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Original article

Prevalence and Signal Detection of Adverse Drug Events from Inappropriate Sources in the Community: an Analysis of Reports in the Thai Databases on Adverse Drug Events (Thai Vigibase)

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Abstract

Self-medication from inappropriate drug sources in the community can result in adverse events (AEs) that require hospitalization. Previous studies are not nationwide studies on the magnitude of the problem and risk. We conducted a retrospective descriptive study using data from spontaneous AE reports in the Thai Vigibase for 2021–2022 to analyze the national level of the prevalence of AEs from drugs received from inappropriate drug sources and assessed the signals detection for risk of severe AEs in three target drug groups: non-steroidal anti-inflammatory drugs (NSAIDs), steroids, and antibiotics. The data were analyzed using descriptive statistics, encompassing numbers and percentages. Additionally, reporting odds ratios and 95% confidence intervals were calculated to assess risk signals. By using the STATA/IC version 14.0, we could make an analysis, which revealed that the number of AEs stemming from inappropriate drug distribution sources in 2021 and 2022 was 279 out of a total of 136,453 events and 295 out of a total of 99,642 events, respectively. Grocery stores were the most common inappropriate source of drug distribution, accounting for 75.27 percent of AEs in 2021 and 72.88 percent in 2022. The top three drug groups that caused the most AEs in both years were anti-inflammatory and anti-rheumatic products, systemic antibiotics, and analgesics, respectively. The top three drugs with the most AEs in both years were NSAIDs and antibiotics, namely piroxicam, tetracycline, and diclofenac. The prevalence of AEs from all drugs received from inappropriate drug sources in 2021 and 2022 was 0.20 and 0.30, respectively. The prevalence of the target drug groups to be monitored, namely NSAIDs, antibiotics, and steroids, in 2021 was 0.009, 0.004, and 0.003, respectively, and in 2022 it was 0.013, 0.004, and 0.03, respectively. NSAIDs were the only drug group with risk signals for severe AEs in both years, and diclofenac was the only drug with risk signals in 2021. The findings

of this study can serve as baseline information for monitoring and evaluating the implementation of the Ministry of Public Health's guidelines for the rational use of medicine in communities. Furthermore, Risk management measures should be established at both national and local levels to address the issue of NSAIDs and diclofenac, which display signs of serious AEs. All hospitals should establish a proactive drug safety surveillance system with rational drug use guidelines to ensure the availability of high-quality data to Thai Vigibase.

Keywords: self-medication; adverse drug events; rational use of drugs

Introduction

Inappropriate drug use in the community has been an important problem that has remained in Thailand,⁽¹⁾ with more than half of drugs that are controlled for sale according to the law being distributed in general outlets such as grocery stores, marketplaces held at a stated time, or online stores.⁽²⁾ It has effects on the safety of people or illnesses from using drugs. This is shown in the occurrence of adverse drug events (AEs) and visits to healthcare facilities.

Since 2022, Ministry of Public Health has implemented the national policy on rational use of drug named "Rational Drug Use country" ("RDU country") at the local level in all provinces under the name of "RDU Province."⁽³⁾ This policy aims to enhance the quality of pharmaceutical services across all healthcare facilities, encompassing both public and private hospitals, as well as various medical establishments like clinics, pharmacies, and other drug distribution outlets within the community. The ongoing initiative aims to establish a comprehensive monitoring system to ensure the safe and appropriate use of drugs, and medicine safety on "RDU country" policy will be monitored by AEs data. The national database of AEs from medicines and health products, namely Thai Vigibase, is mostly input by pharmacists who work in hospitals, drug stores, and the community. Addressing the gap in the healthcare system, especially concerning

the use of drugs from improper distribution sources within the community, remains a critical priority.

Therefore, we conducted this study to analyze the national magnitude of the problem and risks associated with inappropriate drug distribution sources within the community, by utilizing the Thai Vigibase. Previous research on drug safety surveillance primarily focused on epidemiological analysis specific to different community areas and hospitals, which provided insights into safety issues related to inappropriate drugs within the community.⁽⁴⁻⁸⁾ But, these studies did not demonstrate the national scale of adverse drug events or illnesses in communities, nor did they address the extent of risk associated with drugs from inappropriate sources. Furthermore, previous studies predominantly analyzed AEs related to specific types of medicines within certain disease groups.⁽⁹⁻¹³⁾ Moreover, there has been a lack of research investigating risk signals originating from inappropriate drug distribution sources. This study aimed to analyze the prevalence and potential signal for risk of adverse drug events from using drugs obtained from inappropriate drug sources in the community by using Thai Vigibase in 2021–2022.

