

ORIGINAL ARTICLE

# Proposed algorithm on a community-based adverse event reporting system for herbal products in the Philippines

John Nicolas B. Mejia\* and Jocelyn S. Bautista-Palacpac  
 College of Pharmacy, University of the Philippines Manila, Manila, Philippines

## ABSTRACT

**Background:** The pharmacovigilance system in the Philippines aims to ensure the safe use of medicines, including herbal products. However, there is a lack of reporting on adverse events related to herbal products, indicating a need for an improved monitoring system.

**Objectives:** This study seeks to develop a community-based adverse event reporting system for herbal products in Calamba and Los Baños Laguna to enhance pharmacovigilance practices in the Philippines. The primary objectives include assessing consumer knowledge, willingness to report adverse events, and evaluating the feasibility of implementing such a system in community pharmacies.

**Methodology:** A mixed-methods approach was employed, involving surveys with herbal product consumers and focus group discussions with community pharmacists. Data analysis utilized Likert scaling for surveys and thematic analysis for discussions, providing a comprehensive understanding of consumer perceptions and pharmacist experiences.

**Results:** The study revealed limited consumer awareness of herbal safety risks but with a positive attitude towards reporting adverse events through community pharmacies. The developed algorithm, tailored to consumer and pharmacist preferences, demonstrated potential benefits in enhancing pharmacovigilance and promoting the rational use of herbal products.

**Conclusion:** The proposed community-based adverse event reporting system for herbal products in the Philippines offers a practical and accessible solution to improve pharmacovigilance, empower consumers, and ensure the safe utilization of herbal products. Implementation of this system has the potential to significantly enhance public health outcomes and contribute to the overall well-being of the Filipino population.

## Introduction

As one of the countries with the most biodiverse natural resources, the Philippines has a significant stake in the development of alternative medicines, particularly those produced from plants. Due to the increasing cost of healthcare in the country, there is an increasing demand for traditional and complementary medicine, more explicitly on primary health care as it is often seen as the more acceptable and accessible health care modality. Herbal medicine involves the use of medicinal plants and herbal preparations with active ingredients for therapeutic purposes, reflecting a traditional healthcare approach across cultures [1]. On the other hand, complementary medicine encompasses diverse healthcare practices like acupuncture, chiropractic therapy, and herbal remedies, used alongside conventional medicine to complement treatment for various health conditions (DOH, n.d.). Together, herbal and complementary medicine offer alternative approaches to healthcare, emphasizing holistic well-being and personalized care within global healthcare systems.

Despite this, efforts to promote and advocate traditional and complementary medicine in our country are beset with many challenges because of a lack of effective communication strategy. The safety of herbal products has been highlighted because of the huge growth in global consumption. There is now a lot of misinformation and prejudice about the safety of herbal medication. As a result, objective comprehension, neutral and fair interpretation, and public awareness are required [1].

According to the World Health Organization (2019), Adverse Drug Events (ADEs) are a health problem or injury occurring from medical intervention related to a medicine. It includes adverse drug reactions and overdose. Adverse drug reaction (ADR) monitoring is a part of Pharmacovigilance which studies the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem. The purposes of medication monitoring systems are to increase consumer safety, improve public health, and support medication evaluation, effectiveness, and understanding.

There has been growing evidence that herbal products could lead to serious adverse effects, such as liver toxicity and injuries [2], hypertension, arrhythmia, and stroke [3]. They could also cause significant interactions with conventional drugs [4]. Although most herbal products have promising

potential and are widely used, many of them remain untested and their use also not monitored. These could result in inadequate knowledge of their mechanisms of action, adverse reactions, contraindications [5] and interactions with concurrent pharmaceuticals products [6].

Herbal medicine pharmacovigilance is still in its infancy, and monitoring the safety of such preparations presents issues because there is yet no system established specifically for herbal medicines and herbal supplement. To assess the negative effects induced by herbal products, a "herbavigilance" system must be constructed [6]. The information acquired from patients and community pharmacists can be crucial in providing the necessary data for recognizing pharmacovigilance signals [7].

Evaluation of the knowledge and practices of consumers of herbal products in the Calamba and Los Baños, Laguna areas would offer a foundation for developing an appropriate and feasible strategy for promoting the use of these preparations in a community setting. This study therefore assessed the knowledge, attitude, and practices of herbal products consumption among the general population of Calamba and Los Baños. Specifically, it aimed to: (1) determine the knowledge and awareness of consumers regarding safety risks with the use of herbal products; (2) evaluate the willingness of consumers in reporting adverse events related with the use of herbal products; and (3) evaluate the modality of choice for consumers in reporting adverse events related with the use of herbal products. Furthermore, this study also determined the willingness of community pharmacists in implementing an adverse reporting system specific for herbal products. With these, the operational feasibility for the development of a community based adverse reporting system with the use of herbal products was explored.

