2020, 18 November 2020, Magelang, Central Java, Indonesia, Magelang, Indonesia, 2021*. doi: 10.4108/eai.18-11-2020.2311762.
- [24] R. Braund, C. K. Lawrence, L. Baum, B. Kessler, M. Vassart, and C. Coulter, 'Quality of Electronic Records Documenting Adverse Drug Reactions Within a Hospital Setting: Identifi Cation of Discrepancies and Information Completeness', vol. 132, no. 1488, 2019.
- [25] Kementerian Kesehatan Republik Indonesia, *Peraturan Menteri Kesehatan Republik Indonesia Nomor 46 Tahun 2017 Tentang Strategi E-Kesehatan Nasional*. 2017.
- [26] *Peraturan Pemerintah Republik Indonesia Nomor 46 Tahun 2014 Tentang Sistem Informasi Kesehatan*. 2014.
- [27] A. Wasylewicz et al., 'Identifying Adverse Drug Reactions from Free-Text Electronic Hospital Health Record Notes', *Brit J Clinical Pharma*, vol. 88, no. 3, pp. 1235–1245, Mar. 2022, doi: 10.1111/bcp.15068.
- [28] S. Karimi, C. Wang, A. Metke-Jimenez, R. Gaire, and C. Paris, 'Text and Data Mining Techniques in

- Adverse Drug Reaction Detection', *ACM Comput. Surv.*, vol. 47, no. 4, pp. 1–39, Jul. 2015, doi: 10.1145/2719920.
- [29] P. Annu, 'ADR Monitoring: An Essential Need for Better Health Care and Safety', *PharmaTutor*, vol. 4, no. 8, pp. 13–16, 2016, doi: 2347 - 7881.
- [30] K. Sienkiewicz, M. Burzyńska, I. Rydlewska-Liszkowska, J. Sienkiewicz, and E. Gaszyńska, 'The Importance of Direct Patient Reporting of Adverse Drug Reactions in the Safety Monitoring Process', *IJERPH*, vol. 19, no. 1, p. 413, Dec. 2021, doi: 10.3390/ijerph19010413.
- [31] R. A. Raschke et al., 'A Computer Alert System to Prevent Injury From Adverse Drug Events: Development and Evaluation in a Community Teaching Hospital', *JAMA*, vol. 280, no. 15, p. 1317, Oct. 1998, doi: 10.1001/jama.280.15.1317.