Methods

We conducted a retrospective descriptive study from March to July 2023 by using data from

spontaneous reports of adverse events (AEs) associated with a suspected health product (suspected product: S) in the Thai Vigibase for 2021–2022. We examined the prevalence of AEs from drugs obtained from inappropriate sources of drug distribution and the potential signals for risk of severe AEs in three target drug groups: non-steroidal anti-inflammatory drugs (NSAIDs), steroids, and antibiotics. We also focused on the drugs in the medicine set that in Thai so-called “Ya Chud” or health products intended to be used as medicine, which were the priority of the working group of system development for rational use of drug and medicine safety, Ministry of Public Health.⁽¹⁴⁾

The data were analyzed using descriptive statistics, encompassing numbers and percentages on issues such as age, gender, drug groups, generic names of drugs that cause AEs, drug distribution sources in the community (grocery stores, marketplaces held at a stated time, drug resting points in the community, general merchandise, wholesale stores, online media, direct sales), AEs that caused abnormalities in the human body systems and provinces where AEs were reported.

The prevalence of AEs was calculated from all inappropriate drug sources classified by drug group according to the formula for prevalence. In addition, this analysis used the risk signal assessment criteria of the Health Product Vigilance Center (HPVC), Food and Drug Administration, and the reporting odds ratio (ROR) and its 95% confidence interval (CI) analyses were done using STATA/IC version 14.

For the risk signal calculation, the computation of ROR was conducted for each year using three target drug groups obtained from all inappropriate drug sources. The number of reports of each pair of drug

group – serious AEs was put in the below 2-by-2 frequency table.

	AEs of interest	All other AEs
Drug of interest	a	b
All other drugs	c	d

- a: The number of reports with the interested AEs associated with the interested drugs.
- b: The number of reports of other AEs associated with the drug of interest.
- c: The number of reports of interested AEs associated with other drugs.
- d: The number of reports with other AEs associated with other drugs.

ROR was defined as the ratio between the odds of occurrence of the AEs of interest in people who received the drug of interest to the odds of the occurrence of those AEs among people who did not receive the drug of interest.

ROR and its 95% CI⁽¹⁵⁾ were then calculated using the following formula

$$\text{reporting odds ratio} = \frac{ad}{bc}$$

$$95\%CI = e^{\ln(ROR) \pm 1.96 \sqrt{\frac{1}{a} + \frac{1}{b} + \frac{1}{c} + \frac{1}{d}}}$$

The criteria for considering whether an association between a drug and AEs was a signal of risk, the following three characteristics were necessary:

- 1) There were 3 or more reports (cell a) indicating that when patients received the drug of interest, the AEs of interest occurred.
- 2) The ROR value was above 1 and the lower bound of the 95% confidence interval is greater than 1.

3) AEs that were classified by the World Health Organization as a serious type.

Definitions

1. Serious adverse event: an adverse event is any undesirable experience associated with the use of a medical product in a patient. The event is serious and should be reported to HPVC when the patient outcome is death, life-threatening, hospitalization (initial or prolonged), disability or permanent damage, and congenital anomaly/birth defect.⁽¹⁶⁾

2. Signal detection: the discovery of the possible harm to patients as it relates to their use of medicines.⁽¹⁷⁾

3. Inappropriate drug source in the community: places or operations, including grocery stores, marketplaces held at a stated time, drug resting points in the community, wholesale shops, online stores, and direct sales, where drugs are sold beyond the limits set in the law, such as grocery stores selling prescription drugs.