## Methodology

**Corresponding author's email address:**

jbmejia2@up.edu.ph

**Keywords:** Herbal Products, Pharmacovigilance, Adverse Events (Aes), Community Based Reporting, Pharmacist

This research was presented to the following events:  
 September 22, 2022: DOST ASTHRDP Scholars Conference  
 October 26, 2022: UP Manila Graduate Research Colloquium  
 January 28, 2024: 4th Philippine Herbal Medicine Summit (UP NIH) (3rd Place), Sheraton Manila Bay Hotel, Adriatico St. Malate, Metro Manila



## 2.1. Study Design

In conducting this study, a mixed research approach was adopted to ensure a comprehensive understanding of the knowledge, attitudes, and practices of consumers and community pharmacists regarding herbal products and adverse event reporting in the Calamba and Los Baños, Laguna areas. The research methodology comprised both quantitative and qualitative methods to gather diverse insights. Initially, a quantitative approach was utilized through an online survey administered to consumers of herbal products in the specified areas. This quantitative phase aimed to collect structured data on consumer behaviors, preferences, and awareness related to herbal products. Subsequently, a qualitative approach was employed involving focus group discussions with community pharmacists working in small-scale drugstores in Calamba and Los Baños. This qualitative phase delved deeper into the perceptions, experiences, and challenges faced by pharmacists in handling herbal products and adverse event reporting. Lastly, additional focus group discussions were conducted with selected respondents to evaluate the effectiveness and feasibility of the developed algorithm for a community-based adverse event reporting system specifically tailored for herbal products in the Calamba and Los Baños Laguna areas.

In the context of the research, herbal products refer to substances derived from plants or plant extracts in a packaged in a pharmaceutical dosage forms being sold in community pharmacies that are used for medicinal purposes, highlighting the prevalent use of these traditional remedies in the Philippines and the importance of understanding their potential risks and benefits through effective monitoring and reporting systems.

## 2.2. Study Locale

Calamba and Los Baños were strategically chosen as the study sites for the proposed algorithm on a community-based adverse event reporting system for herbal products in the Philippines based on purposive convenience sampling as well as three key parameters. Firstly, the high prevalence of herbal product use in the Philippines is evident in these areas, providing a significant consumer population for studying consumption patterns and adverse event reporting behaviors. Additionally, as urbanized rural areas, Calamba and Los Baños offer a unique blend of traditional practices and modern healthcare services, making them ideal locations to understand the intertwined use of herbal products. Lastly, the abundance of community pharmacies in these areas ensures easy access to healthcare services and establishes a direct connection between consumers and the national pharmacovigilance center, emphasizing the crucial role of community pharmacies in the proposed reporting system.

## 2.3. Population and Sampling Technique

For the consumers, a convenience sampling technique was carried-out in the study. Based on the 2020 PSA census, Calamba City has a total population of 539, 671 while Los Baños has a total population of 115, 353. Although the sampling followed a convenience method, still, required samples were determined using the Cochran Formula with 95% confidence level and a 5% margin of error. With this, the required number of respondents for this study was computed at 384 participants. Meanwhile, community pharmacies were determined using mixed purposive and voluntary response sampling.

## 2.4. Data Collection Procedure

A pre-testing of 30 selected respondents to assess the comprehensibility of the questionnaire was done and assessment was done through computation of Cronbach's Alpha. The inclusion criteria for the pre-testing of the questionnaire are: resident of Calamba City; 18 years old and above; have experience in taking herbal medicines or herbal supplements for at least a month; and, can understand Tagalog. For the community pharmacist's Focus Group Discussion (FGD), a guide question was developed which then forwarded to them for initial review and checking. The main inclusion for community pharmacists are practicing pharmacists in the small-scale community drugstore.

## 2.5. Data Processing and Analysis

The consumers and respondents were informed about the study's goals, and a consent form was incorporated into the questionnaires. The information

provided by the study participants in the questionnaires were kept confidential and only the collected data were processed. The questionnaire was formulated in the local language (Tagalog). Structure of questions was based on Likert scaling; Likert-type or frequency scales use fixed choice response formats and are designed to measure attitudes or opinions. Descriptive statistics using mode was used to determine the characteristics of the study population based on the questions given.

