

# MedAlisto: A Collaborative Intervention Program with FDA-CDRR for Adverse Drug Effect Reporting Among Community Pharmacies in Davao City

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## ABSTRACT

Underreporting of Adverse Drug Events (ADE) in the Philippines presents a persistent challenge, hindering the optimization of the Pharmacovigilance system. This issue is compounded by factors such as limited awareness, time constraints, and inadequate reporting methods. To address this, a study was conducted to evaluate the effectiveness of the collaborative intervention program (MedAlisto) with FDA-CDRR for ADE reporting among community pharmacies in Davao City. The study implemented a QR code system disseminated through standees, cards, and stickers across fourteen local community pharmacies. Researchers used a one-group posttest case study design and an adopted questionnaire to collect data. Statistical analyses were performed due to non-normal data distribution, including mean, Spearman rho, and Kruskal-Wallis test. Findings revealed high awareness (SD = 1.01) and moderate levels of diffidence (SD = 0.44), convenience (SD = 0.44), apprehension (SD = 0.48), dependency (SD = 0.38), repeatability (SD = 0.41), and liability (SD = 0.44) of consumers towards the intervention. Increased awareness and usage of cards and standees correlated with higher repeatability and liability, while stickers mainly enhanced convenience. Convenience (p= 0.012) was perceived as leading to increased apprehension (p=0.369) and dependency (p=0.100) across all tools except for diffidence, which was not linked to stickers. Dependency (p= 0.100) on standees and stickers contributed to higher convenience (p=0.012) and repeatability (p=0.136), while liability appeared independent in sticker usage. Users demonstrated similar levels of awareness (p=0.756), diffidence (p=0.311), apprehension (p=0.369), dependency (p=0.100), and repeatability (p= 0.136) regardless of the intervention. However, sticker users found the system more convenient, while standee users felt more liable for using it. While the effectiveness of interventions in influencing user behavior did not significantly vary, prioritizing sticker interventions to enhance user experience and encourage system usage may be beneficial. Efforts to address perceived liability among standee users should be explored to improve overall user satisfaction and engagement with the system.

**Keyword:** Adverse drug effect reporting, community pharmacies, medalisto, quantitative research.

## 1.0 Introduction

1.1 Background of the Study Underreporting of Adverse Drug Events (ADE) is a continuous challenge and a rate-limiting factor for achieving an optimum Pharmacovigilance system in the Philippines (Carandand, *et.al.*, 2015). Underreporting is defined as the erroneous low reporting rates of ADE reporting that may be due to several factors and may be dependent on the methods and interventions of each country (Gahr, *et.al.*, 2017). With the prevalence or underreporting of ADEs, the prevalence of threats to drug safety continue to go unresolved and cause additional damages and risks to patients as well (Performance Health, n.d). Hospital admissions, life-threatening health complications, and death are among the outcomes brought upon the underreporting of ADEs of various drugs in the market (Montastruc, *et.al.*, 2021) (Patrignani, *et.al.*, 2018) (Asiamah, *et.al.*, 2022). With ADEs already considered as the fourth or sixth common cause for death in hospital admissions, it cannot be stressed enough how fatal it is to not sufficiently report these adverse events (Laribièrè A, *et.al.*, 2015) (Brvar, *et.al.*, 2009) (Pirmohamed, *et.al.*, 2004) (Montastruc, *et.al.*, 2021).

Common factors affecting the prevalence of underreporting in the healthcare system is the lack of awareness, time-constraint, hesitancy and uneasiness of accessing current reporting systems by consumers and patients (Kitisopee, *et.al.*, 2017) (Lopez-Gonzalez, *et.al.*, 2009) (Irujo, *et.al.*, 2007). With the varying factors from each country and each healthcare setting, the theory of Inman's 'Seven Deadly Sins' of Adverse Drug Event Underreporting remains the mainframe that explains the components and perspective of each consumer as to why they are less likely to report ADEs with respect to the reporting platforms (Marques, *et.al.*, 2015) (Bello, *et.al.*, 2011). In addition, Pharmacovigilance and Drug Surveillance studies from Ghana and Pakistan, also revealed similar factors such as awareness, knowledge, attitude, time-constraint, and accessibility, such as lack of online report platforms, were frequent reasons affecting the sufficiency of reporting of Adverse Drug Reports (Yawson, *et.al.*, 2022) (Hussain, *et.al.*, 2022). , 5 5

As of the year 2022, the current methods of ADE reporting to the Philippines' Food and Drug Administration is done through online reporting, paper-based reporting and through hotline numbers as per PHFDA's advisory No. 2021-229 (FDA, n.d). Although with the presence of variety in reporting, the awareness for each intervention remains divided in the Philippines. Such as that paper-based reporting is the most known and recognized method of report submissions (58.5%) which is based upon a research study conducted by the Philippine Women's University-Pharmacy Department. Additionally, from this research, the respondents were also aware of the reporting systems through online reporting (43.1%) and hotline reporting (13.4%), while the rest of the respondents remain to have no idea about the present Adverse Drug Event reporting methods (20.2%) (Philippine Women's University, 2022). Paper-based methods are considered to be the pioneers of initiating Adverse Drug Event reporting with dates coming back to 1967 in the Philippines (Cuyegken, 1986). Since then, paper-based reporting systems were continuously improved and modified to cope up with the sign of the times but they remain to become outdated and the least preferred method due to its time and effort consuming quality (Worankunphanich, *et.al.*, 2022) On the other hand, E-mails and hotlines pose a challenge on sufficient reports despite being considered as the most efficient methods. Emails require critical formatting of letters to fully create a comprehensive report, and hotlines require load credit which is not always available, presenting a hindering factor of accessibility (Vergeire-Dalmacion *et.al.* 2015). Although proven effective, spontaneous reporting is another factor affecting efficient pharmacovigilance as it solely relies on free time and motivation of health professionals who often are already busy with their own main tasks

(Schrurer, 2019) (Hansberry, 2017).

In the Philippines, only a handful of ADE reporting initiatives have been published; among the well-known ones were the Bantay Gamot Program of FDA, the Texting-Based Reporting from UP-Manila, and VigiFlow eReporting (Gaje, 2009) (Vergeire-Dalmacion, *et.al.*, 2015) (Philippine Women's University, 2022). In spite of that, none of these initiatives were fully adapted in the healthcare system and put into the public for everyone to be aware about which makes the further creation and development of ADR interventions, a necessity (Carandand, *et.al.*, 2015) (Vergeire-Dalmacion, *et.al.*, 2015). Currently, the FDA-CDRR (Center for Drug Regulation and Research) has a reporting system made with developers from Sweden, in which consumers are able to submit their adverse drug reports (FDA, 2022). However, it is not fully known by the public. It is accessible yet it is not familiar to With this, the researchers would like to develop a relevant ADE reporting intervention that will provide an increase in knowledge, efficiency, and accessibility of Drug Reporting in health professionals and consumers. The intervention will be made to address and cope with the investigated elements that affect underreporting in the Philippines. The FDA, Community Pharmacies, and MedAlisto researchers will be working close together to bridge the gap between the consumers and the reporting authorities and ease the current gap between them. This will give the FDA a more perceptive vantage point of the current situation of adverse effects within the pharmaceutical market. Furthermore, MedAlisto aims to pursue the modernization and further promotion of Adverse Drug Reporting methods in the Philippines.

The sole purpose of this study is to measure the effectiveness of the integration of Adverse Drug Effect Reporting promotional interventions among Davao's Community Pharmacies. The researchers are to determine if the implementation of a QR code system through standees, calling cards, and stickers can aid in the eventual increase of Adverse Drug Event Report platforms. This research will also benefit medical consumers to have a more efficient and accessible channel for Adverse Drug Events Reporting here in Davao City.

## 1.2 Literature Review

Barriers and facilitators that influence Underreporting

Adverse Drug Events are a big deal in the medical field. It is really important to handle and lessen them to keep patients safe and maintain high-quality healthcare. (Aldryhim, 2019). But even though Adverse Drug Events have a big effect on healthcare, many of them still are not being reported enough (Hussain, *et.al.*, 2022). A 2022 research study executed by Tanattha Kitisopee with her colleagues, entitled "Consumers' Adverse Drug Event Reporting via Community pharmacists; three stakeholder perception", tackled factorial themes such as 'Cognition', 'Reporting', 'Inducers', and 'Obstacles' that were significant in affecting the frequency and intensity of Adverse Drug Reports. The degree of awareness, mindset, and obligation that users have towards ADE cases is referred to as Cognition. Also, when it comes to reporting, factors like skills, not having enough information, things getting complicated, and feedback play a role. Meanwhile, "Inducer" is about how pharmacists help consumers by guiding them, giving them information, setting rules, encouraging them, and maybe even rewarding them. Lastly, Obstacle, alludes to the doubt, belief and prosecution of the consumers themselves (Kitisopee, *et.al.*, 2022).

These factorial themes were found to greatly influence the motivation of consumers to report and the amount of aggregate reports that would be gathered (Kitisopee, *et.al.*, 2022). It was also discussed that for each theme, a specific reason overlaps the others.

## 1. Cognition:

### 1.1 Awareness

From the study conducted, it was tallied that majority of the respondents from patients and community pharmacists were not fully aware of submission channels on where to submit ADR reports which contributed to the low amount of tabulated reports received by the FDA (Kitisopee, *et.al.*, 2022). It was also greatly suggested by the interviewed community pharmacists that continuous and evident publication of the reporting channels should be prioritized to increase the awareness of consumers which in return increases the amount of reporting outputs (Kitisopee, *et. al.*, 2022). In addition to this finding, a similar research from Dweik, *et.al.* (2017) heavily emphasized that poor patient awareness was the main hurdle for the presence of ADR reports (Dweik, *et.al.*, 2017). By developing awareness and knowledge about ADRs and ADR reporting, the community will be more affined to practicing ADR vigilance (Bodolubova, *et.al.*, 2018).

### 1.2 Attitude

The attitude segment referred to the perspective of the consumers towards partaking significance in their reports (Kitisopee, *et.al.*, 2022). From the tallied reports, both pharmacists and consumers have thought of the benefits of ADR reporting and most had a positive attitude towards it. However, a handful of the respondents still believe that their reports would not be used, causing them to not report their complaints (Kitisopee, *et.al.*, 2022) (Duu, *et.al.*, 2009).

## 2. Reporting Process

### 2.1 Complication

Degree of complication refers to the degree of efficiency and user-friendly value of the reporting channel. Most consumers have felt that the overall process of ADR reporting was time-consuming and too complicated (Kitisopee, *et.al.*, 2002), (Khan, 2013), (Irujo, *et.al.*, 2007). With the difficulty and laboriousness of the reporting process, more people are less inclined to report and go through the process (Khan, 2013). As noted by one of the respondents from Kitisopee and her colleagues' study, usual spontaneous reporting is not worth the time and effort to travel and submit the report. The presence of complication leads to an overall lack of efficiency for the side of the consumers (Irujo, *et.al.*, 2007).

### 2.2 Information Deficiency

For this reason, the presence of privacy and anonymity is of concern. From the results of the study it was discovered that consumers are hesitant to approach a spontaneous method of reporting as this would affect their privacy and would risk unwanted exposure (Kitisopee, *et.al.*, 2022). Additionally the employment of several management safeguards, such as network (firewall), physical (limited access), and operating security (user access keys) are needed to provide utmost comfort and safety for each person to address their ADRs (Small, *et.al.*, 2021)

## 3. Inducer

### 3.1 Regulation

Lack of mandated and regulated ADR reporting is considered one of the reasons for the prevalence of underreporting (Kitisopee, *et.al.*, 2022). Community pharmacies as of this time are not commonly required to promote and exercise ADR reporting. With the deficiency in constant regulation of ADRs less people are likely to know what ADRs are and how to report them (Kitisopee, *et.al.*, 2022)

## 4. Obstacle

### 4.1 Doubts

Consumers often have doubts that what they are experiencing is not enough to be considered an ADR (Kitisopee, *et.al.*, 2022). Oftentimes, consumers try to diminish the severity of what they are experiencing as they are not sure whether it came from the medicine they took or from the environmental factors they are surrounded with (Kitisopee, *et.al.*, 2022).