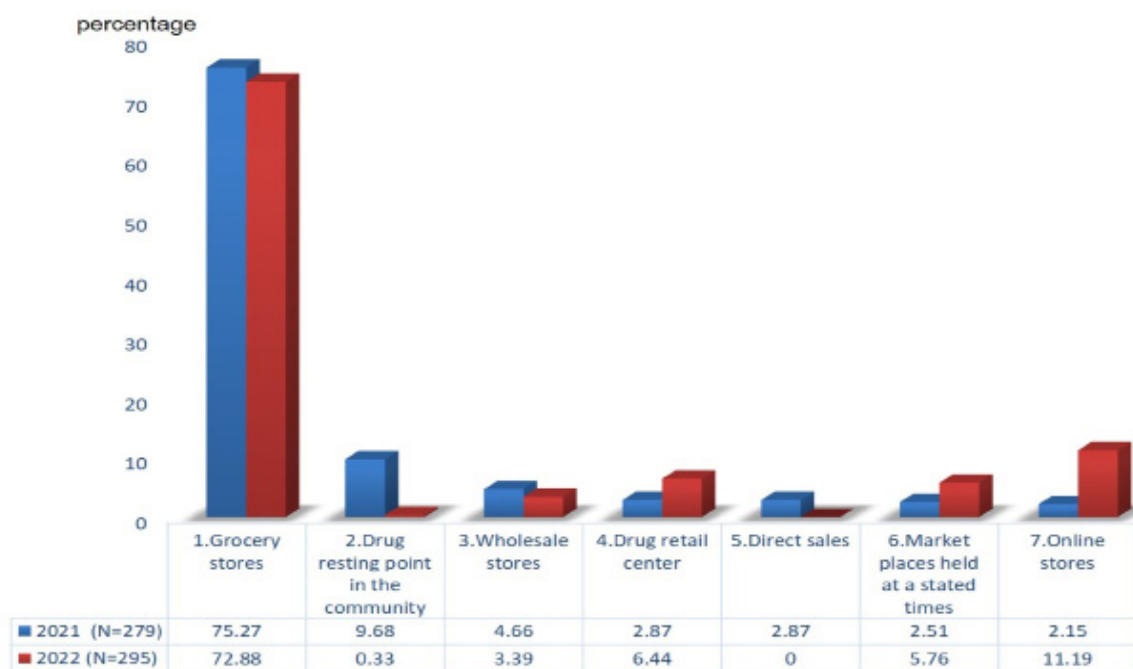
Results

In 2021 and 2022, the total numbers of reported AEs were 136,453 and 99,642, and AEs from inappropriate sources of drug distribution in 2021 and 2022 were 279 and 295 events, respectively.

The majority of people, who suffered from AEs due to using drugs from inappropriate sources of drug distribution, were working-age adults. The mean age in 2021 was 46.90 ± 20.84 years, and in 2022 it was 45.11±19.63 years.

The top three drug distribution sources with the highest reported cases of adverse events (AEs) in 2021 were grocery store stands (75.27%), drug distribution points within the community (9.68%), and general wholesale stores (4.66%). In 2022, the leading sources were grocery stalls (72.88%), social media (11.19%), and general merchandise wholesale stores (6.44%) (Figure 1).

Figure 1 Percentage of AEs classified by inappropriate sources in the community for 2021 and 2022

