MOH/F/FAR/175.25(RR) - e

MINISTRY OF HEALTH MALAYSIA

PHARMACY RESEARCH REPORTS

Volume 8 • Issue 2 • November 2025

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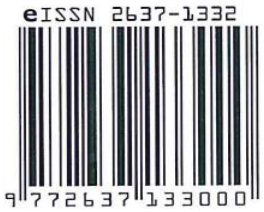
November 2025



No. Siri Penerbitan KKM
MOH/F/FAR/175.25(RR) – e

No. Pendaftaran Dokumen Program Perkhidmatan Farmasi
D-RR-126

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Volume 8 • Issue 2 • November 2025

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ACKNOWLEDGEMENT

The Editorial Board of the Pharmacy Research Reports wishes to express our deepest appreciation to the reviewers for their valuable time and efforts in reviewing the manuscripts.

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A Feasibility Study for Quality Control Testing on Raw Materials Used in Natural Products in Malaysia

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Abstract

Introduction: In Malaysia, quality control (QC) testing of finished products is compulsory for the registration of natural products. However, there was minimal control on the quality of raw materials.
Objective: This study aimed to assess the feasibility of implementing the requirement of QC testing on raw materials by Malaysian natural product manufacturers.
Methods: A cross-sectional study was carried out among natural product manufacturers in Malaysia using an online questionnaire on the Google platform from 15th July to 30th August 2023. The 50-question questionnaire was developed and revised based on the experts' feedback. The data collected via the Google platform were exported into Microsoft Excel for further processing.
Results: Out of 156 potential participants, 72 responded to the questionnaire, resulting in a response rate of 46.15%. Of the 72 respondents, 61.1% of them reported conducting QC testing on the raw materials used. The majority (65.3%) acknowledged the importance of testing raw materials. Primary QC tests conducted included organoleptic (97.4%), moisture content (53.8%), microbial limit content (30.8%), and heavy metal testing (23.1%). Of the 44 manufacturers with QC testing facilities, only 8 claimed their testing facility were accredited, and 23 of them followed standard reference methods for identification testing. In real-world practice, despite most respondents (72.2%) realised the necessity of identification tests to ensure the safety of product (38.9%), nearly half (43.1%) disagreed and 29.2% hesitated with implementing mandatory QC testing on raw materials for natural product registration, due to budget constraints (58.8%), whereas 27.8% agreed.
Conclusion: It may be feasible to implement QC testing on raw materials for registration of natural products, if a phased approach is proposed. Current gaps could be potentially addressed by incorporating industry engagement, targeted training for regulators and manufacturers, and the expansion of testing infrastructure.
Keywords: Raw Material, Quality Control, Natural Product

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Introduction

Globally, the natural product market is experiencing remarkable growth. The global herbal medicine market size was valued at USD 233.08 billion in 2024. It was expected to expand to USD 251.25 billion in 2025 and projected to reach USD 437 billion by 2032, registering a compound annual growth rate (CAGR) of 8.23% over the forecast period (1). With the expansion of global market for herbal medicines, the safety and quality of herbal medicines become a primary concern for health authorities, industries and public. Considering this, the World Health Organization (WHO), since 2003, had urged the Member States to ensure the safety and quality of herbal medicines, including the raw material (2). It is essential to ensure that plant materials used in herbal formulations are of high quality, free from contaminants, and accurately identified (3). According to the "WHO Global Report on Traditional & Complementary Medicine 2019", 83 out of 179 WHO Member States reported having Good Manufacturing Practices (GMP) in place for manufacturing herbal

medicines. The GMP standards specify the need for QC of raw materials which includes proper identification (4). Reflecting these, the Therapeutic Goods Administration (TGA) in Australia and European Medicines Agency (EMA) emphasise identity testing using macroscopic, microscopic, and chromatographic methods to authenticate herbal materials. Specifications should be based on recognised pharmacopeia standards and include contaminant limits (5, 6).

Malaysia, recognised as one of the twelve most biodiverse countries in the world, serves as a global hub for natural products in which they have contributed significantly to the country gross domestic product (GDP) (7). In Malaysia, the category of natural products includes traditional medicines, herbal products, homeopathic medicines, natural products with modern claim and natural products with therapeutic claim (8). Natural products were regulated under the Control of Drugs and Cosmetic Regulations (CDCR) 1984. According to these regulations, all natural products must be registered with the Drug Control Authority (DCA), with some exceptions such as extemporaneous preparations, traditional preparations that are produced solely through the drying process, traditional medicines used as food, spices or flavouring of food that do not have any medicinal claim, as well as traditional preparations used solely for cosmetic purposes (8, 9). For natural product registration in Malaysia, safety and quality testing evidence, such as organoleptic, disintegration, uniformity of weight, microbial contamination test and heavy metal contamination tests, are mandatory for finished products (8). However, there is minimal control on the quality of raw materials, indicating gaps to strengthen the QC for raw materials used in natural products.