The thorough analysis of these factors allows for the continuous understanding and comprehension of better solutions to improve the overall system of Adverse Drug Reporting (Vallano, *et.al.*, 2005). In addition the curation of the barriers relating to awareness, attitude, and accessibility should heavily be prioritized in terms of making an effective increase in ADR reporting (Gurmesa, *et.al.*, 2016).

### Effects of Underreporting

Adverse drug effects alone comprise the top 4 and 6 reasons for hospital deaths (Laribièrè A, *et.al.*, 2015). In connection to this, Drug-Related-Deaths (DRDs) were also accentuated to be the common cause for death in hospitals (Coleman, *et.al.*, 2016). ADEs cause about 10% of outpatient visits, 5–10% of hospital admissions, and 10–20% of prolonged stay in hospital admissions (WHO, 2021) (EU Parliament, 2010) (Edwards, *et.al.*, 2006). According to a study of Montastruc, *et.al.* (2021), about 3 million participants in their study have experienced ADEs and 43, 645 of these participants experienced a more fatal ADE, resulting in life-threatening conditions and even death. (Montastruc *et al.*, 2021). In a similar study focusing on anticancer drugs, the results heavily emphasized the lack of ADE reporting of potentially serious toxicity experienced by the patients due to the lack of awareness of reporting channels by physicians and for the patients in general (Seruga *et al.*, 2016).

Arellano, *et.al.* (2021), notes that with the alarming presence of DRDs it is important to increase and improve the method of pharmacovigilance within the healthcare system. It was found out in their study that 50% of the collected DRDs were preventable if only they were reported and verified earlier on (Arellano, *et.al.*, 2021). Parallel to this finding, was from the study of Il Seon Yun, *et.al.*, 2012 in South Korea, in which they have indicated that spontaneous methods of drug reporting alone is not sufficient to support and prevent the increase of DRDs in the community. As it is the most simple method for ADE reporting, it is however, inefficient causing the increase of underreporting levels (Il Seon Yun, *et.al.*, 2012) (Hazell, *et.al.*, 2006). Methods of improvement and development of ADE reporting must be prioritized to alarm drug officials about such dangerous drugs and to allow the consumers to immediately get the sufficient medical aid they need (Arellano, *et.al.*, 20210

### Methods of Adverse Drug Reporting Around the World

Different countries have their own ways of keeping track of medicines and their effects. They set up systems to do this, following the rules from the World Health Organization (WHO). (Sankaranarayanan, 2021). These systems are typically managed by specific government bodies or agencies, like the Food and Drug Administration in the United States and the Philippines, the European Medicines Agency (EMA) in Europe, and the Health Products and Food Branch in Canada. (Kumar, 2013) (Health Canada, 2015). Sankaranarayanan (2021) also mentions that these agencies often set up systems by doing things like passive surveillance, cohort event monitoring, or targeted clinical investigations. In Europe, the EMA has improved its drug safety monitoring by making a systematic database called EudraVigilance. This system lets people report individual cases of suspected bad reactions to drugs online, and it gives clear instructions



on how to gather, check, and present this information (Europa, 2022). Similar to Europe, Canada also uses a database system called Oracle Argus. It is a thorough platform for managing bad reactions to drugs, and it's used by companies in the life sciences field to keep an eye on drug safety (Oracle 2013). Integration of pharmacovigilance databases makes it possible to gather and analyze reported adverse drug reactions in an accessible way, which can inform both medical professionals and the general public. (Bihan, *et.al*, 2020). The World Health Organization also implemented the Global surveillance and Monitoring System (GSMS). In this, the system's objective is to improve the reporting of substandard medical products, strengthen regional and national regulatory capacities to prevent, detect and respond to substandard medical products, and their adverse effects and these reports will be then submitted to the World health organization via an electronic raid alert form (WHO Global Surveillance and Monitoring System, 2013).

FDA produced various strategies to control drugs that are released in the Market. With this an Administrative order was implemented which is known to be the National Policy and Program of Pharmacovigilance. This order implements a strategic framework for the implementation of Pharmacovigilance policies. In this order the FDA and DOH shall collaborate in order to thoroughly assess the collected reports that showed risk to the community (OFFICE of the SECRETARY, n.d.) . Republic Act No. 3720, or also known as "Food, Drug, and Cosmetic Act." which is declared that the State shall insure the safety and quality of food, drug and cosmetic, and to also regulate the production and sales of this products to ensure the well-being of the people (Republic Act No. 3720, n.d.).

### **Social value of the Study**

Adverse Drug Effect reporting is a major asset in societal aspect, A study includes UK Yellow Card Scheme (YCS) it is another type of drug surveillance system that is implemented in the United Kingdom, according to this the YCS was a great deal for it showed the views and perspective of consumers in terms of the adverse effects bought from different pharmacies or drug store (Anderson et al., 2011). This research could heighten the exposure to how serious the Drug Adverse effects are and can help in decreasing the risk of drugs that are released to the public. The methodology will be able to be done since these procedures are the one that will suffice the needed intervention of our research. The reason why it would implement the methodology.

### **Bantay Gamot Initiative in the Philippines**

The FDA in the Philippines along with the Department of Health (DOH) and the provision of WHO currently utilizes the Bantay Gamot initiative for its Drug Surveillance actions since its launch on October 28, 2009 (Gaje, 2009). Bantay is the Filipino word for 'watch' and Gamot is the Filipino translation for 'drug' (Meriam-Webster, n.d) (Tagalog Dictionary, n.d). The Bantay Gamot initiative started its service as a paper-based report system but has since expanded its accessibility through systemized hotlines and email reporting service (Vergeire-Dalmacion, *et.al.*, 2015) (Gaje, 2009).

Bantay Gamot can be accessed through its landline number or through its two mobile numbers, and its email address. However it has since been noted that the hotline and mobile numbers have not been updated since its release in 2009 and may be considered unavailable as of the current year (Gaje, 2009). As of the year 2022, the only credible resources for submission of ADRs are through sending emails and actual mail reports to the headquarters of the FDA. The Bantay Gamot initiative was made to allow consumers to

report their concerns regarding purchased drugs whether there may be issues about their validity, adverse effects, counterfeit ability and many more (Gaje 2009).

As a means of improving the wide accessibility of Bantay Gamot, in 2010 the Philippine FDA once again collaborated with DOH and now with its Information Management System to create an online ADR reporting system (Vergeire-Dalmacion, 2015). However, according to an interviewed FDA's key informant officer, an ample amount of health professionals and pharmacovigilance officers had a difficult time accessing its website, affecting the overall effectiveness of the initiative (Vergeire-Dalmacion, 2015).

### **Texting-based reporting of adverse drug reports in the Philippines**

In 2015, a feasibility study regarding texting-based reporting for adverse drug effects was conducted by Vergeire-Dalmacion and her colleagues from the University of the Philippines, Manila. The study entitled, 'Texting-based Reporting of Adverse Drug Reactions to Ensure Patient Safety: A feasibility study was conducted around implementing a text hotline for Adverse Drug Reporting within a tertiary hospital in Manila (Vergeire-Dalmacion, *et. al.*, 2015). To evaluate the feasibility, the reports were recorded through a texting-computer reporting system created by the researchers. The amount of texting-based reports was compared to the data on the amount of existing paper-based reporting from the 'Bantay Gamot' initiative of FDA through the UP-PGH's Pharmacy and Drug Committee; During the launch of the text researchers collated about 277 ADR reports from the paper-based method and have only received 3 ADR reports from the text-base system (Vergeire-Dalmacion, *et.al.*, 2015).

Vergeire-Dalmacion and her colleagues (2015), also adds that the utilization of technology through means of computers, the internet, and gadgets has not been a new scenario in the pharmacovigilance field. A similar study conducted in Cambodia by Baron *et.al.*, also utilized a text-based system. The text-based system was conducted to assess and compile reports from patients who have recently received vaccination (Baron, *et.al.*, 2013). With this intervention, Baron, *et.al.*, (2013) were able to garner 54.9% out of a 100% of immediate SMS replies regarding the unwanted effects of the vaccine, concluding that such intervention is useful in Cambodia. It could be denoted that the effectivity of the intervention varies between the population and the community as rate-limiting factors such as technical glitches, frequent power interruptions, insufficient load and credit balance could exist per location, such as in the Philippines (Vergeire-Dalmacion, *et.al.*, 2015).

### **QR Code systems in Adverse Drug Reporting**

Numerous studies and interventions in the medical field have started to utilize QR Code Systems (Klein & Stolk, 2018). QR stands for quick response; as a whole, QR code is an extended form of the usual barcode found in most technological advancements (Hayes, 2021). Another study of using an automated system for managing medical data and generating service reports using Android smartphones was created and put into use (D'Addio *et al.*, 2017). In this study, QR Codes were utilized to identify and monitor individuals receiving rehabilitation therapies. Through this intervention, the effectiveness of health system operations were improved, information transcribing errors were avoided, and work schedules for healthcare professionals were reduced (D'Addio *et al.*, 2017). In another study relating the use of QR code, the management of creative vaccination programs in Latin America and the Caribbean countries was treated with the QR code intervention. The application of the system was used to track whether the patient experienced any negative drug side effects and with the treatment. Further on, it was noted that such intervention allowed the patients to have a more accessible means of reporting and most have felt

the satisfaction and assurance of the presence of pharmacovigilance (Tregnaghi *et al.*, 2022). With the already existing significance of the QR code system in the healthcare scene, it cannot be denied that further usage of it may help improve other aspects of the healthcare system. Other aspects such as the need for more accessible online ADR reporting system for pharmacovigilance can greatly benefit from the QR Code Interventions (Hussain *et.al.*, 2022)

### 1.3 Theoretical Framework

This section indicates the theories and system of beliefs this study is grounded upon.

The Seven Deadly Sins Theory of Adverse Drug Effect Reporting

The Seven Deadly Sins of ADE Underreporting theory was presented by Inman in 1976 and was further amended in 1986 and extended 1996 (Inman, 1976) (Inman, 1986) (Inman, 1996). The theory tackles the attitude and possible factors that influence a person to prevent his/herself from reporting Adverse Drug Events and was initially constructed to comprehend the factors of common drug safety issue which according to Inman is mainly due to (i) failure to identify ADR (ii) failure to report the identified ADR (Lopez-Gonzalez *,et.al.*, 2009). For this study, the latter division is significant in understanding the possible factors that could be alleviated with the MedAlisto Intervention.

According to Inman, these are the 7 Deadly Sins of Underreporting in accordance with the failure to report the identified ADR as based on the consumers' point-of-view (Lutz, 2014 (Bottoni, 2009) (BMA Board of Science, 2006). The order of each factor below is based upon their prevalence and their level of significance in affecting the levels of underreporting as associated with the systematic review of Elena Lopez-Gonzalez, *et.al.*, (2009). Ignorance being the most frequent and liability being the least (Lopez-Gonzalez, *et.al.*, 2009)

1. **Ignorance.** *"I don't know where and how to report"*.
2. **Diffidence.** *"I am afraid of looking ridiculous and awkward when I send a report."*
3. **Convenience.** *"Reporting is too time-consuming and requires too much effort."*
4. **Apprehension.** *"I am afraid of being litigated for legal liabilities."*
5. **Guilt.** *"I am afraid of causing distress to officials when I ask where and how to report."*
6. **Repeatability.** *"I would rather share the report myself by mouth or through social media."*
7. **Liability.** *"My report does not matter as I think all drugs in the market are already safe."*

This framework together with the supporting related literature can aid the researchers in formulating a MedAlisto to be a database that could address most, if not all, of the proposed 'Seven Deadly Sins'. In addition to this, the researchers can further formulate a survey questionnaire that is based upon this to assess whether the proposed MedAlisto is able to target Inman's Seven Deadly Sins of Underreporting.