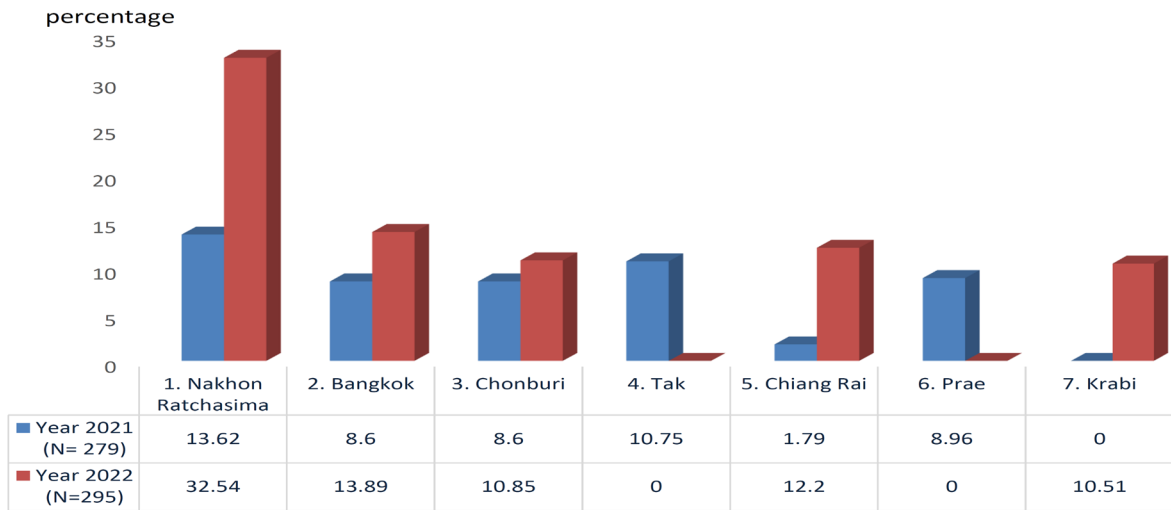


ความชุกและสัญญาณความเสียหายของเหตุการณ์ไม่พึงประสงค์ของยาที่ได้รับจากแหล่งกระจายยาไม่เหมาะสมในชุมชน

Among 33 reported provinces, the top three provinces having the occurrence of AEs from inappropriate drug distribution sources in 2021 were Nakhon Ratchasima (13.62 percent), Tak (10.75 percent),

Phrae (8.96 percent), respectively, and in 2022 they were Nakhon Ratchasima (32.54 percent). Bangkok (13.89 percent) and Chiang Rai (12.20 percent), respectively (Figure 2).

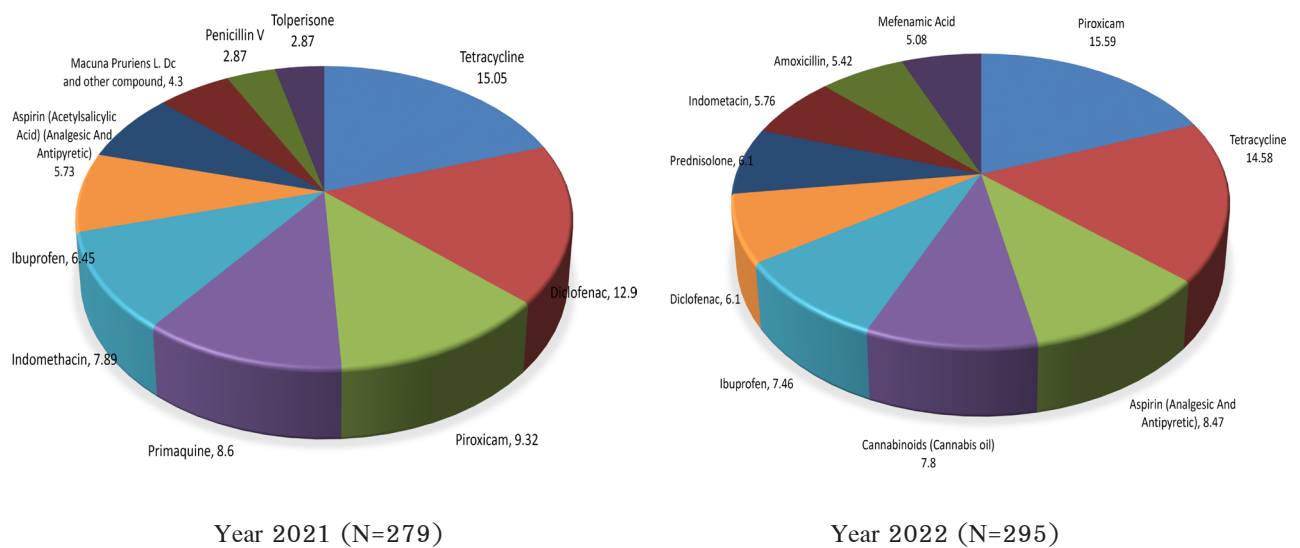
Figure 2 Top 5 provinces reporting the highest AEs Year 2021 and Year 2022



The three-drug groups that caused the most AEs in both years were anti-inflammatory and antirheumatic products, systemic antibiotics, and analgesics,

respectively. The three drugs that caused the highest number of AEs in both years were piroxicam, tetracycline, and diclofenac (Figure 3).