The focus group discussion with community pharmacists was video-recorded, transcribed verbatim, and thematically analyzed and used narratological interpretation. The first step was the familiarization of the data collected. Subsequently, the transcripts were arranged and organized in a systematic and meaningful form. All the large data collections were reduced to smaller, relevant, and appropriate themes. These were coded and displayed in matrices using Microsoft Word 2010. Content analysis was subsequently performed on the qualitative data generated and interpreted using narratological technique.

## 2.6. Ethical Considerations

The study was reviewed and approved in 2022 by the University of the Philippines Manila Research Ethics Board (UPMREB) under the approval number UPMREB 2022-0060-01.

# Results

There was a total of 384 respondents from the municipality of Calamba Laguna in which 50.3 % were male and 49.7% were female. Majority of the respondents belong to the 25-34 years age groups and 35-44 years age groups respectively. Based on their responses, the majority of them have a history of consuming or currently consuming both herbal medicines and herbal supplements.

**Table 1.** Respondents Socio Demographic Profile

	Frequency (n)	Percentage
<b>Gender</b>		
Male	193	50.3
Female	191	49.7
Did not disclose	0	0
<b>Age</b>		
18-24 years old	68	17.7
25-34 years old	163	42.4
35-44 years old	101	26.3
45-54 years old	43	11.2
55-64 years old	7	1.8
65 years old and above	2	0.5

Table 1 shows the demographic distribution of the study participants. Based on gender, it shows a nearly equal representation of males (50.3%) and females (49.7%), with no participants opting not to disclose their gender. In terms of age groups, the majority of respondents fall within the 25-34 years old category (42.4%), followed by the 35-44 years old group (26.3%). The data also indicate smaller proportions in the older age brackets, with 18-24 years old at 17.7%, 45-54 years old at 11.2%, 55-64 years old at 1.8%, and those aged 65 years and above at 0.5%.

**Table 2.** Profile of the Respondents in terms of Products Consumed

Type of Herbal Product	Frequency	Percentage
Herbal Medicine	13	3.4
Herbal Supplement	60	15.6
Both Herbal Medicine and Herbal Supplement	311	81.0

Table 2 shows the distribution of herbal product consumption. Among the respondents reveals that the majority (81.0%) reported using both herbal medicines and herbal supplements, indicating a prevalent trend of utilizing a combination of these products. A smaller proportion reported consuming only herbal medicines (3.4%), while a higher percentage reported using herbal supplements exclusively (15.6%). This data highlights the widespread preference for a holistic approach to health and wellness through the consumption of various types of herbal products among the study participants.

**Results based on Knowledge in Herbal Products**

The study revealed significant insights into the knowledge and awareness of consumers regarding herbal products in Calamba. The data indicated a prevalent use of both herbal medicines and herbal supplements, with (n=311) 81.0% of respondents reporting the consumption of both types of products. This highlights a widespread reliance on herbal products for healthcare needs within the community.

The findings underscore the need for enhanced education and awareness initiatives regarding the safety risks associated with herbal products. With only (n=13) 3.4% of respondents reporting the consumption of herbal medicine alone and (n=60) 15.6% consuming herbal supplements exclusively, most consumers are utilizing a combination of both types of products. This pattern of consumption emphasizes the importance of comprehensive knowledge and awareness of the potential risks and benefits associated with herbal products.

The data also indicates a potential lack of understanding among consumers regarding the distinctions between herbal medicines and herbal supplements, as well as the specific safety considerations associated with each type of product. This underscores the necessity of targeted educational interventions to equip consumers with the knowledge required to make informed decisions about the use of herbal products and to recognize and report adverse events effectively.

These findings have significant implications for the development of the adverse event reporting system, as they highlight the need for tailored educational initiatives to enhance consumer knowledge and awareness of herbal product safety. By addressing these knowledge gaps, the reporting system can empower consumers to actively participate in pharmacovigilance efforts and contribute to the overall safety and rational use of herbal products within the community.all herbal products are safe.

**Results based on Awareness in Risk of Herbal Products**

The study provided valuable insights into the awareness of consumers regarding the risks associated with herbal products in Calamba. The data revealed that only 10% of consumers who use herbal products are aware of the safety risks, indicating a significant gap in awareness within the community. This finding underscores the need for targeted educational initiatives to enhance consumer awareness of the potential risks associated with herbal products.

Furthermore, the study highlighted that consumers are willing to report adverse events related to herbal products to community pharmacies, either through physical visits or electronic reporting. This willingness to report adverse events signifies a potential opportunity to engage consumers in pharmacovigilance efforts and empower them to contribute to the safety monitoring of herbal products.