### The Theory of Diffusion of Innovations

It is described as the rate at which various new concepts, goods, and practices would spread throughout the market (Halton, 2021). According to Sahin (2006), Rogers defined the term "diffusion" as the social system's use of specific channels for communication.

There are four (4) elements of diffusion of Innovation these are: Communication Channels, Social Systems, and Time. Each element significantly influences the success that affects the spread of innovation (Sirk, 2020), In addition to this, there are also five (5) stages under the Theory of Diffusion of Innovation namely, Knowledge, Persuasion, Decision, Implementation and Confirmation. Knowledge denotes the user's awareness of the innovation and its use; Persuasion denotes the user's evaluation of the innovation's

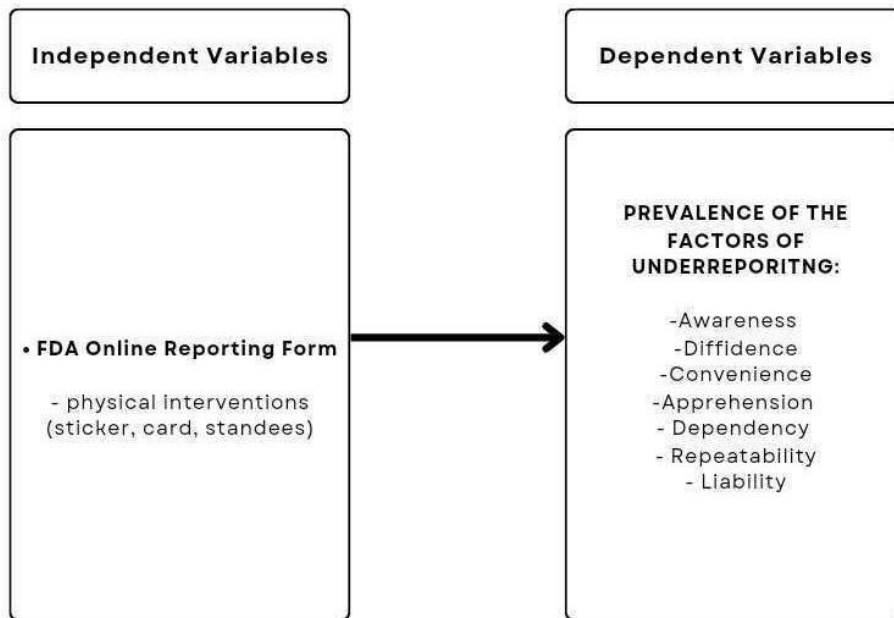


positive and negative aspects; Decision denotes the user's consideration of whether to accept or reject the innovation; Implementation denotes the execution of the innovation following their acceptance of the innovation; and Confirmation denotes the user's final support and reinforcement of the decision implemented.(Durak, et.al., 2016).

The MedAlisto intervention is one example of an experiment that frequently makes use of diffusion theory and has a short window of opportunity to clearly have an impact on the entire community. (Health Communication Capacity Collaborative , 2014). Even though the impact is only temporary, this does not automatically imply that the innovation is not important. Health Community Capacity Collaborative (2014) added that in order for the innovation to have a significant impact, access to it must be prioritized for important community members and subjects.

Despite the time constraints, MedAlisto aims to thoroughly show the possible diffusion of the intervention towards the community and the population it includes.

### 1.4 Conceptual Framework



**Figure 1. Independent and Dependent Variables**

The researcher used the MedAlisto interventions in aiding patients towards Adverse Drug Effects Reporting, wherein, the participants were then led into the own website of the FDA ADE reporting platform. Interventions that were used were the stickers, calling card and standees. Through the website and the physical interventions, the researchers were able to measure the indicated independent variables. The dependent variables were based upon the ‘Seven Deadly Sins of ADE Underreporting’ by Inman and was the mainframe for the variables with the rendition of the supplementing studies in the Related Literature that supported it.

Awareness here indicated the knowledge related to behavior, which explored the understanding of respondents towards ADR reporting and its importance (Potlog Shchory et al., 2020). Diffidence stated the confidence of the community to report, in a study, healthcare professionals were reported to avoid report ADRs because they are not confident enough to report and are scared of the embarrassment if the

report is dimmed to be a false accusation (Mirbaha et al., 2015). convenience was perceived as the ability to be time-consuming. For this a survey was given to patients wherein they were encouraged to be active in post-marketing surveillance and to spend a lot of time assessing the adverse effects of drugs in the market which resulted in increased ADR reports (Härmark et al., 2012). In this study, participants may experience apprehension of legal liabilities. 54.6% of respondents in the study are scared to be involved in further investigations of drugs that cause ADR (Agarwal et al., 2013). Guilt is one's attitude that affects underreporting, a study showed that being the cause of someone's illness influences a person to keep the error or report for themselves (Zabari & Southern, 2018). Repeatability, respondents believe that they should receive financial reimbursement for the ADR they reported, this shows that this could be a factor of underreporting (Agarwal et al., 2013). Lastly, liability states that ADRs are not serious since drugs that are on the market are already known to have side effects. According to Lopez-Gonzalez et al., 2009 67% of their study showed liability.

The words used in our dependent variables are known to be neutral in order to avoid biases that can manifest negatively into our study, bias-free language are used to avoid confusion (Northern Illinois University, n.d.).

### 1.5 Statement of the Problem

The study evaluates the effectiveness of the *Collaborative Intervention Program with FDA-CDRR for Adverse Drug Effect Reporting among Community Pharmacies in Davao City*. The research is guided by the following questions:

1. What is the *level of each parameter* with the use of the MedAlisto Reporting Database System:
  - 1.1. Awareness
  - 1.2. Diffidence
  - 1.3. Convenience
  - 1.4. Apprehension
  - 1.5. Dependency
  - 1.6. Repeatability
  - 1.7. Liability
2. Is there a significant correlation between the parameters from each physical intervention?
3. Is there a significant difference between the parameters from each physical intervention
  - 3.1. Awareness
  - 3.2. Diffidence
  - 3.3. Convenience
  - 3.4. Apprehension
  - 3.5. Dependency
  - 3.6. Repeatability
  - 3.7. Liability
4. What is the prevalence of similarities and differences of answers on the FDA ADR form with regards to the following questions:
  - 4.1. Number of Reports sent by individuals or in behalf of their relatives and by professionals
  - 4.2 Outcome of Reaction
  - 4.3 Severity of Reaction
  - 4.4 Duration of Reaction

#### 4.5 Action taken with Medicine

### 1.6 Hypotheses

#### Null Hypothesis ( $H_0$ )

There is no significant correlation between the interventions and the level of parameters.

#### Alternative Hypothesis ( $H_a$ )

There is a significant correlation between the interventions and the level of parameters.

### 1.7 Definition of Variables

This section aims to supplement the definition and usage of the words that are deemed significant in the study.

**Med.** *Noun.* This word is an abbreviation for medication (Britannica Dictionary, n.d.).

**Alisto.** *Adjective.* Means alert in English. quick to see, understand, and act in a particular situation (Cambridge Dictionary, 2022).

**FDA-CDRR.** *Noun.* Known as the Food and Drug Administration's Center for Drug Regulation and Research; It is the section of FDA assigned to mandate activities and programs regarding drugs and the aspects that concerns it (FDA, 2022).

**Adverse Drug Reporting.(verb).** This is the act of reporting any harmful side effects of a medication (FDA, 2018) . The term used in the study refers to a consumer's act of reporting any negative effects by scanning the QR code and filling out the online report form on the website.

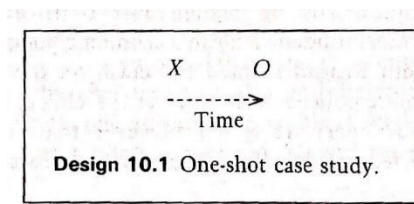
**Community Pharmacy.** *Noun.* This refers to the most common type of pharmacy that allows the public access to their medications and advice about their health. (Smith, 2019).The word used in the study to denote a location where the QR code system must be implemented.

### 2.0 Methods

This chapter aimed to expound the study design, participants, data instruments, data collection, data analysis, and ethical considerations used in the core structure of this study.

#### 2.1 Study Design

This study is conducted in a One-Shot or One-Group Posttest only design case study. A One-Shot case study is the research design appropriate for the use of training programs, policy changes, medical treatments, or the launching of health programs (Chouery, 2023). One-shot case studies do not require control groups and are simply catered to voluntary public participation which is the experimental group (Jaikumar, 2018). One-Shot Studies, according to Campbell and Stanley of the book of *Quasi Experimental designs in Research*, follow on two factors in the research namely the **X** and **O**. The **X** simply refers to the intervention or program that will be initiated through a given time, while **O** refers to the aftermath or the result of a given situation after **X** was applied, thus there are no pre-tests involved. In this case, MedAlisto as a ADR reporting program is the **X** indicated in the study while the **O** refers to the post-situation after its designated launching duration. The study described the aftermath of MedAlisto and compared it to the situation on the number of accumulated reports before MedAlisto.



**Figure 2. One-shot Case Study**

For a One-Shot study, a convenience sampling was applied. Convenience sampling is a form of non-probability sampling where components are chosen for the sample based on their accessibility to the researcher or in this case the MedAlisto interventions. This may be as a result of close proximity geographically, availability at a specific moment, or desire to take part in the study (Nikolopoulou, 2022).

## 2.2 Research Locale

Fourteen (14) local community pharmacies in the City of Davao, Philippines, were selected as the study's research ground. Geographically, the City of Davao is situated on Mindanao, an island inside the Southern Philippines. Moreover, the city is located in the Southeastern part of the Mindanao island. On the global map, it is located in the grid squares 6°58' to 7°34' N latitude and 125°14' to 125°40' E longitude (NEDA-RDC, n.d.) The fourteen participating local pharmacies will hold the QR Code interventions such as stickers, standees, and calling cards.

## 2.3 Subjects or Participants

The main subjects that were analyzed according to their report and post-perception towards MedAlisto were the mass population of Davao City medicinal and pharmaceutical product users. This included those who had acquired experiences with Adverse Drug Effects. Their experiences with ADE were the only requirement for them to become participants in the program, as their reports sufficed to assess the effectiveness of integrating MedAlisto as a program in the FDA.

The date of the Adverse Drug Event and the type of ADE report that the subjects submitted did not matter, as these topics were beyond the knowledge of the researchers. This was done to honor the subjects' privacy, as per the request by the FDA.

### 2.3.1 Recruitment Process

The recruitment process of the main subjects is done through public promotions such as launching a Facebook Page wherein the target audience and participants may be able to inquire about MedAlisto, what it stands for, how to use it, and the locations on where to find it. In the Facebook Page, the target participants are able to seek through the public campaign materials or graphics that invites them to inquire on the page and inquire questions regarding ADR reporting. The limitation of the Facebook Page however is that it does not contain the QR Code Imagery of Medalisto to limit abuse and traffic of possible unnecessary reports or remarks. In this way we would be able to guide the target participants into the community pharmacies in which the QR Code is located. This is to ensure that only those who are eager to report and have an actual reason to report are held as the target population. However, the recruitment process is not limited to the Facebook Page as possibilities of sharing the program may be done through word of mouth. Such as persons with interest in MedAlisto sharing the program and their acquired QR Code to their relatives. In addition, FDA-CDRR and the FDA-XI Regional extended their hand to promote the program. Additional publicity of the program such as in news outlets also sufficed in the recruitment process of the target population.