Figure 3 Percentage of AEs classified by top 10 drug names from inappropriate sources in the community, years 2021 and 2022



In 2021 and 2022, 51.97% and 35.59% of adverse events that occurred from inappropriate sources were serious AEs, respectively. Other than that, they were non-serious AEs. The most frequent AEs in both years were severe allergic reactions (anaphylaxis) and angioedema (Figure 4).

The prevalence of AEs from all drugs obtained from inappropriate sources in 2021 and 2022 was 0.20 and 0.30, respectively. The prevalence of the monitored drug groups, namely NSAIDs, antibiotics, and steroids, in 2021 was 0.009, 0.004, and 0.003, respectively, and in 2022 it was 0.013, 0.004, and 0.03, respectively.

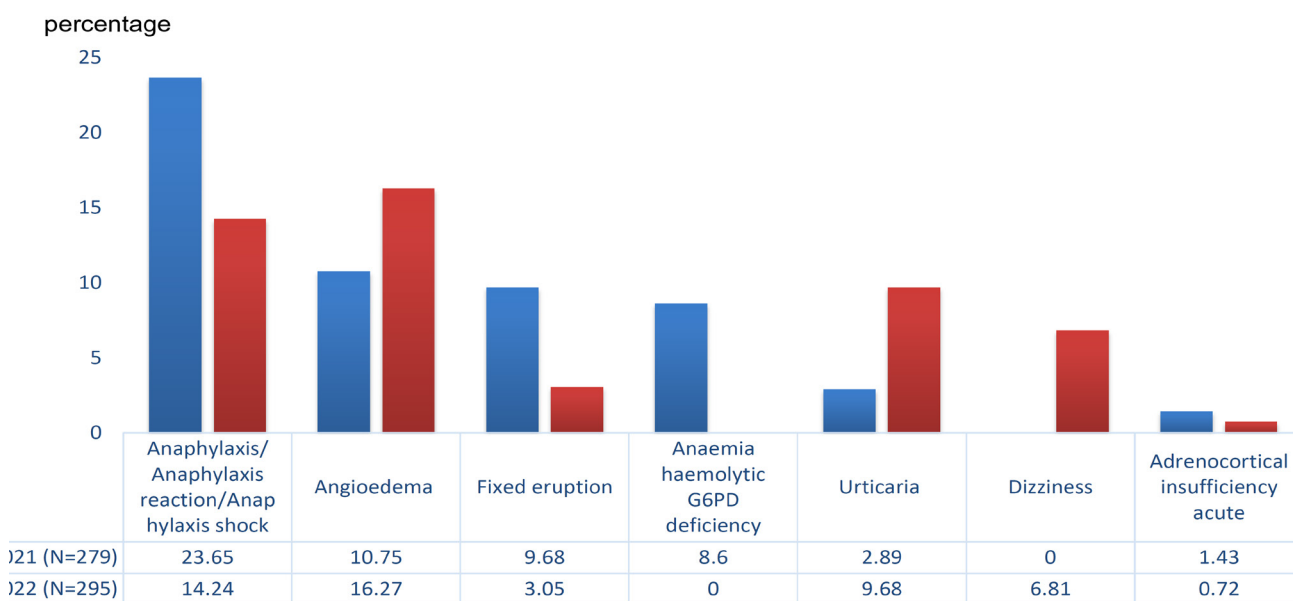
NSAIDs were the only target drug group that showed risk signals, with a ROR of 1.82 (95% CI 1.019–3.248, P = 0.0288) in 2021 and a ROR of 2.22 (95% CI 1.13–4.39, P = 0.0116) in 2022, resulting from a risk signal from diclofenac and its occurrence of severe AEs.

Discussion

1) This study finds the prevalence and risk signs of AEs from people receiving drugs from inappropriate drug distribution sources in the community by using the Thai Vigibase. It can be used to track and monitor the adverse events of the drugs from inappropriate sources in a community at the national level such that we can understand the magnitude and risk factors of serious AEs due to using the drugs from inappropriate sources in the community. It is also essential to consider incorporating information from additional sources, such as the National Learning and Reporting System (NRLS) of the Institute for Accreditation of Healthcare Institutions (Public Organization) to ensure a comprehensive understanding of the situation.

2) Grocery stores are a significant source of inappropriate drug distribution in the community that should be continuously monitored because grocery stores are the major source of the highest number of AEs.