The data also indicated that consumers have self-perceived harms associated with the use of herbal products, such as the potential to cause other diseases and side effects. Despite these concerns, the willingness to report adverse events suggests a proactive stance among consumers in addressing safety issues related to herbal products.

These findings underscore the importance of developing an effective and accessible adverse event reporting system for herbal products. By leveraging the willingness of consumers to report adverse events, the community-based reporting system can harness consumer engagement to enhance the detection and monitoring of adverse events associated with herbal products. Additionally, targeted educational initiatives can address the awareness gaps and empower consumers to make informed decisions about the use of herbal products, ultimately contributing to the overall safety and rational use of herbal products within the community.

**Results based on Attitude about reporting possible adverse events associated with herbal products and willingness to report possible adverse events associated with herbal products**

The study provided valuable insights into the attitudes and willingness of consumers to report possible adverse events associated with herbal products in Calamba. The data revealed that consumers are willing to report any adverse events experienced in community pharmacies, either through physical visits or electronic reporting. This willingness to report adverse events signifies a potential opportunity to engage consumers in pharmacovigilance efforts and

empower them to contribute to the safety monitoring of herbal products.

Furthermore, the study indicated that consumers strongly agree to report adverse events through text messaging or social media platforms such as Facebook Messenger and Viber. This preference for electronic reporting methods highlights the importance of implementing user-friendly and accessible reporting channels to facilitate consumer engagement in adverse event reporting.

The data also revealed that consumers are willing to disclose personal details and information for reporting purposes, indicating a high level of commitment to contributing to the safety monitoring of herbal products. Additionally, consumers expressed a strong desire for feedback regarding their initiated reports, emphasizing the importance of establishing a system that provides timely and informative feedback to consumers who report adverse events.

These findings underscore the significance of developing a community-based adverse event reporting system that aligns with consumer preferences and attitudes. By leveraging electronic reporting methods and ensuring transparent feedback mechanisms, the reporting system can effectively engage consumers in the reporting process and enhance the overall detection and monitoring of adverse events associated with herbal products. Additionally, the willingness of consumers to disclose personal information for reporting purposes signifies a strong commitment to contributing to the safety monitoring of herbal products, highlighting the potential for active consumer participation in pharmacovigilance efforts.

**Results based on Methods of reporting for possible adverse events associated with herbal products**

The study provided valuable insights into the preferred methods of reporting possible adverse events associated with herbal products among consumers in Calamba. The data revealed that consumers expressed a willingness to report adverse events through various channels, including text messaging or SMS, social media platforms such as Facebook Messenger and Viber, as well as physical visits to community pharmacies. These findings underscore the importance of implementing a multifaceted reporting system that accommodates diverse consumer preferences and communication channels.

The study indicated that consumers agree and are willing to report adverse events through text messaging or social media platforms, highlighting the potential for leveraging electronic communication channels to facilitate consumer engagement in adverse event reporting. Additionally, the strong agreement among consumers regarding the willingness to visit community pharmacies to report adverse events emphasizes the importance of establishing accessible reporting mechanisms within community healthcare settings.

Furthermore, the data revealed that consumers strongly agree to provide personal details and information for reporting purposes, indicating a high level of commitment to contributing to the safety monitoring of herbal products. This willingness to disclose personal information underscores the potential for active consumer participation in pharmacovigilance efforts and the importance of establishing trust and transparency in the reporting process.

**Focus Group Discussion**

Four female community pharmacists took part in the focus group discussion; all of them are the pharmacist and the owner of the pharmacy at the same time. Two of the respondents have four years of experience in community practice while the other two have five years of practice. All of them are catering OTC medicines, ethical medicine, medical supplies and

**Table 3.** Profile of Community Pharmacists

No	Sex	Age	Role	Years of Practice	Pharmacy Services
1	F	25	Pharmacist / Owner	4 years	OTC, Ethical, Medical Supplies, Consumables
2	F	26	Pharmacist / Owner	5 years	OTC, Ethical, Medical Supplies, Consumables
3	F	27	Pharmacist / Owner	5 years	OTC, Ethical, Medical Supplies, Consumables
4	F	25	Pharmacist / Owner	4 years	OTC, Ethical, Medical Supplies, Consumables

consumables, in their pharmacies.