## INCLUSION CRITERIA

### Pharmacies where the intervention will be placed

- An FDA approved certificate
- Business Permit with not less than two (2) years of remaining validity of the license.
- A License To Operate (LTO) with not less than two (2) years of remaining validity of license.
- DFA certificates with the complete name of the head pharmacist

### Consumers

- Anyone who wished to report their adverse drug reaction regarding any medicines was welcome to report as long as they had purchased a medicine that needed a prescription.
- Anyone who had a smartphone capable of scanning could report.

## EXCLUSION CRITERIA

- Anything that are not in accordance with what is stated above is the exclusion criteria

The study was mainly conducted and mandated by the researchers. However, the dissemination of the interventions towards the public mass was done by the Local Community Pharmacies and their staff, as they held the most accessibility to the consumers. In this regard, the researchers remained the main supervisors, providing instructions to the Pharmacy staff on what interventions to disseminate and how to do so. The role of the consumers in the study was to scan the QR code, which was in the form of a calling card or sticker located in the pharmacy. The chosen pharmacies served as the medium to spread the interventions. Furthermore, all customers from the selected Community Pharmacies were strongly encouraged to participate in the Adverse Drug Report submission process.

## 2.4 Instruments

### 2.4.1 QR Code Stickers and Card

#### QR Code Stickers

- This physical intervention will include the QR Code of the MedAlisto Website. Actual size of the sticker is 2.5 cm by 2.5 cm. *See Appendix J.3.*

#### QR Code Card

- The physical intervention included the QR Code of the MedAlisto Website, a quick background of MedAlisto's initiative, and instructions on how to access the website. Supplemental details, such as the hotline numbers and the website of MedAlisto, were also provided. The card was also provided in the Filipino language to cater to the majority of Davao City's population. Actual size of the calling card is 3.5 cm by 2 cm. *Please refer to Appendix J.4*

#### QR Code Standee

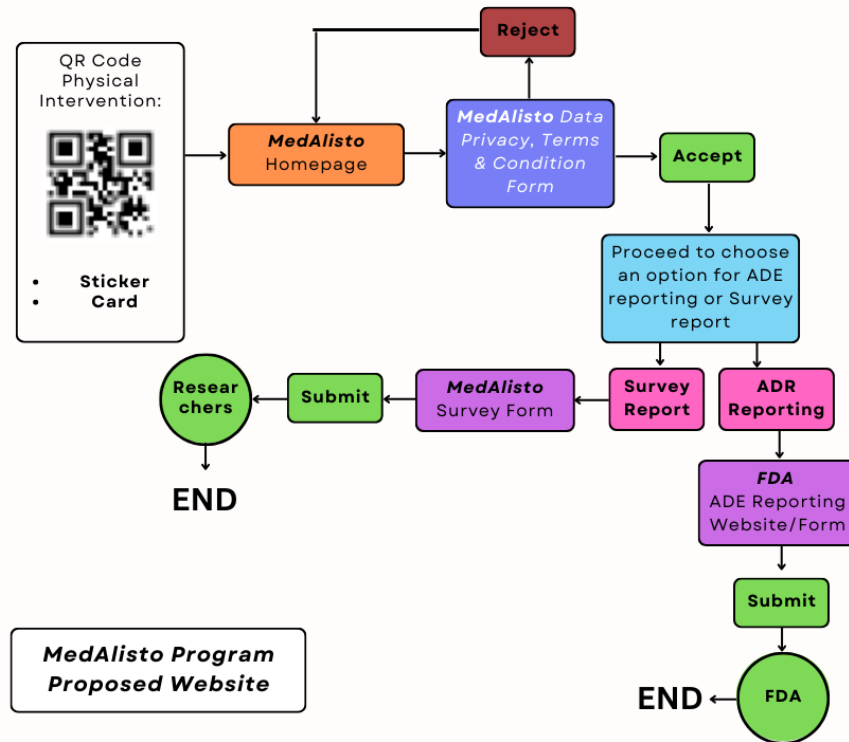
- The QR code standee simply contained the QR code of the MedAlisto, logo of San Pedro College and FDA, short description about MedAlisto, names of the researchers and research adviser, fb page of MedAlisto. Actual size of the standee is 21 cm by 29.7 cm. *Please refer to Appendix J.5*

### 2.4.2 Website

#### 2.4.2.1 MedAlisto Algorithm



Below is a conceptual illustration on how the MedAlisto Website will be utilized to obtain Pharmacovigilance reports.



**Figure 3. MedAlisto: QR Code System Algorithm**

The system started as soon as the consumer scanned the QR Code provided by the Community Pharmacy from which they had purchased the product. After scanning, they were led to the Data Privacy form and Terms & Conditions form, where they had the option to accept or reject. If accepted, they proceeded further; if rejected, they were led back to the homepage. For consumers who accepted the Data Privacy and Terms & Conditions forms, they then moved on to the options page, where they could choose to submit the ADE report itself or complete a survey after using MedAlisto. If they chose to send an ADE report, they were directed to the FDA reporting website. There, they filled in their age, gender, location, name, and contact details, with the latter two being optional. Next, they were taken to the main body of the system, the ADE report form, where they provided the details of the medication and their complaint. Once filled in, they could click submit, and their report would be sent to the FDA. On the other hand, if they chose to complete a survey, they were directed to the MedAlisto survey website, where they filled in the survey summary. The tallied survey answers were then sent to the researchers as part of their results.

#### 2.4.2.2 Consumer-to-Pharmacy

Consumers were given a QR code, either in the form of a sticker to be placed on the medicine’s packaging or a call card, where the consumers scanned it. After scanning, the Consumers are directed to the MedAlisto Website. On the website, they promptly filled up the form with the complaints and reports, then clicked the submission form.

Consumers in this study are the ones who bought drugs from our partnered pharmacy. Specifically, the ones who used the physical interventions that we have released from the Partnered pharmacies such as

calling cards, standee, and stickers. Since our scope stated that it is within Davao City, Consumers were local buyers and are regular customers from Partnered pharmacies.

#### 2.4.2.3 Virtual Private Network (VPN)

Along with the UAS Database System, another component of the system is the Virtual Private Network (VPN) of the database. VPN is a network that creates an encrypted online connection allowing the internet users to have more secured privacy and anonymity online (Gillis, 2021). There are three (3) advantages of using the VPN; the Encryption of your IP address, Encryption of protocols, and Two-factor authentication (Kaspersky, 2022) VPN is now used in a variety of circumstances like the free-wifi in the public to ensure that third-party operators or outside operators are not able to (*e.g.*, airport, school, train *etc.*) (Whitemore, 2021). The data will be protected through the Virtual Protection Network that will be applied to the whole stability of the website.

#### 2.4.2.4. Informed Consent

Before each participant could submit their report or survey, they were first led to the HomePage of MedAlisto, where they were presented with a paragraph of the Terms & Conditions along with the link to a file of a Formal Informed Consent Letter. This letter made them aware of the research program, its benefits, risks, and processes. Once they assessed the Terms and Conditions and the Informed Consent Form, they were able to tick the box that stated, "I have read and understood the Terms & Conditions, and I consent to participate in the Program." Ticking this box ensured that the possible target participants gave their utmost voluntary consent. However, if they did not agree with both the Terms and Conditions and the ICF, they were unable to access the Reporting Forms and Survey Forms. One limitation of this method was that the researchers were unable to know the identities and contact details of the participants who had accepted the aforementioned matters. This was because such information was beyond the knowledge accessibility of the research and was done as a way for the researchers to respect the participants, as advised by the offices of FDA-CDRR and FDA-XI. The tallied number of accepted or ticked boxes relating to the aforementioned matters would be collected through the Database of MedAlisto.

#### 2.4.3 Post-Survey

Gathered answers from the research parameters aforementioned in the statement of the problem, were utilized by the researchers in this section/ The survey was done after the submission of the ADE report. The questionnaire involved 20 questions. The researchers made sure that the website and the system was efficient and usable. The QR code has been scanned using the scanner from the reporter's phone that will give them the direct link to the MedAlisto website.

The questionnaire contained a section that consisted of seven (7) categories: awareness, diffidence, convenience, apprehension, dependency, repeatability, liability, that contained questions related to these parameters. Each category is composed of 5 questions. The instrument was structured in the modified Likert scale, on a 5-point scale, ranging from "Strongly agree" (5), through "Agree" (4), "Neither agree" (3), "Disagree" (2), "Strongly disagree" (1). Likert scale is used to determine properly the results rather than having a yes or no which we cannot really tell the specific results (McLeod, 2008).

The response of the respondents in all statements indicated in the questionnaire was tallied and analyzed using the scale, descriptive equivalent, and interpretation below.

### Table 1 Scales in the questionnaire with corresponding descriptive equivalent and interpretation.

| Scale in the Instrument | Descriptive Equivalent | Interpretation   |
|-------------------------|------------------------|--|
| 5                       | Strongly Agree         | The consumers' parameter variables are predictor statements and are strongly concurred by the respondents. |
| 4                       | Agree                  | The consumers' parameter variables are predictor statements and are concurred by the respondents.          |
| 3                       | Neither Agree          | The consumers' parameter variables are predictor statements and neither concurred by the respondents.      |
| 2                       | Disagree               | The consumers' parameter variables are predictor statements and opposed by the respondents.                |
| 1                       | Strongly Disagree      | The consumers' parameter variables are predictor statements and strongly opposed by the respondents.       |

The responses of each item statement were interpreted accordingly. Range of means stated below is the basis of response in all times of each indicator. This would provide a typical index of the item statements in the questionnaires.

**Table 2 Range of Means with Corresponding Descriptive Equivalent and Interpretation**

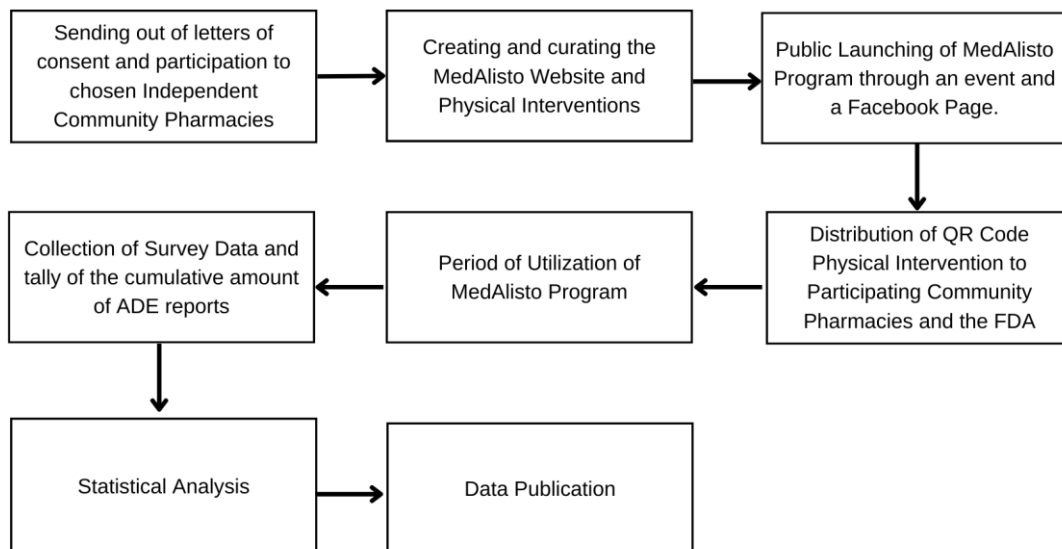
| Range of Means | Descriptive Equivalent | Interpretation   |
|----------------|------------------------|--|
| 4.21-5.00      | Very High              | This indicated that the indicator for the intervention is very high and manifested about 9-10 out of 10 occasions. |
| 3.41-4.20      | High                   | This indicated that the indicator for the intervention is very high and manifested about 7-8 out of 10 occasions.  |
| 2.61-3.40      | Moderate               | This indicated that the indicator  |

|           |          |   |
|-----------|----------|---|
|           |          | for the intervention is very high and manifested about 5-6 out of 10 occasions.                                   |
| 1.81-2.60 | Low      | This indicated that the indicator for the intervention is very high and manifested about 3-4 out of 10 occasions. |
| 1.00-1.80 | Very Low | This indicated that the indicator for the intervention is very high and manifested about 0-2 out of 10 occasions. |

The researcher gathered information from the customers after a week of using the QR Code method. It utilized the same set of surveys to compare the effectiveness level before and after implementation.