The quality of natural products depends on the starting materials (raw materials), manufacturing process, building, equipment and personnel involved. It is important to recognise that QC shall not rely solely on finished product testing but to be built into the product (10). The identification and quantification of active ingredients play a crucial role in addressing challenges such as adulteration, misidentification, and quality inconsistency within the herbal medicine industry (3). Chapter 6 (QC) of the Malaysian Guidelines on GMP for Traditional Medicines and Health Supplements (TMHS) specifies that the identity and quality of starting materials, including the raw materials, shall be tested (10). Recognising the significance of QC testing for raw materials and aligning with the guidelines, the National Pharmaceutical Regulatory Agency (NPRA) intended to enhance QC testing requirements for raw materials of natural products for product registration purpose. Given the importance of understanding manufacturer's awareness and readiness before implementing more rigorous QC requirements, this study was carried out to determine the feasibility of performing QC testing on herbal raw materials by natural product manufacturers in Malaysia.

Method

This was a cross-sectional study conducted among natural product manufacturers in Malaysia. The study was registered with the National Medical Research Register (NMRR ID-23-01134-8JO) and approved by the Medical Research and Ethics Committee (MREC), Ministry of Health, Malaysia.

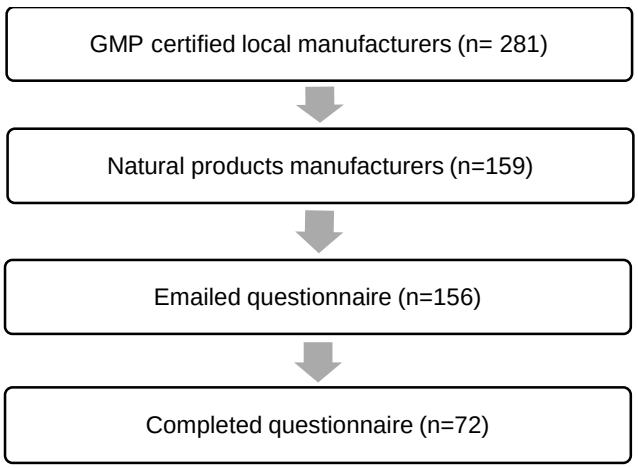

Figure 1: Study flow

The targeted respondents were identified from an updated list of local manufacturers with GMP certification provided by the Centre of Compliance and Quality Control, NPRA. These manufacturers produce a variety of products, including pharmaceuticals, natural products, health supplements, and/or cosmetics. The inclusion criteria for this study were limited to local manufacturers who produced natural products. Manufacturers who produced pharmaceutical products, health supplements and cosmetics were excluded from this study. The study identified 159 natural product manufacturers out of 281 GMP certified local manufacturers. However, three of these manufacturers lacked email addresses in the database and could not be reached for participation. As a result, the number of potential participants decreased to 156 (Figure 1).

The initial draft of the questionnaire was developed by the Committee on Strengthening Quality Control Testing of Natural Products (JKPPKKPS). The questionnaire was distributed to the members of JKPPKKPS to collect feedback with the aim of improving the questionnaire's content and readability. Following the feedback, the questionnaire was revised and reviewed by officers from the Complementary and Alternative Medicine Section, Centre of Product Evaluation and Cosmetic, NPRA for further evaluation on its clarity, comprehensiveness, and suitability. Subsequent revisions were made based on feedback from the NPRA Research and Development (R&D) Committee to ensure better alignment with the study objectives and to facilitate clearer comprehension by participants. The translation process was carefully managed to preserve the instrument's accuracy and relevance. The survey questions were developed in both Malay and English to ensure inclusivity and allow participation from individuals literate in either language. Following this, the link to the final version of the online questionnaire was sent via email to 156 manufacturers as an invitation to participate in this study. The questionnaire, hosted on the Google platform, was open from 15th July to 30th August 2023.

The questionnaire comprised of 50 questions, encompassing both close-ended and open-ended formats. It started with a participant information sheet (PIS) and a request for informed consent. Only participants who provided consent would proceed to answer the questionnaire, which was divided into four domains: i) manufacturers' characteristics; ii) manufacturers' awareness on QC testing of raw material; iii) feasibility of QC testing of raw material in terms of technical aspects, human resources, and market demand; and iv) manufacturers' preparedness regarding the implementation of QC testing for raw material. The responses were kept anonymous to encourage open and honest feedback from the participants.

The data collected from the Google platform were compiled into Microsoft Excel worksheet. Quantitative data were organised and presented in frequency (n) and percentages. The qualitative responses from open-ended questions exhibiting similar meaning and context were aggregated and expressed as frequency (n) and percentages. The data were subsequently presented alongside the corresponding quantitative findings.