Table 3 shows the profile of community pharmacists who participated in the focus group discussion. The selected respondents in the table were female

pharmacists who also served as owners of their respective pharmacies, aged between 25 to 27 years old, with 4 to 5 years of experience in pharmacy services, specializing in over-the-counter (OTC) products, ethical products, medical supplies, and consumables. In choosing these respondents, three inclusion criteria were likely considered: being a practicing pharmacist, owning a pharmacy, and having experience in the field. Exclusion criteria may have involved factors such as not meeting the age or experience requirements (23-45 years old), not owning a pharmacy, or not practicing in the specified services. It was argued that there was no dropout or withdrawal of participants during the study, suggesting a high level of engagement and commitment from the selected respondents. These pharmacists were chosen based on their geographic location and their involvement in catering herbal products, with a focus on those who had received reports related to herbal issues. Furthermore, participants were provided with an informed consent form to ensure they were fully aware of the study's purpose, procedures, and their rights before participating in the research.

### **Herbal Medicine and Herbal Supplements Prevalence**

The FGD with community pharmacists provided valuable insights into the prevalence of herbal medicine and herbal supplements within the community pharmacy setting in Calamba and Los Baños. The data revealed that the pharmacies are catering to a wide range of herbal products, including commonly purchased items such as Sambong Tablet, Lagundi Tablet and Syrup, Malunggay capsule, and Barley capsule. This indicates a significant demand for herbal products among consumers within the community.

The FGD participants, who were all female pharmacists and owners of their respective pharmacies, emphasized that herbal medicines and supplements are commonly purchased by consumers, often without prescriptions. This aligns with previous research findings that highlighted the influence of anecdotal evidence and aggressive marketing tactics in driving consumer demand for herbal products, even in the absence of physician prescriptions.

The data also indicated that middle-aged and senior citizens are the primary demographic groups that frequently purchase herbal products, reflecting a notable pattern of consumption within the community. This demographic insight provides valuable context for understanding the consumer base and preferences related to herbal products within the study area.

These findings have significant implications for community pharmacists and healthcare professionals, as they underscore the importance of understanding and addressing the prevalent use of herbal products within the community. By recognizing the demand for herbal medicines and supplements, pharmacists can play a pivotal role in providing informed guidance, education, and monitoring of consumer usage to ensure safe and rational use of herbal products.

Furthermore, the insights from the FGD highlight the need for pharmacists to be equipped with comprehensive knowledge of herbal products and their potential interactions with conventional medications. This knowledge is essential for addressing consumer inquiries, providing accurate counseling, and promoting the safe and effective use of herbal products within the community pharmacy setting.

### **Pharmacovigilance system**

The FGD with community pharmacists provided valuable insights into the pharmacovigilance systems within the community pharmacy setting in Calamba and Los Baños. The data revealed that the pharmacists have a general understanding of the importance of pharmacovigilance in promoting safer medicines and rational drug use. However, the pharmacists also expressed concerns regarding the lack of awareness and reporting culture among consumers regarding adverse events associated with herbal products.

The FGD participants emphasized the need for a community-based adverse event reporting system that accommodates diverse reporting methods and ensures transparent feedback mechanisms. They also highlighted the importance of establishing accessible reporting mechanisms within community healthcare settings, such as community pharmacies, to facilitate consumer engagement in adverse event reporting.

The pharmacists also expressed the need for comprehensive education and training on pharmacovigilance systems and herbal products to enable them to provide accurate counseling and guidance to consumers. They emphasized

the importance of establishing a well-designed and simplified reporting system that is not burdensome to pharmacy personnel or consumers.

Furthermore, the pharmacists highlighted the importance of establishing a mechanism to validate electronically submitted reports to filter out authentic reports from non-authentic ones and ensure data privacy and eliminate data breaches. They also emphasized the need to consider possible hindrances of electronic-based reporting, such as poor ICT infrastructure in some areas.

### **Pharmacy capacity and capability of accepting and processing of reports**

The FGD with community pharmacists provided valuable insights into the capacity and capability of community pharmacies in Calamba and Los Baños to accept and process reports of adverse events associated with herbal products. The data revealed that the pharmacists expressed a willingness to participate in the reporting and monitoring of adverse events, highlighting the potential for community pharmacies to play a pivotal role in pharmacovigilance efforts.

The FGD participants emphasized the importance of implementing an electronically-based adverse event reporting system while acknowledging the need for a mechanism to validate electronically submitted reports and ensure data privacy. They also expressed a preference for face-to-face reporting of adverse events, as it allows for comprehensive communication and immediate counseling and information services to consumers.

The pharmacists highlighted the need for comprehensive training and education on adverse event reporting and pharmacovigilance systems, emphasizing the importance of user-friendly reporting tools and simplified reporting systems. They also underscored the potential for community pharmacists to provide training for pharmacy assistants, further enhancing the capacity of community pharmacies to accept and process reports of adverse events. Furthermore, the data indicated that the pharmacists recognized the importance of establishing feedback mechanisms and communication exchange between the parties involved in adverse event reporting. They emphasized the need for information campaigns and dissemination regarding herbal products to enhance consumer awareness and participation in adverse event reporting.