### 2.5 Data Collection

To fully understand the workflow process of this program, this section will be divided into the main phases of data collection.



**Figure 4. Data Collection Procedure**

#### 2.5.1 Letter of Consent Submission & Letter of Collaboration

The channels for intervention dissemination were the Local Community Pharmacies that had been chosen by the researchers and had given their utmost consent and approval to be part of the study. Community Pharmacies visited by the researchers had an attending Pharmacist during office hours. Ghost Pharmacies were not included in the scope of the study. To choose the channel of intervention, the researchers roamed around the areas located within the scope of Davao City for a given period of 2 weeks. By roaming around, they were able to inquire and ask for permission and participation from each Local Community Pharmacy

to join in the research. After attesting their consent and approval, the pharmacist within each Community Pharmacy affixed their signature in the form, along with their name, contact number, and date of affixation. Once the interventions were ready, the researchers disseminated them to each participating Community Pharmacy. The main participants who would submit the survey were taken from the customers and visiting consumers of the chosen Local Community Pharmacies once the launching period was initiated. The consumers, of their own will and consent, scanned the QR Code and had the choice to submit the survey after submitting the ADR report. The data collection began with the submission of a 'letter of consent' among the chosen Davao City Community Pharmacies, and a 'letter of collaboration' was sent to the Davao Regional Office of the Food and Drug Administration. The FDA responded with interest and agreement to the collaboration. Both letters were significant to ensure the consent of participation between the subjects and the researchers. The letters, which comprised the subject, purpose, methods, and goals of the study, were sent out to the qualified subjects to garner their trust and participation. Once ethical considerations were upheld through both letters, the researchers proceeded to the next phase.

### **2.5.2 Creation and Curation of MedAlisto Website and Physical Interventions**

The creation of the entire database was done with the aid of an IT professional who was hired by the researchers. The cooperation was done to create the design, format, structure, flow, and mainframe of the overall system. The researchers had set a maximum time frame of 10 weeks for the IT professional to finish the system database. The estimated date of completion was between January 31 and February 25, 2023. The creation of the MedAlisto physical intervention, on the other hand, was done with the collaboration of a Layout Artist and a selected Printing Shop. MedAlisto was a modernized intervention for the drug reporting scene in the Philippines. It was a QR code system that aided the FDA in advertising the adverse effects of drugs sold in the market. The intervention was used as a vehicle to spread awareness of adverse drug effects and report them. According to research, there was a similar type of reporting in the past, but it used physical forms such as paper and Dropbox. In this study, a QR code system was used. The researchers believed that this study could positively spread awareness and information to the public since the website was in collaboration with the FDA, ensuring that the information and questions asked were valid and legitimate.

### **2.5.3 Distribution of QR Code Physical Intervention**

The distribution of QR Code Physical Intervention to patients was done through the attachment of stickers or cards. These were given by the community pharmacist after every patient's purchase. The stickers or cards were only given to those patients who bought medications with a prescription. The distribution of the physical interventions was sent 3 days after the website completion.

### **2.5.4 Launching and Signing of FDA Collaboration**

To fully publicize the program, a launching and signing event was held in the chosen premise, preferably inside San Pedro College. In this event, FDA officials and the researchers signed papers to officiate the collaboration. Additionally, this promoted the program to the public, initiating the start of the MedAlisto Initiatives. A brief event was conducted to address the goals and objectives of MedAlisto, raising awareness about the program and the value of pharmacovigilance as well.

### **2.5.5 Period of Utilization**

The period of utilization of the intervention was estimated to be 3 months and started immediately after the completion of the system database. The period of utilization was closely monitored by the researchers and the FDA. The data was only accessible by the researchers on the website's survey questionnaire, but



for the adverse effect report, it was only accessible by the FDA. The researchers did not know who filled up the reporting form since the FDA had access to the report. The participants were protected by the Privacy Act, which was incorporated in every aspect of the study. If the findings were effective, it would show how small-scale research uncovered the flaws of written or text-based reporting. It would also serve as a reference for future large-scale research. If the findings were not effective, the study would serve as a basis for other cities, provinces, regions, or the entire nation, where results may differ from this study.

#### **2.5.6 Collection of Survey Data and Tallying of Cumulative Reports**

The data from the survey was collected by the researchers through the 'user' account in the system database of the MedAlisto website. Through this, the researchers were able to access the contents of the survey but not the content of the ADE reports, as that was accessed by the FDA. To ensure that only those who had submitted a report in the FDA ADE form were able to access the survey form, they were given a corresponding reference number, which they could input in the survey form. The data was protected through the Virtual Protection Network applied to the entire stability of the website.

#### **2.5.7 Statistical Analysis**

For this portion, the researchers asked for assistance with the data analysis through a hired Statistical Analyst. The Data Analyst, together with the researchers, retrieved, analyzed, and interpreted the gathered results. Before drawing conclusions and recommendations, the data was cross-checked to further prove its authenticity.

#### **2.5.8 Data Publication**

The researcher's study was published after the final paper was approved and revised. The research paper was then printed, with a copy given to the San Pedro College-Learning Resource Center.

### **2.6 Limitations of the Study**

This study focuses only on people who bought medicine or visited certain independent pharmacies in Davao City. One main issue with this study was 'attrition bias'. It is an experimental study, and there were some consistent differences in the numbers that might have caused some subjects to drop out over time (Nunan et al., 2018). MedAlisto is in collaboration with FDA and the researcher's targeted the community pharmacies that are located in Davao City. This said the medications covered are all that are sold in local pharmacies, from over-the-counter medications to prescription drugs. Based on the report sheet of the FDA which the researchers used, all drugs that caused an adverse drug reaction are asked to be indicated, and the sheet has an option on what type of medication is the drug under (FDA, 2021).

This study covers 14 community pharmacies in Davao City. Since they have different numbers of customers every day, there might be issues with handling and keeping track of data in the pharmacies. However, all the collected data is kept safe and organized to get the most accurate and useful results (Eaker, 2016). For this experimental research, there is a lot of good resources. But because we did not have a lot of data, due to this, there is a chance our statistics might not be super strong. Also, there's a possibility of some unintended bias in the data we collected (Resnik & Elliott, 2013). Another limitation with this study is that we might not have gotten all the important information from the consumers. This could make the research findings less believable and could hurt how valid the study is, both internally and externally (Faber & Fonseca, 2014). Lastly, a limitation to watch out for is how well the website works overall. There might be issues like bugs or technical problems that affect how it operates (Atwood et al., 1995).

Since the researchers have discussed the possibility of lacking subjects, the researchers decided to partner up with more Community Pharmacies and expanded the advertisement with the use of Advertising companies like Mindanao Times. The researchers had already validated an IT specialist in order to ensure the safety of the Data collected from the researcher. The IT specialist was hand in hand with the researchers in ensuring that the website is fully functional and foolproof against bugs and technical errors. The questionnaire and survey forms were already validated by certified validators which the researchers can ensure that the data collected will suffice the problem needed for the study.

## 2.7 Data Analysis

For the analysis of the data, the researchers utilized the following statistical tools that obtained the utmost research findings relevant in the study.

**Normality Test.** This was used to verify whether the dataset is well-modeled by a normal distribution. It calculates the probability of a properly distributed random variable underlying the data set. (Krishnan, 2022)

**Mean.** This was used to determine the averaging area of the responses' distribution regarding the QR code system usage according to the establishments (Ali & Bhaskar, 2016).

**Standard Deviation.** This was used to calculate the respondents' responses to their profiles. How they perceive the factors affecting their usage of the new QR system to its mean where if the data values are farther than average, a higher deviation within the data set is concluded. (El Omda & Sargent, 2021)

**Spearman Rho.** This was used to determine the correlation of the data. Two variables were measured on at least an ordinal scale through nonparametric measure of strength and direction of association (Al-Jabery, et al., 2020)

**Kruskal-Wallis Test One Way Analysis.** This test was used to analyze the nonparametric method for testing given that the results for normality were not normal. Kruskal-Wallis is also called one-way ANOVA in which it does not assume a normal distribution of the underlying data, which made it more suitable for the results of this research (Xia, 2020).

## 2.8 Ethical Consideration

Throughout the research process, The researchers were guided and monitored by the assigned research adviser. This One-shot study research was submitted to the SPC-Research Ethics Committee in which they evaluated, approved, and monitored the progress of the research. But despite the monitoring, the researchers are responsible for upholding the objectives, which includes providing the correct information, being truthful, and avoiding errors (Chetty, 2016). Informed consent, beneficence and nonmaleficence, voluntary participation, conflicts of interest, privacy and anonymity, risk of harm, and ethical expectations would all be needed to be taken into account in this study (Barrow, *et.al.*, 2019)

**Informed consent.** While everyone agrees that research participants should give informed consent, there are different opinions on how much information should be disclosed and the best way to obtain that consent (Xu et al., 2020). The respondents for the given survey in this study were able to provide their consent by checking the box beside the approval sentence after the Data Privacy Act and Terms of Condition were presented in the first part of the system. Should they wish to not participate in the study, they simply chose the 'No' option and it led back into the MedAlisto mainpage.

**Beneficence and Nonmaleficence.** The principles of beneficence and nonmaleficence ensure they do not hurt participants, prevent harm whenever possible, and remove any sources of harm that might exist

(Townsend et al., 2010). The researchers made sure that by following the principle of doing good, they implemented specific measures to lessen suffering or prevent harm. (Barrow et al., 2021)

**Voluntary Participation.** Every respondent has the option to stop participating in the study at any time without feeling obligated to do so. Participants understood that refusing to participate will have no consequences or negative repercussions. They spent time helping the researchers with their study, therefore the researchers should accept their decision and did not force them to participate (Bhandari, 2021)

**Conflict of Interest.** Conflicts of interest happen when other goals, like making money or advancing professionally, might affect professional decisions in the wrong way. This bias could be deliberate or unintentional, and it could involve money or other factors. (Romain, 2015). Even though it is inevitable, it was managed to keep the conflict of interest under control or reduce it. (Bano, 2021).

**Potential of Harm.** One of the most frequent types of harm is legal harm, which has to do with respondents' privacy. It is best to take into account every potential cause of danger in the research, as well as practical solutions to reduce them. The researchers made sure that communication was upheld in any potential risks of harm to participants before the study and this was done by revealing the transparency of the Terms & Conditions in the intervention (Bhandari, 2021).