Results

Out of 156 potential participants, 72 responded to the questionnaire, resulting in a response rate of 46.2%. The background characteristics of the respondents were reported in Table 1. More than half of the manufacturers focused only on producing natural products (69.4%), had over 10 years of experience in manufacturing finished products (72.2%) and conducted in-house QC testing for raw material (61.1%).

Apart from their core activity of manufacturing natural products, 15.3% of manufacturers also imported raw materials, and approximately 9.7% provided laboratory service to others. The raw materials that they used were primarily in powder form (62.5%) and sourced locally (88.9%). For imported raw materials, the majority came from China (92.5%), followed by India (43.4%), and Taiwan (22.6%).

Table 1: Background characteristics of the respondents (n=72)

Background characteristics	n (%)
Other services besides manufacturing natural products *	
None	50 (69.4)
Raw material importer	11 (15.3)
Raw material supplier	8 (11.1)
Raw material manufacturer	6 (8.3)
Laboratory service	7 (9.7)
Product registration service, export product	1 (1.4)
Years of experience as manufacturer of finished product	
3 – 5 years	6 (8.3)
6 – 10 years	13 (18.1)
> 10 years	52 (72.2)
Not applicable (inactive or manufacture raw materials)	1 (1.4)
Conduct In-house QC testing for raw materials	
Yes	44 (61.1)
No	28 (38.9)
Source of raw materials *	
Local	64 (88.9)
Imported	45 (62.5)
Self-produced	9 (12.5)
Country of origin for imported raw material (n=53) *	
China	49 (92.5)
India	23 (43.4)
Taiwan	12 (22.6)
US	8 (15.1)
Australia	3 (5.7)
Indonesia	2 (3.8)
Others: Thailand, Japan, Korea, South Africa, Brazil, Sri Lanka	6 (11.3)
Form of raw materials *	
Powder	45 (62.5)
Extract powder	36 (50.0)
Crude	35 (48.6)
Liquid or oil	23 (31.9)
Extract liquid	13 (18.1)
Standardised extract	12 (16.7)

* Multiple responses were allowed for these questions.

Manufacturers' awareness on QC testing of raw material

Manufacturer awareness on QC testing of raw material was presented in Table 2. Majority of the manufacturers (n=47, 65.3%) recognised the importance of testing raw materials, highlighting the need to verify the correct supply of materials (80.9%) and detect any adulterants (59.6%). Conversely, among those who deemed such testing unimportant (n=18, 25.0%), nearly all cited cost restraints (94.4%) and considered raw material supplier documentation to be sufficient (72.2%). When suppliers could not provide COA for raw materials, 75.0% of manufacturers conducted QC testing on the raw materials. Majority of manufacturers (73.6%) were aware of standard methods available for identifying herbs.

Table 2: Manufacturers' awareness on QC testing of raw materials # (n=72)

Awareness on QC testing of raw materials	n (%)
Important to test the raw materials (n=72)	
Yes	47 (65.3)
No	18 (25.0)
Unsure	7 (9.7)
Reasons of being important (n=47) *	
Ensure the supply of correct raw materials.	38 (80.9)
Adhere to regulatory requirement.	31 (66.0)
Ensure no adulterant.	28 (59.6)
Ascertain the content of raw materials.	27 (57.4)
Ensure free from contamination by heavy metals, microbes or chemicals.	2 (4.3)
Reasons of being not important (n=18) *	
It incurs cost.	17 (94.4)
Suppliers have provided sufficient documentation.	13 (72.2)
It will delay manufacturing plan.	12 (66.7)
Wastage of raw materials.	6 (33.3)
Finished product will be tested.	5 (27.8)
It is not a regulatory requirement.	4 (22.2)
CoA provided by suppliers of raw materials (n=72)	
Yes	55 (76.4)
No	12 (16.7)
Occasionally	5 (6.9)
Conduct QC testing for raw materials if CoA is not provided by the supplier (n=72)	
Yes	54 (75.0)
No	18 (25.0)
Aware of the standard methods for identifying herb (n=72)	
Yes	53 (73.6)
No	19 (26.4)

* Multiple responses were allowed for these questions. Abbreviation: CoA = Certificate of Analysis.
# The complete responses for Domain 2 Manufacturers' awareness on QC testing of raw material can be found in the Appendix.

Feasibility for conducting QC testing on raw material

The feasibility for manufacturers performing QC testing on raw materials was assessed across three dimensions: technical, personnel competency and market demand as presented in Table 3. In terms of technical feasibility, 46 out of 72 manufacturers (63.9%) possess QC testing facilities, but only eight among them were accredited. The primary QC testing conducted by these manufacturers was organoleptic testing (97.4%), moisture content (53.8%) and microbial limit content (30.8%). When inquiring about the accreditation of both the manufacturers' laboratory (Question 2) and the outsourced laboratory (Question 5), many respondents were unable to identify the correct accreditation body (please refer to the complete responses in Appendix).