### **Methods of reporting to the Philippine FDA**

The FGD with community pharmacists provided valuable insights into the methods of reporting adverse events associated with herbal products to the Philippine FDA. The data revealed that the pharmacists expressed a preference for electronic means of reporting, such as sending a picture of the accomplished form or scanned form via electronic portal, messenger, or mobile application. They also emphasized the importance of establishing lead-time depending on the severity of the adverse event reported by the consumers.

The pharmacists highlighted the need for comprehensive training and education on adverse event reporting and pharmacovigilance systems, emphasizing the importance of user-friendly reporting tools and simplified reporting systems. They also underscored the potential for community pharmacists to provide training for pharmacy assistants, further enhancing the capacity of community pharmacies to accept and process reports of adverse events. Furthermore, the data indicated that the pharmacists recognized the importance of establishing feedback mechanisms and communication exchange between the parties involved in adverse event reporting. They emphasized the need for information campaigns and dissemination regarding herbal products to enhance consumer awareness and participation in adverse event reporting. The pharmacists also expressed the need for a mechanism to validate electronically submitted reports to filter out authentic reports from non-authentic ones and ensure data privacy. They also highlighted the importance of considering possible hindrances of electronic-based reporting, such as poor ICT infrastructure in some areas.

### **Feed-back mechanism**

The FGD with community pharmacists provided valuable insights into the feedback mechanisms associated with adverse event reporting for herbal products. The data revealed that the pharmacists emphasized the importance of feedback and communication exchange between the parties involved in adverse event reporting. They highlighted the need for transparent feedback

mechanisms to ensure that consumers and community pharmacies receive timely and relevant feedback on the status of their reports.

The pharmacists expressed a willingness to post advisories regarding herbal product risks and information in their community pharmacies, as well as on their social media platforms like Facebook pages. They emphasized the importance of targeted and relevant information dissemination to enhance consumer awareness and participation in adverse event reporting.

Furthermore, the data indicated that the pharmacists recognized the importance of establishing feedback mechanisms and communication exchange between the parties involved in adverse event reporting. They emphasized the need for information campaigns and dissemination regarding herbal products to enhance consumer awareness and participation in adverse event reporting.

The pharmacists also highlighted the importance of the Philippine FDA addressing and providing feedback to both consumers who initiated the report and the community pharmacies who submitted the report. They emphasized that transparent feedback mechanisms would ensure that consumers feel their concerns are properly addressed and managed, thereby encouraging them to report adverse events in the future.

Overall, the FGD data provides valuable insights into the feedback mechanisms associated with adverse event reporting for herbal products. The data underscores the importance of transparent and timely feedback to consumers and community pharmacies, as well as the need for targeted information dissemination to enhance consumer awareness and participation in adverse event reporting. The data also emphasizes the importance of tailored interventions and communication strategies to support the effective reporting and monitoring of adverse events within the community pharmacy setting.

## Discussion

The Philippine' pharmacovigilance system was developed with the goal of promoting safer medicines and rational drug usage. The use of herbal products has expanded in the Philippines, however there is a low culture of reporting adverse events. Adverse drug events (ADEs) must be reported to improve patient care and safety when taking drugs.

There was a high prevalence of herbal products used in the municipality of Calamba. Notably, the knowledge and awareness of consumers regarding risks with the use of herbal medicines and herbal supplements are considered lacking or insufficient. According to Ekor (2014), patients' freedom of choice of practitioner encourages them to choose alternative treatments and herbal remedies, even though many people choose herbal medicines based on anecdotal evidence, such as "it worked for a friend or relative [8,9]." Furthermore, according to Robinson, perceived health status was a cue to action construct, with many patients claiming to consume herbal products as a response to feeling unwell and it showed that many of them believed that herbal products were advantageous, especially for the treatment of illnesses and relief of symptoms [10]. And lastly, according to Hartigan-Go, the use of herbal products in conjunction with conventional medicine, or their substitution for conventional medicine, should raise serious concern among health care professionals, as these practices put patients at risk of adverse events and suggest noncompliance with scientifically proven treatment regimens[11].

The study highlights the need for a community-based adverse event reporting system to promote the safe use of herbal products in the Philippines. The study utilized a mixed-methods approach, including an online survey and focus group discussions with community pharmacists, to gather insights on the existing knowledge, attitudes, and practices of consumers and community pharmacists regarding herbal products and adverse event reporting.