**Privacy and Anonymity.** Confidentiality and anonymity are ethical procedures used to protect the privacy of human subjects. The method of collecting data anonymously is doing it without obtaining any personally identifiable information (Allen, 2017). The researchers took extra steps to ensure that none of the information provided by the respondents is available to people who did not participate in the study and will strictly exercise the Data Privacy Act of 2012 (10173). The Data Privacy Act was heavily applied in the reports of each consumer in the MedAliso intervention, as the researchers themselves were not able to access the reports and will strictly be seen by only the FDA authority themselves. This process is duly important to secure the identity, ADE, and other personal information the consumer has submitted to the intervention. In addition, the MedAlisto Database System utilized the Virtual Private Network where it ensured that no third-party or outside operators was able to access the reports in the database system.

**Ethical Compliance.** It is really important to stick to ethical rules when doing research for a few reasons. One big reason is that these rules help us achieve the goals of research, like finding out new things, uncovering the truth, and avoiding mistakes (Resnik, 2020). Throughout the course of the study research procedure, the honesty, validity, and reputational policies of San Pedro College must be upheld. The panel's comments, objections, and suggestions, as well as the Research Ethics Committee, would be carefully considered when altering the study's material to reorient it around the study's goal. The data collection would be started right away after the Ethics Committee approved the adjustments as stated.

### 3.0 Results

#### Results

This chapter deals with the presentation, analysis, and interpretation of the data gathered using the statistical treatment. All statistics were analyzed using statistical software.

#### Level of Each Parameter with the Use of the Medalisto Reporting Database System

The first objective of the study is to identify the level of each parameter with the use of the Medalisto reporting database system. It was determined with the use of a mean formula. The descriptive statistic is examined and presented in Table 1 is the level of each parameter with the use of the Medalisto reporting

database system in terms of awareness, diffidence, convenience, apprehension, dependency, repeatability and liability.

**Table 1 Level of each parameter with the use of the MedAlisto Reporting Database System**

| Variable      | Mean | SD   | Description |
|---------------|------|------|-------------|
| Awareness     | 3.66 | 1.01 | High        |
| Diffidence    | 3.04 | 0.44 | Moderate    |
| Convenience   | 3.05 | 0.42 | Moderate    |
| Apprehension  | 3.29 | 0.48 | Moderate    |
| Dependency    | 3.21 | 0.38 | Moderate    |
| Repeatability | 3.09 | 0.41 | Moderate    |
| Liability     | 3.20 | 0.36 | Moderate    |

As supported in the data displayed in Table 1 is the level of each parameter with the use of the Medalisto Reporting Database System. The highest and the only parameter described as high was attained by awareness with a mean score of 3.66 (SD = 1.01). This indicated that the awareness of the respondents toward the intervention is high and manifested about 7-8 out of 10 occasions. This means that the consumers are aware of the use of the Medalisto reporting database system. Meanwhile, among the items described as moderate, the least was obtained by diffidence, with a mean score of 3.04 (SD = 0.44). This indicated that the diffidence of the respondents for the intervention is neutral and manifested about 5-6 out of 10 occasions. This means that consumers are either confident or not with the use of the Medalisto reporting database system. The interventions have effectively mitigated consumer hesitation and fostered greater confidence.

Moreover, consumers have described the following parameter as moderate: apprehension (M = 3.29; SD = 0.48), dependency (M = 3.21; SD = 0.38), liability (M = 3.20; SD = 0.36), repeatability (M = 3.09; SD = 0.41), and convenience (M = 3.05; SD = 0.42). It means that the consumers have shown a neutral apprehension, dependency, liability, repeatability and convenience with the use of the Medalisto reporting database system.

**Correlation Between the Parameters from Each Physical Intervention**

The study’s second objective was to examine the relationship among parameters from each physical intervention. Since the data was found to be not normal, the researchers used spearman rank correlation as the non-parametric equivalent of Pearson r. Hence, the analysis involved calculating the spearman rho between the mean scores of each parameter with the use of the Medalisto reporting database system, as displayed in Table 2, Table 3 and Table 4.

**Table 2 Correlation Between the Parameters in terms of Card**

|  | Card  |            |                |                |
|--|-------|------------|----------------|----------------|
|  | $r_s$ | $p$ -value | Decision on Ho | Interpretation |
|  |       |            |                |                |

|                              |        |       |                |                 |
|------------------------------|--------|-------|----------------|-----------------|
| Awareness ↔ Diffidence       | 0.260* | 0.038 | Reject         | Significant     |
| Awareness ↔ Convenience      | 0.010  | 0.938 | Fail to Reject | Not Significant |
| Awareness ↔ Apprehension     | 0.163  | 0.198 | Fail to Reject | Not Significant |
| Awareness ↔ Dependency       | -0.004 | 0.975 | Fail to Reject | Not Significant |
| Awareness ↔ Repeatability    | 0.424* | 0.000 | Reject         | Significant     |
| Awareness ↔ Liability        | 0.394* | 0.001 | Reject         | Significant     |
| Diffidence ↔ Convenience     | 0.469* | 0.000 | Reject         | Significant     |
| Diffidence ↔ Apprehension    | -0.052 | 0.683 | Fail to Reject | Not Significant |
| Diffidence ↔ Dependency      | 0.409* | 0.000 | Reject         | Significant     |
| Diffidence ↔ Repeatability   | 0.531* | 0.000 | Reject         | Significant     |
| Diffidence ↔ Liability       | 0.354* | 0.004 | Reject         | Significant     |
| Convenience ↔ Apprehension   | 0.434* | 0.000 | Reject         | Significant     |
| Convenience ↔ Dependency     | 0.677* | 0.000 | Reject         | Significant     |
| Convenience ↔ Repeatability  | 0.424* | 0.000 | Reject         | Significant     |
| Convenience ↔ Liability      | 0.382* | 0.002 | Reject         | Significant     |
| Apprehension ↔ Dependency    | 0.444* | 0.000 | Reject         | Significant     |
| Apprehension ↔ Repeatability | 0.247* | 0.049 | Reject         | Significant     |
| Apprehension ↔ Liability     | 0.312* | 0.012 | Reject         | Significant     |
| Dependency ↔ Repeatability   | 0.613* | 0.000 | Reject         | Significant     |
| Dependency ↔ Liability       | 0.349* | 0.005 | Reject         | Significant     |
| Repeatability ↔ Liability    | 0.331* | 0.008 | Reject         | Significant     |

\*Correlation is significant at the 0.05 level

As presented in Table 2 is the result of the analysis on the correlation between each parameter of those consumers who have use card in Medalisto reporting database system. The following are the correlations who have found to be significant as perceived by the consumers who have used card in Medalisto reporting



database system since their p-value is less than 0.05, the alpha level of significance: awareness and diffidence have a weak relationship ( $r_s = 0.260$ ;  $p = 0.038$ ), awareness and repeatability have a strong relationship ( $r_s = 0.424$ ;  $p = 0.000$ ), awareness and liability have a moderate relationship ( $r_s = 0.424$ ;  $p = 0.001$ ), diffidence and convenience have a strong relationship ( $r_s = 0.469$ ;  $p = 0.000$ ), diffidence and dependency have a strong relationship ( $r_s = 0.409$ ;  $p = 0.000$ ), diffidence and repeatability have a strong relationship ( $r_s = 0.4531$ ;  $p = 0.000$ ), diffidence and liability have a moderate relationship ( $r_s = 0.354$ ;  $p = 0.004$ ), convenience and apprehension have a strong relationship ( $r_s = 0.434$ ;  $p = 0.000$ ), convenience and dependency have a strong relationship ( $r_s = 0.677$ ;  $p = 0.000$ ), convenience and repeatability have a strong relationship ( $r_s = 0.424$ ;  $p = 0.000$ ), convenience and liability have a moderate relationship ( $r_s = 0.382$ ;  $p = 0.002$ ), apprehension and dependency have a strong relationship ( $r_s = 0.444$ ;  $p = 0.000$ ), apprehension and repeatability have a weak relationship ( $r_s = 0.247$ ;  $p = 0.049$ ), apprehension and liability have a moderate relationship ( $r_s = 0.444$ ;  $p = 0.000$ ), dependency and repeatability have a strong relationship ( $r_s = 0.613$ ;  $p = 0.000$ ), dependency and liability have a moderate relationship ( $r_s = 0.349$ ;  $p = 0.005$ ), and repeatability and liability have a moderate relationship ( $r_s = 0.331$ ;  $p = 0.008$ ).

Furthermore, it signifies that the increase in consumer’s awareness of using cards in the Medalisto reporting database system also tends to increase their repeatability and liability. Also, the increase in consumer’s diffidence in using cards in the Medalisto reporting database system also tends to increase their convenience, dependency, repeatability and liability. This also signifies that consumers who have used cards in the Medalisto reporting database system believe that the higher convenience they have, the higher apprehension, dependency, repeatability, and liability. This also means that the higher the apprehension, the higher dependency, repeatability and liability the consumer will get in using a card for the Medalisto reporting database system. The increase in consumer’s dependency in using cards for the Medalisto reporting database system also tends to increase their repeatability and liability. Lastly, consumers have a high repeatability in using cards for the Medalisto reporting database system that is related to their liability.

**Table 3 Correlation Between the Parameters in terms of Standee**

|                           | Standee |         |                |                 |
|---------------------------|---------|---------|----------------|-----------------|
|                           | r-value | p-value | Decision on Ho | Interpretation  |
| Awareness ↔ Diffidence    | 0.282*  | 0.002   | Reject         | Significant     |
| Awareness ↔ Convenience   | -0.172  | 0.062   | Fail to Reject | Not Significant |
| Awareness ↔ Apprehension  | 0.177   | 0.056   | Fail to Reject | Not Significant |
| Awareness ↔ Dependency    | 0.025   | 0.792   | Fail to Reject | Not Significant |
| Awareness ↔ Repeatability | 0.182*  | 0.049   | Reject         | Significant     |

|                              |        |       |                |                 |
|------------------------------|--------|-------|----------------|-----------------|
| Awareness ↔ Liability        | 0.280* | 0.002 | Reject         | Significant     |
| Diffidence ↔ Convenience     | 0.195* | 0.035 | Reject         | Significant     |
| Diffidence ↔ Apprehension    | 0.059  | 0.527 | Fail to Reject | Not Significant |
| Diffidence ↔ Dependency      | -0.075 | 0.420 | Fail to Reject | Not Significant |
| Diffidence ↔ Repeatability   | 0.189* | 0.041 | Reject         | Significant     |
| Diffidence ↔ Liability       | 0.134  | 0.149 | Fail to Reject | Not Significant |
| Convenience ↔ Apprehension   | 0.157  | 0.091 | Fail to Reject | Not Significant |
| Convenience ↔ Dependency     | 0.477* | 0.000 | Reject         | Significant     |
| Convenience ↔ Repeatability  | 0.275* | 0.003 | Reject         | Significant     |
| Convenience ↔ Liability      | 0.122  | 0.190 | Fail to Reject | Not Significant |
| Apprehension ↔ Dependency    | 0.177  | 0.057 | Fail to Reject | Not Significant |
| Apprehension ↔ Repeatability | 0.084  | 0.368 | Fail to Reject | Not Significant |
| Apprehension ↔ Liability     | 0.148  | 0.112 | Fail to Reject | Not Significant |
| Dependency ↔ Repeatability   | 0.253* | 0.006 | Reject         | Significant     |
| Dependency ↔ Liability       | 0.107  | 0.250 | Fail to Reject | Not Significant |
| Repeatability ↔ Liability    | 0.050  | 0.590 | Fail to Reject | Not Significant |

\*Correlation is significant at the 0.05 level

The result of the analysis on the correlation between each parameter of those consumers who have used standee in Medalisto reporting database system as shown in Table 3. The following are the correlations who have found to be significant as perceived by the consumers who have used standee in Medalisto reporting database system since their p-value is less than 0.05, the alpha level of significance: awareness and diffidence have a weak relationship ( $r_s = 0.282$ ;  $p = 0.002$ ), awareness and repeatability have a negligible relationship ( $r_s = 0.182$ ;  $p = 0.049$ ), awareness and liability have a weak relationship ( $r_s =$

0.280;  $p = 0.002$ ), diffidence and convenience have a negligible relationship ( $r_s = 0.195$ ;  $p = 0.035$ ), diffidence and repeatability have a negligible relationship ( $r_s = 0.189$ ;  $p = 0.041$ ), convenience and dependency have a strong relationship ( $r_s = 0.477$ ;  $p = 0.000$ ), convenience and repeatability have a weak relationship ( $r_s = 0.275$ ;  $p = 0.000$ ), and dependency and repeatability have a strong relationship ( $r_s = 0.253$ ;  $p = 0.006$ ).