Figure 4 Percentage of top 5 AEs caused by drugs received from inappropriate sources in the community Year 2021 and Year 2022



3) The prevalence of adverse drug events from inappropriate drug sources in 2021 and 2022 was mostly caused by NSAIDs and antibiotics, which is consistent with other national and international studies. The prevalence of adverse events from all drugs obtained from inappropriate sources in this study is in line with the findings from a study conducted in Metropolitan Areas of Thailand by Chandrakan, et al. in Thailand,⁽¹⁸⁾ where approximately 0.6 to 6.6 percent of respondents reported experiencing adverse drug reactions after self-medication by the purchase of drugs from inappropriate source.

4) NSAIDs are the only drug group under surveillance that has shown signs of risk. There are risk signs from diclofenac and the occurrence of severe AEs. The results of this study are consistent with those of both domestic and international studies that NSAIDs are the most common drug group used for self-medication and the most frequent cause of AEs is from NSAIDs. These results are confirmed by local surveys in Thailand,^(5,18,19) domestic and international pharmacovigilance databases,^(12,20) and systematic reviews and meta-analyses.⁽²¹⁾

The findings of this study can serve as baseline information for monitoring and evaluating the implementation of the Ministry of Public Health's guidelines for the rational use of medicine in communities. Furthermore, these results can help establish risk management measures at both the central and provincial levels concerning NSAIDs and diclofenac, which exhibit signs of serious adverse events (AEs). All hospitals should establish a proactive drug safety surveillance system with rational drug use guidelines to ensure the availability of high-quality data in Thai Vigibase.

Recommendations

1) The National Drug Policy Division of the Thai Food and Drug Administration should consider extracting information on education levels, occupations, trade names, and drug forms from the Thai Vigibase database for further analysis. This data can facilitate risk management tailored to specific target groups.

2) The Health Product Vigilance Center (HPVC) should encourage hospitals to increasingly report adverse events (AEs) in the database system and develop a comprehensive Thai Vigibase database specifically for AEs associated with the use of drugs, health products, and their related components. Additionally, HPVC should implement public relations aimed at promoting the reporting program to the public.

As shown in the above results, both the Food and Drug Administration and the provincial health office should have measures to manage the risk of inappropriate drug distribution sources and to create appropriate health literacy in self-medication for the public. In addition, an information system should be developed to continuously monitor drug distribution sources in the community by using modern technology, including analyzing and designing the country's health system to support people's access to information and health-care facilities for self-care.

Limitations

This study used the Thai Vigibase database, which is spontaneous reporting. Although it is the main method of surveillance systems around the world including Thailand. In practice, the number of reported ADRs might be lower than the actual occurrence

(under-reporting). This might affect the data that are analyzed.

Recommendations for future study

Other forms of study methods should be used, such as prospective studies conducted at the hospital level and systematic reviews of existing research within the country to support the analysis results based on Thai Vigibase.

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ความชุกและสัญญาณความเสี่ยงของเหตุการณ์ไม่พึงประสงค์ของยาที่ได้รับจากแหล่งกระจายยาไม่เหมาะสมในชุมชน โดยวิเคราะห์จากฐานข้อมูลรายงานเหตุการณ์ไม่พึงประสงค์ของผลิตภัณฑ์สุขภาพ ประเทศไทย