The study found that there is a high prevalence of herbal product use in the Philippines, but there is a low culture of reporting adverse events associated with these products. The lack of reporting is a significant concern as it hinders the ability to monitor and manage the risks associated with herbal products. The study highlights the need for a community-based adverse event reporting system that can effectively capture and monitor adverse events associated with herbal products.

The proposed algorithm for the community-based adverse event reporting system emphasizes the role of community pharmacies as a link between consumers and the national pharmacovigilance center. The algorithm stresses the importance of a simplified and clear reporting system that is accessible to consumers and community pharmacists. The system should also ensure maximum data security and privacy of the consumers who initiate the report.

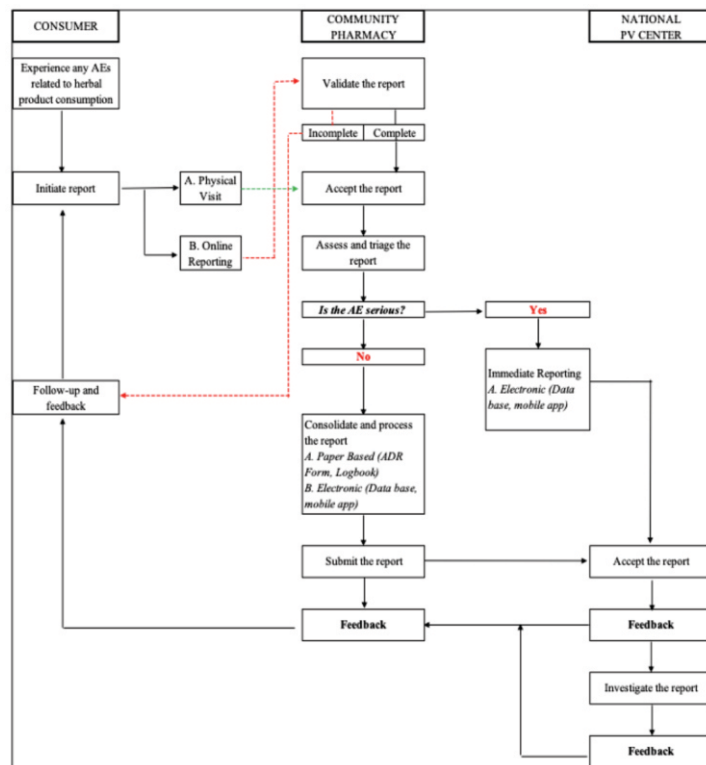
The study also highlights the importance of feedback and communication exchange between the parties involved in adverse event reporting. The study emphasizes the need for transparent feedback mechanisms to ensure that consumers and community pharmacies receive timely and relevant feedback on the status of their reports. The study also highlights the importance of targeted and relevant information dissemination to enhance consumer awareness and participation in adverse event reporting.

Overall, the study provides valuable insights into the existing knowledge, attitudes, and practices of consumers and community pharmacists regarding herbal products and adverse event reporting in the Philippines. The proposed algorithm for a community-based adverse event reporting system highlights the potential for community pharmacies to play a pivotal role in pharmacovigilance efforts. The study underscores the importance of tailored interventions, training, and user-friendly reporting mechanisms to support the effective reporting and monitoring of adverse events within the community pharmacy setting. The study's findings have significant implications for promoting the safe use of herbal products in the Philippines and enhancing the overall health of Filipinos.

### Proposed Algorithm for a Community-based Adverse Event Reporting System for Herbal Products.

The proposed algorithm for a community-based adverse event reporting system for herbal products emphasizes the role of community pharmacies as a link between consumers and the national pharmacovigilance center. The algorithm outlines the steps involved in reporting an adverse event associated with herbal products and stresses the importance of a simplified and clear reporting system that is accessible to consumers and community pharmacists.

The first step in the algorithm is for the consumer to report the adverse event to the community pharmacy. The community pharmacy will then assess the report and determine if it is an adverse event related to herbal products. If it is, the community pharmacy will then complete the adverse event report form and submit it to the national pharmacovigilance center.



The second step in the algorithm is for the national pharmacovigilance center to assess the report and determine if it is a valid adverse event. If it is, the national pharmacovigilance center will then investigate the adverse event and determine if any action is necessary.

The third step in the algorithm is for the national pharmacovigilance center to provide feedback to both the consumer who initiated the report and the community pharmacy who submitted the report. The feedback should be transparent and timely to ensure that consumers feel their concerns are properly addressed and managed, thereby encouraging them to report adverse events in the future.