Moreover, it signifies that the increase in consumer’s awareness in using standee in the Medalisto reporting database system also tends to increase their repeatability and liability. Also, the increase in consumer’s diffidence in using standee for Medalisto reporting database system also tends to increase their convenience and repeatability. This also signifies that consumers who have used standee in the Medalisto reporting database system believe that the higher convenience they have, the higher diffidence, dependency and repeatability they will get. In addition, consumers who have used standee in Medalisto reporting database system believe that apprehension is not related to the other parameters. Also, the increase in consumer’s dependency in using standee for the Medalisto reporting database system also tends to increase their convenience and repeatability. Consumers have a high repeatability in using standee for the Medalisto reporting database system that is related to their awareness, diffidence, convenience, and dependency. Lastly, if the consumers who have used standee in the Medalisto reporting database system have high liability, their awareness also will increase.

**Table 4 Correlation Between the Parameters in terms of Sticker**

|                           | Sticker |         |                |                 |
|---------------------------|---------|---------|----------------|-----------------|
|                           | r-value | p-value | Decision on Ho | Interpretation  |
| Awareness ↔ Diffidence    | 0.086   | 0.702   | Fail to Reject | Not Significant |
| Awareness ↔ Convenience   | 0.482*  | 0.023   | Reject         | Significant     |
| Awareness ↔ Apprehension  | 0.419   | 0.052   | Fail to Reject | Not Significant |
| Awareness ↔ Dependency    | 0.378   | 0.087   | Fail to Reject | Not Significant |
| Awareness ↔ Repeatability | 0.161   | 0.475   | Fail to Reject | Not Significant |
| Awareness ↔ Liability     | 0.003   | 0.990   | Fail to Reject | Not Significant |
| Diffidence ↔ Convenience  | -0.149  | 0.508   | Fail to Reject | Not Significant |

|                              |        |       |                |                 |
|------------------------------|--------|-------|----------------|-----------------|
| Diffidence ↔ Apprehension    | 0.061  | 0.787 | Fail to Reject | Not Significant |
| Diffidence ↔ Dependency      | -0.086 | 0.703 | Fail to Reject | Not Significant |
| Diffidence ↔ Repeatability   | 0.064  | 0.776 | Fail to Reject | Not Significant |
| Diffidence ↔ Liability       | 0.158  | 0.482 | Fail to Reject | Not Significant |
| Convenience ↔ Apprehension   | 0.581* | 0.005 | Reject         | Significant     |
| Convenience ↔ Dependency     | 0.655* | 0.001 | Reject         | Significant     |
| Convenience ↔ Repeatability  | 0.393  | 0.070 | Fail to Reject | Not Significant |
| Convenience ↔ Liability      | 0.218  | 0.330 | Fail to Reject | Not Significant |
| Apprehension ↔ Dependency    | 0.841* | 0.000 | Reject         | Significant     |
| Apprehension ↔ Repeatability | 0.484* | 0.022 | Reject         | Significant     |
| Apprehension ↔ Liability     | -0.112 | 0.621 | Fail to Reject | Not Significant |
| Dependency ↔ Repeatability   | 0.546* | 0.009 | Reject         | Significant     |
| Dependency ↔ Liability       | 0.157  | 0.485 | Fail to Reject | Not Significant |
| Repeatability ↔ Liability    | 0.401  | 0.065 | Fail to Reject | Not Significant |

\*Correlation is significant at the 0.05 level

Displayed in Table 4 is the result of the analysis on the correlation between each parameter of those consumers who have used stickers in the Medalisto reporting database system. The following are the correlations who have found to be significant as perceived by the consumers who have used sticker in Medalisto reporting database system since their p-value is less than 0.05, the alpha level of significance: awareness and convenience have a strong relationship ( $r_s = 0.482$ ;  $p = 0.023$ ), convenience and apprehension have a strong relationship ( $r_s = 0.581$ ;  $p = 0.005$ ), convenience and dependency have a strong relationship ( $r_s = 0.655$ ;  $p = 0.001$ ), apprehension and dependency have a very strong relationship ( $r_s = 0.841$ ;  $p = 0.000$ ), apprehension and repeatability have a strong relationship ( $r_s = 0.484$ ;  $p = 0.000$ ), and dependency and repeatability have a strong relationship ( $r_s = 0.546$ ;  $p = 0.009$ ).

Furthermore, consumers who have used stickers in the Medalisto reporting database system believe that the increase in their awareness in using stickers also tends to increase their convenience only. Also, they believe that diffidence is not related to the other parameters when using stickers in the Medalisto reporting database system. However, it signifies that consumers who have used stickers in the Medalisto reporting database system believe that the higher convenience they have, the higher apprehension and dependency they will get. They also believe that when using stickers, as their apprehension increases, their dependency, convenience and reliability also tends to increase. Also, the increase in consumer’s dependency in using stickers for the Medalisto reporting database system also tends to increase their convenience, apprehension, and repeatability. Consumers have a high repeatability in using standee for the Medalisto reporting database system that is related to their apprehension and repeatability. Lastly, consumers who have used stickers in the Medalisto reporting database system believe that liability is not related to the other parameters.

**Significant Difference of Each Parameter with the Use of Medalisto Reporting Database System When Analyzed According to Physical Intervention**

The third research question was an analysis of the difference of each parameter with the use of the Medalisto reporting database system when analyzed according to physical intervention. However, the data was found to be not normal, the researchers used Kruskal Wallis Test as the non-parametric equivalent of Analysis of Variance (ANOVA). This has been addressed by computing for the mean rank of each intervention, card, standee and sticker regarding consumer’s awareness, diffidence, convenience, apprehension, dependency, repeatability and liability in the use of the Medalisto reporting database system.

**Table 5 Significant Difference of Each Parameter with the Use of Medalisto Reporting Database System When Analyzed According to Physical Intervention**

| Parameter   | Intervention | Mean Rank | p-value | Decision on Ho | Interpretation  |
|-------------|--------------|-----------|---------|----------------|-----------------|
| Awareness   |              |           | 0.756   | Fail to Reject | Not Significant |
|             | Card         | 101.24    |         |                |                 |
|             | Standee      | 104.56    |         |                |                 |
| Diffidence  | Sticker      | 95.09     |         |                |                 |
|             |              |           | 0.311   | Fail to Reject | Not Significant |
|             | Card         | 110.11    |         |                |                 |
| Convenience | Standee      | 100.42    |         |                |                 |
|             | Sticker      | 91.52     |         |                |                 |
|             |              |           | 0.012   | Reject         | Significant     |



|               |         |        |       |                |                 |
|---------------|---------|--------|-------|----------------|-----------------|
|               | Card    | 117.97 |       |                |                 |
|               | Standee | 92.35  |       |                |                 |
|               | Sticker | 111.95 |       |                |                 |
| Apprehension  |         |        | 0.369 | Fail to Reject | Not Significant |
|               | Card    | 104.16 |       |                |                 |
|               | Standee | 98.87  |       |                |                 |
|               | Sticker | 117.14 |       |                |                 |
| Dependency    |         |        | 0.100 | Fail to Reject | Not Significant |
|               | Card    | 111.07 |       |                |                 |
|               | Standee | 95.39  |       |                |                 |
|               | Sticker | 115.68 |       |                |                 |
| Repeatability |         |        | 0.136 | Fail to Reject | Not Significant |
|               | Card    | 111.98 |       |                |                 |
|               | Standee | 99.86  |       |                |                 |
|               | Sticker | 89.05  |       |                |                 |
| Liability     |         |        | 0.023 | Reject         | Significant     |
|               | Card    | 115.14 |       |                |                 |
|               | Standee | 100.37 |       |                |                 |
|               | Sticker | 77.14  |       |                |                 |

The comparison of each intervention, card, standee and sticker toward each parameter with the use of Medalisto reporting database system was presented in Table 5. Furthermore, based on the analysis, there is no significant difference on the awareness, diffidence, apprehension, dependency and repeatability of consumers with the use of Medalisto reporting database system when analyzed according to physical intervention. Since the p-value of the awareness ( $p = 0.756$ ), diffidence ( $p = 0.311$ ), apprehension ( $p = 0.369$ ), dependency ( $p = 0.100$ ) and repeatability ( $p = 0.136$ ) are greater than 0.05, the alpha level of significance, then the difference is not significant. This means that regardless of the intervention (card, standee or sticker), consumers have the same or similar level of awareness, diffidence, apprehension, dependency and repeatability in using Medalisto reporting database system.

However, there is a significant difference in the convenience and liability with use of the physical interventions in the Medalisto reporting database system. Since the p-value of convenience ( $p = 0.012$ ) and liability ( $p = 0.023$ ) are less than 0.05, the alpha level of significance, then the difference is significant. Hence, consumers who have used card, sticker and standee have a different level of convenience and liability in using the Medalisto reporting database system. For convenience, with a mean rank of 117.97 for card users, 111.95 for sticker users and 92.35 for standee users, it shows that those consumers who have used card in the Medalisto reporting database system tend to be higher compared to sticker and standee users. This means that consumers who have used cards in Medalisto reporting database system are more convenient than sticker and standee users. A comparable mean rank also was found between sticker and standee users in terms of convenience. Hence, consumers who have used stickers are more convenient than standee users using the Medalisto reporting database system.

Meanwhile, in terms of liability, with a mean rank of 115.14 for card users, 100.37 for standee users and 77.14 for sticker users, it shows that those consumers who have used card in Medalisto reporting database system tend to be higher compared to sticker and standee users. This also means that consumers who have used cards in the Medalisto reporting database system have shown more liability than sticker and standee users. A comparable mean rank also was found between sticker and standee users in terms of liability. Hence, consumers who have used standee are more liable that sticker users using Medalisto reporting database system.

**Prevalence of Similarities and Differences of Answers on the FDA ADR Form**

The fourth objective of the study was to determine the prevalence of similarities and differences of answers on the FDA ADR form in terms of number of reports sent, outcome of reaction, severity of reaction, duration of reaction, and action taken with medicine. This was determined using the mean formula as the descriptive statistic was displayed in Table 6.