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บทคัดย่อ: การซื้อยารักษาตนเอง จากแหล่งกระจายยาไม่เหมาะสมในชุมชน ส่งผลให้เกิดเหตุการณ์ไม่พึงประสงค์จากยา และการเข้ารับการรักษาในสถานพยาบาล การศึกษาที่ผ่านมาจึงไม่มีการวิเคราะห์ขนาดปัญหาและขนาดความเสี่ยงของเหตุการณ์ไม่พึงประสงค์จากแหล่งกระจายยาไม่เหมาะสมในชุมชนภาพรวมประเทศ การศึกษาเชิงพรรณนาแบบย้อนหลังนี้ เป็นการศึกษาความชุกและสัญญาณความเสี่ยงของเหตุการณ์ไม่พึงประสงค์ที่รุนแรงของยาจากแหล่งกระจายยาไม่เหมาะสมในชุมชนภาพรวมประเทศ โดยวิเคราะห์จากข้อมูลเหตุการณ์ไม่พึงประสงค์จากการใช้ยาและผลิตภัณฑ์สุขภาพ (adverse events: AEs) ปี 2564 – 2565 จากฐานข้อมูลรายงานเหตุการณ์ไม่พึงประสงค์ของผลิตภัณฑ์สุขภาพ ประเทศไทย (Thai Vigibase) ในกลุ่มยาเป้าหมายที่กระทรวงสาธารณสุข เฝ้าระวัง ได้แก่ กลุ่มยาต้านการอักเสบที่ไม่ใช่สเตียรอยด์ (NSAIDs) ยาสเตียรอยด์ (steroids) และยาปฏิชีวนะ (antibiotics) ใช้การวิเคราะห์ข้อมูลด้วยสถิติเชิงพรรณนา ได้แก่ จำนวน และร้อยละ ค่าขนาดค่า reporting odds ratio และช่วงความเชื่อมั่น เพื่อวิเคราะห์สัญญาณความเสี่ยง โดยใช้โปรแกรม STATA/IC version 14.0 พบว่า จำนวน AEs จากแหล่งกระจายยาไม่เหมาะสม ปี 2564 และ 2565 เท่ากับ 279 จากจำนวนเหตุการณ์ทั้งหมด 136,453 เหตุการณ์ และ 295 จากเหตุการณ์ทั้งหมด 99,642 เหตุการณ์ตามลำดับ ร้านขายเป็นแหล่งกระจายยาไม่เหมาะสม ที่ส่งผลต่อให้เกิด AEs มากที่สุด (ปี 2564 ร้อยละ 75.27 ปี 2565 ร้อยละ 72.88) กลุ่มยาที่ทำให้เกิด AEs มากที่สุด 3 ลำดับแรก ได้แก่ anti-inflammatory and antirheumatic products, systemic antibiotics และ analgesics ตามลำดับ โดยชื่อยาที่พบ AEs มากที่สุดใน 3 ลำดับแรก คือ กลุ่มยา NSAIDs และ antibiotic ได้แก่ piroxicam, tetracycline, diclofenac ทั้งนี้ความชุกของเหตุการณ์ไม่พึงประสงค์ของยาจากแหล่งกระจายยาไม่เหมาะสม ปี 2564 และปี 2565 มีค่าเท่ากับ 0.20 และ 0.30 ตามลำดับ ความชุกของกลุ่มยาเป้าหมายที่เฝ้าระวัง ได้แก่ NSAIDs, Antibiotic และ Steroid ในปี 2564 มีค่าเท่ากับ 0.009, 0.004 และ 0.003 ตามลำดับและ ปี 2565 มีค่าเท่ากับ 0.013, 0.004 และ 0.03 ตามลำดับ โดย NSAIDs เป็นกลุ่มยาเดียวที่พบสัญญาณความเสี่ยงต่อการเกิด AEs ที่รุนแรง ซึ่ง diclofenac เป็นยาชนิดเดียวที่พบสัญญาณเสี่ยง ในปี 2564 ผลการศึกษาดังกล่าว กระทรวงสาธารณสุข สามารถใช้เป็นข้อมูลพื้นฐานเพื่อติดตามผลตามแนวทางการใช้ยาอย่างสมเหตุผลในชุมชนของกระทรวงสาธารณสุข และกำหนดมาตรการจัดการความเสี่ยง ทั้งส่วนกลางและพื้นที่ ต่อกลุ่มยาที่มีสัญญาณความเสี่ยงจากการเกิด AEs รุนแรง รวมทั้งส่งเสริมให้ทุกโรงพยาบาลทุกสังกัดวางระบบเฝ้าระวังความปลอดภัยด้านยาเชิงรุกในโรงพยาบาล ตามแนวทางดังกล่าว ตลอดจนส่งเสริมให้โรงพยาบาลรายงานข้อมูลให้ครบถ้วน ถูกต้อง เพื่อให้มีข้อมูลคุณภาพสู่ Thai Vigibase เพื่อใช้เฝ้าระวังอย่างต่อเนื่องต่อไป

คำสำคัญ: การซื้อยารักษาตนเอง; เหตุการณ์ไม่พึงประสงค์จากยา; การใช้ยาอย่างสมเหตุผล