The proposed algorithm also emphasizes the importance of data security and privacy. The algorithm stresses that all data collected should be kept confidential and secure to protect the privacy of the consumers who initiate the report.

Overall, the proposed algorithm for a community-based adverse event reporting system for herbal products provides a clear and simplified reporting system that is accessible to consumers and community pharmacists. The algorithm emphasizes the importance of transparency, timely feedback, and data security and privacy to ensure that adverse events associated with herbal products are effectively monitored and managed. The proposed algorithm has significant implications for promoting the safe use of herbal products in the Philippines and enhancing the overall health of Filipinos.

## Conclusions

The study highlights the need for a community-based adverse event reporting system to promote the safe use of herbal products in the Philippines. The study provides valuable insights into the existing knowledge, attitudes, and practices of consumers and community pharmacists regarding herbal products and adverse event reporting in the Philippines. It emphasizes the importance of a simplified and clear reporting system that is accessible to consumers and community pharmacists. The proposed algorithm for a community-based adverse event reporting system highlights the potential for community pharmacies to play a pivotal role in pharmacovigilance efforts. The study underscores the importance of tailored interventions, training, and user-friendly reporting mechanisms to support the effective reporting and monitoring of adverse events within the community pharmacy setting. Overall, the study's findings have significant implications for promoting the safe use of herbal products in the Philippines and enhancing the overall health of Filipinos. The proposed algorithm for a community-based adverse event reporting system provides a clear and simplified reporting system that is accessible to consumers and community pharmacists. The recommendations proposed can support the effective reporting and monitoring of adverse events associated with herbal products and promote the safe use of herbal products in the Philippines.

## Conflict of Interest Statement

Authors declare that they have no conflict of interest.

## Acknowledgements

The authors acknowledge the help of the following for their valuable input and suggestions in the completion of this study; Carlo L Perete, Edwin C Ruamero, Clinton R Gomez, and Gracielle Ilo-Atienza.

## Data Availability

The authors confirm that the data supporting the findings of this study are available within the article. Raw data that support the findings of the study are available from the corresponding author, upon reasonable request.

## References

1. DOH. (2019) Integrating Traditional and Complementary Medicine in Universal Health Care. <https://doh.gov.ph/NHSM-briefs/Integrating-Traditional-and-Complementary-Medicine-in-Universal-Health-Care>
2. Zhang J, *et al.* (2014) The Safety of Herbal Medicine: From Prejudice to Evidence. Evidence-Based Complementary and Alternative Medicine Volume 2015, Article ID 316706.: <http://dx.doi.org/10.1155/2015/316706>
3. Wink M. (2015) Modes of action of herbal medicines and plant secondary metabolites. *Medicines Journal*, vol 2:251-286.
4. Izzo A. (2018) An Interactions between Herbs and Conventional Drugs: Overview of the Clinical Data. *Med Principle Practice*: 21:404-428. doi: 10.1159/000334488
5. Kahraman C, *et al.* (2020) The Clinical Importance of Herb-Drug Interactions and Toxicological Risks of Plants and Herbal Products, *Medical Toxicology, IntechOpen*, DOI: 10.5772/intechopen.92040.
6. WHO. (2019) WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems. Retrieved at: <https://apps.who.int/iris/bitstream/handle/10665/43034/924159214>
7. Farooq N, and F Amin. (2019) Role of community pharmacist in pharmacovigilance. *Khyber medical university journal*, Vol. 11, no. 3, pp. 181-3, doi:10.35845/kmu.2019.18589.
8. Ekor M. (2014) The growing use of herbal medicines: issues relating to adverse reactions and challenges in monitoring safety. *Frontiers in pharmacology*, 4, 177. <https://doi.org/10.3389/fphar.2013.00177>
9. Hantanto H, and Valmores C. (2006) Facilitating Collective Action and Enhancing Local Knowledge: A Herbal Medicine Case Study in Talaandig Communities in the Philippines. <https://ideas.repec.org/p/fpr/worpps/50.html>
10. Robinson N. (2016) Integrated traditional Chinese medicine. *Complementary Therapeutics and Clinical Practice*. 12, 132–140.
11. Hartigan-Go K. (2002) Developing a pharmacovigilance system in the Philippines, a country of diverse culture and strong traditional medicine background. *Toxicology*, 181-182, 103–107. [https://doi.org/10.1016/s0300-483x\(02\)00263-9](https://doi.org/10.1016/s0300-483x(02)00263-9)
12. WHO. (2019) WHO Global Report on Traditional and Complementary Medicine 2019. <https://www.who.int/traditional-complementary-integrative-medicines>