**Table 6 Prevalence of Similarities and Differences of Answers on the FDA ADR Form (n = 204)**

| Variable          |   | f   | %     |
|-------------------|---|-----|-------|
| Number of Reports | Individuals or in behalf of the relatives | 189 | 92.65 |
|                   | Medical Professionals                     | 15  | 7.35  |
| Outcome Reaction  | Fatal                                     | 0   | 0.00  |
|                   | Not recovered                             | 8   | 3.92  |
|                   | Recovered or resolved                     | 171 | 83.82 |
|                   | Recovered/ resolved with sequelae         | 3   | 1.47  |
|                   | Recovering/Resolving                      | 11  | 5.39  |
|                   | Unknown                                   | 11  | 5.39  |
|                   |   |     |       |

|                            |   |     |       |
|----------------------------|---|-----|-------|
| Severity of Reaction       | Caused / prolonged hospitalization  | 1   | 0.49  |
|                            | Caused / prolonged hospitalization/Other medically important condition  | 1   | 0.49  |
|                            | Disabling / incapacitating  | 2   | 0.98  |
|                            | Disabling / incapacitating, Caused / prolonged hospitalization  | 2   | 0.98  |
|                            | Disabling / incapacitating, Life threatening  | 2   | 0.98  |
|                            | Disabling / incapacitating, Life threatening, Caused / prolonged hospitalization                                    | 1   | 0.49  |
|                            | Disabling / incapacitating, Life threatening, Congenital anomaly / birth defect, Caused / prolonged hospitalization | 1   | 0.49  |
|                            | Life threatening  | 1   | 0.49  |
|                            | Other medically important condition   | 9   | 4.41  |
|                            | Results in death, Other medically important condition   | 1   | 0.49  |
|                            | Non-serious   | 183 | 89.71 |
| Duration of Reaction       | Less than 24 Hours  | 56  | 27.45 |
|                            | 1 to 7 Days   | 53  | 25.98 |
|                            | Between 1 Week and 2 Weeks  | 12  | 5.88  |
|                            | Between 2 Wees and 1 Month  | 5   | 2.45  |
|                            | Above 1 Month   | 29  | 14.22 |
|                            | Unknown   | 49  | 24.02 |
| Action Taken with Medicine | Dose not change   | 11  | 5.39  |
|                            | Dose Reduced  | 1   | 0.49  |
|                            | Drug Withdrawn  | 37  | 18.14 |

|  |                |     |      |
|--|----------------|-----|------|
|  | Not applicable | 1   | 0.49 |
|  | Unknown        | 154 | 75.5 |

As shown in Table 6 is the the prevalence of similarities and differences of answers on the FDA ADR form in terms of number of reports sent, outcome of reaction, severity of reaction, duration of reaction, and action taken with medicine, with a 204 total number of reports based on 204 respondents. In addition, in the span of one month, there were a total of 92.65% who sent reports on their own or on behalf of family members, which is a substantially higher percentage. This indicates that users of MedAlisto most likely purchased medications from a neighborhood pharmacy, and utilized the physical interventions of MedAlisto QR code system (e.g card, stickers and standee). Results show a total of 7.35% reports sent by medical health professionals using MedAlisto. This means that only few medical professionals purchase drugs from any target community drug stores and use the intervention of MedAlisto. Moreover, with regard to the outcome reaction, the result shows the higher number of reports indicating resolved outcomes with a total of 83.37%. This means that the reaction experienced by most of the consumers who utilized Medalisto intervention were resolved or recovered the time that they reported using the ADR form.

Regarding the severity of reaction, as the seriousness or the reactions most commonly reported by the respondents, it was revealed that the majority of the respondents' reports fell in the non-serious criteria with a total of 89.71%. Though relatively less harmful, the researchers have noted the presence of disabling and life-threatening reports in which according to Larivière and colleagues to be a serious matter when life threatening ADEs go unreported and unnoticed. Meanwhile, in terms of duration of reaction, the researchers have deduced that a significant number of reports remained to have an 'unknown' duration of reaction with a total of 24.012 % reports. A greater number of reports gathered with a total 25.98% under duration of reaction between 1 to 7 days. A significant report also was found with 27.45% with less than 24 hours duration of reaction. There are respondents who have reported that they have experienced a reaction after 1 month which comprises 14.22% of the respondents. Nevertheless, as to the action taken with medicine after they experienced ADR, results revealed the higher number of reports is unknown action taken with a total of 75.5% reports, second to this highest number of reports is the consumer have the drug withdrawn when the ADE happened with a total of 18.14% reports. This means that for most people who have experienced ADR, we do not know what action they have taken in order to solve the report. Patient reports seem to be a vital component of determining the ADEs and a reliable source of safety data when using medications within healthcare settings.

**Discussion**

To sum up, a thorough analysis of the study's tables confirmed that MedAlisto's interventions were successful in tackling the many issues related to the underreporting of adverse drug reactions. The tables offered valuable insights into the effects of MedAlisto's interventions, and they were consistent with recognized ideas like the Theory of Diffusion of Innovations and Inman's Seven Deadly Sins of ADE Underreporting .The tables illustrated the Seven Deadly Sins theory: improved awareness and understanding handled "ignorance", more readiness and confidence to report mitigated 'diffidence', and streamlined reporting procedures lessened 'convenience/indifference', (Inman, 1976) (Inman, 1986) (Inman, 1996) .Results from the reporting corresponded with the stages of dissemination, such as the quick uptake by consumers and the little involvement of medical experts. The potential of MedAlisto to address the wider issue of ADE underreporting was demonstrated by positive reporting outcomes, such as resolved

cases and non-serious reactions. Essentially, MedAlisto was positioned as a comprehensive solution to improve ADR reporting practices and spark a cultural shift towards proactive ADR vigilance within the community. It did this by addressing specific barriers outlined in the Seven Deadly Sins theory as well as aligning with the more general diffusion theory (Dweik, et al., 2016).

Among various factors like ignorance, convenience, apprehension, guilt, repeatability, and liability, the study's findings highlight "Diffidence" as a significant factor. The research reveals that MedAlisto's interventions notably influence consumer confidence, decreasing diffidence and encouraging a greater willingness to report Adverse Drug Reactions (ADRs). This corresponds with the idea of diffidence in the Seven Deadly Sins of ADE Underreporting theory, suggesting that individuals feel less hesitant about reporting when using MedAlisto. In summary, the study indicates that MedAlisto effectively addresses diffidence, leading to a positive change in ADR reporting practices in the community.

In addition, there was a noticeable difference between the total number of monthly online ADE reports before and after MedAlisto's intervention. The monthly total increased from 89 complaints to 204 reports following MedAlisto's intervention, representing a 56.37% percentage change. This data alone is able to support the gathered evidence that a promotional structured and widened sense awareness of ADE reporting platforms greatly diminish underreporting.

## 5.0 Summary Conclusion, and Recommendations

### Summary

The study assessed the MedAlisto Reporting Database System, revealing high awareness (mean = 3.66) among users and the lowest level of diffidence (mean = 3.04). Moderate ratings were given to parameters like apprehension, dependency, liability, repeatability, and convenience, indicating a neutral attitude towards the system. Significant correlations were observed between parameters from different physical interventions, with notable correlations between awareness and repeatability/liability, and diffidence and convenience/dependency/repeatability/liability. While no significant differences were found in awareness, diffidence, apprehension, dependency, or repeatability based on intervention, disparities were noted in convenience and liability, with card users reporting higher convenience and standee users higher liability. Reports on FDA ADR showed high user engagement (92.65% consumer-reported), with most reactions being resolved (83.37%) and non-serious (89.71%). However, a notable portion had unknown reaction durations (24.012%) and actions taken after experiencing ADRs (75.5% unknown).

### Conclusion

After carefully analyzing and gathering all the data and information needed to supply the conclusion, the researchers thoroughly deduced that the incorporation of the MedAlisto program together with the already established online ADE reporting of the FDA has definitely made a significant improvement in the progress of Pharmacovigilance in the city of Davao. With the aid of previous studies such as the then BFAD initiative of Bantay Gamot (Gaje, 2009) and the texting-based reporting system from UP-Manila (Vergeire-Dalmacion, *et.al.*, 2015). MedAlisto was able to add another perspective from the previous programs. With the gathered data and results from the one-month program, the researchers were able to determine that programs such as MedAlisto increase the level of awareness and confidence of pharmaceutical consumers to report cases and experiences of Adverse Drug Events. Having significantly increased the awareness and the diffidence towards reporting ADE's, MedAlisto has also moderately affected the level of apprehension, convenience, repeatability, dependency and liability which indicated



that the program was able to tackle and target 6 of the 7 Inman's Deadly Sins of Adverse Drug Event Underreporting (Marques, *et.al.*, 2015). Unfortunately, despite the 85.714% of intending the aforementioned Deadly Sins of Underreporting, MedAlisto was not able to thoroughly target the improvement of convenience or the ability to make ADE reporting platforms less time and effort consuming (Kitisopee, *et.al.*, 2022). On the other hand, MedAlisto was able to increase the amount of monthly ADE reports collected by the FDA. From their previous month of 89 reports the amount increased by 56.37% with 204 reports during the running period. All things considered, the researchers finally established that MedAlisto as a program would be an exemplary initiative to continue the rise and improvement of ADE reporting in the country. MedAlisto still has a long way to go to perfect and build a strong foundation to target the obstacles regarding ADE reporting. Nonetheless, MedAlisto and its researchers infer that the data gathered on the research program will eventually be developed and proved by other researchers in the field of Pharmacovigilance (Kitisopee, *et.al.*, 2022).

### Recommendations

The results of this study shows that the MedAlisto intervention has shown some sufficient features that are effective in the further development of ADE Reporting Systems in the city of Davao and eventually the Philippines. With the observed data above the researchers have come up with further suggested improvements to optimize the use of the interventions and MedAlisto as a whole. The following recommendations are as follows.

#### *For the FDA:*

**Ask more questions to the consumers.** More specifications in answering the report. Encourage future respondents (consumers) to further specify the action taken with the medicine to know what measure they made when they experienced the certain ADE. It is also to know what additional measures the FDA can take to combat a certain problem in a certain medication.

**Publicize the online reporting form.** Most consumers have deduced that they were not familiar with the availability of the online reporting platform, thus alluding to the prevalence of underreporting of ADE. If publicized, this will garner more attention and perhaps encourage consumers to safely relay their experienced ADEs. Publicity of the online form may be through the interventions created by MedAlisto such as the standee or through social media platforms.

#### *For the community pharmacists:*

**Encourage customers to report.** As stewards of drug safety it is their responsibility to uphold the value of pharmacovigilance in the market. By encouraging consumers to report their experiences, risks and potentially dangerous effects caused by the medication can be put into attention thus determining the safety of the drug. Pharmacists must ensure the patient's comfort and reliance on the drug that was provided for them.

#### *For the future researchers:*

**Larger scope.** The researchers recommend widen the scope in terms of location and factorial parameters to be studied to enhance the feasibility of the program. Given that this research is solely focused on Davao city Pharmacies. It is better to have a larger scope on where to conduct the study. As much as possible, maximize all of the places where the intervention can be done in order to obtain more results and more perspective with regards to the intervention.

**Longer running time.** When the researchers conducted the study, the researchers only had the intervention running for only a month. However, the researchers still obtained reasonable results. But then, it is still much better for the intervention to have a longer duration of exposure to the public to ensure that many consumers can try the intervention and give out their experiences and opinions. In addition, the longer duration of the study can help the researchers to further enhance the data collected from the FDA and in return the FDA would benefit more from the continuous monitoring and sending of more reports.

**Maximize the number of pharmacies found in Davao City.** It is recommended to recruit more pharmacies as it can lead to more results and more variation of opinions from consumers. In this study, the researchers only utilized local independent pharmacies, so perhaps a wider and more border channel of intervention would widen the results more.

**Enhance the convenience of the intervention.** Given that the rating of the convenience moderate, the researchers recommend to utilize convenience and ease of use to improve the user experience and make the Medalisto reporting system more easily accessible and more convenient to be used.

**Collaborate with the other healthcare professionals.** ADE does not only occur in the pharmacy setting. To further maximize and optimize the usage of the intervention, it is better to collaborate with other healthcare professionals aside from the pharmacists since it can help to further combat underreporting of ADEs.

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