In terms of personnel competency, a significant number of manufacturers responded that a bachelor's degree (34.7%) and diploma (34.7%) were the minimum qualifications required to conduct QC testing. Most still relying on manual analysis by humans (66.7%). Regarding market demand feasibility, 72.2% of manufacturers agreed with the necessity of conducting identification tests for raw materials in natural products to ensure the safety (38.9%) and quality (22.2%) of finished products. However, 26.4% of manufacturers, while acknowledging the importance of such tests, were unwilling to conduct them.

Table 3: Feasibility for conducting QC testing on raw materials from the manufacturers' perspective # (n=72)

Aspects considered for conducting QC testing on raw materials	n (%)
A) Technical Aspect	
Availability of QC testing facilities for raw material (n=72)	
Yes	46 (63.9)
No	26 (36.1)
Accreditation of QC testing facilities (n=41)	
Yes	8 (19.5)
No	33 (80.5)
Outsourcing QC testing of raw materials (n=72)	
Yes	48 (66.7)
No	24 (33.3)
Accreditation of the outsourced laboratory (n=48)	
Yes	45 (93.8)
No	3 (6.3)
Types of in-house QC testing available (n=39) *	
Organoleptic testing	38 (97.4)
Moisture content	21 (53.8)
Microbial limit test	12 (30.8)
Heavy metal test	9 (23.1)
Identification testing	6 (15.4)
Assay of standardised compound	2 (5.1)
Ash content	2 (5.1)
Pesticide and herbicide residue	1 (2.6)
Aflatoxin	1 (2.6)
Types of in-house QC testing available to identify raw material (n=72) *	
Physical or macroscopic examination	49 (68.1)
Chemical testing	6 (8.3)
Thin layer chromatography	3 (4.2)
High performance layer chromatography	3 (4.2)
Others	6 (8.4)
Following standard reference procedure for identification test methods (n=72)	
Yes	23 (31.9)
No	2 (2.8)
Unsure	14 (19.4)
Not applicable as doesn't have a laboratory	33 (45.8)
B) Personnel Competency	
Minimum qualification level for personnel conducting QC testing (n=49)	
Bachelor degree	17 (34.7)
Diploma	17 (34.7)
SPM level or equivalent	14 (28.6)
Below high school	1 (2.0)
Analysis of QC results (n=42)	
Manually by human analysts	28 (66.7)
Both manually and through computerisation	12 (28.6)
Computerised through applications or tools	1 (2.4)
Based on the CoA from Allied Chemists Laboratory	1 (2.4)
Frequency of continuous training for QC testing personnel (n=62)	
Never	11 (17.7)
1 – 2 times yearly	47 (75.8)
3 – 6 times yearly	4 (6.5)
C) Market Demand	
Necessary to conduct identification testing for raw materials (n=72)	
Yes	52 (72.2)

Aspects considered for conducting QC testing on raw materials	n (%)
No	20 (27.8)
Reasons for necessary to conduct identification testing (n=46)*	
To ensure product safety (e.g. avoid adulteration)	28 (38.9)
To improve the quality of finished products	16 (22.2)
To prevent use of raw material contaminated by heavy metal	1 (1.4)
Required for finished product testing	1 (1.4)
Reasons for not necessary to conduct identification testing (n=20)*	
Important for quality, but lack of resource to enforce it	1 (1.4)
Identification test is crucial, but unwilling to conduct it	19 (26.4)
Delay production and increase cost	4 (5.6)
Important for quality, but lack of resource to enforce it	1 (1.4)
Use natural materials	1 (1.4)
No benefit of testing raw materials as the testing of the finished product is the conclusion.	1 (1.4)
Are the time and cost required for raw material identification testing to ensure safety and quality of natural products justified? (n=72)	
Yes	19 (26.4)
No	21 (29.2)
Maybe	32 (44.4)

* Multiple responses were allowed for these questions. Abbreviation: QC = quality control.
# The complete responses for Domain 3 Feasibility for conducting QC testing on raw material can be found in the Appendix.

Manufacturers' preparedness on implementing QC testing for raw material

Among the respondents, a significant portion (43.1%) expressed disagreement with the implementation of QC testing on raw materials for product registration. The primary reasons for disagreement or uncertainty were constraints in resources such as budget (58.8%) and manpower, facilities and time (7.8%) (Table 4).

Table 4: Manufacturers' preparedness on implementing QC testing for raw materials (n=72)

Preparedness	n (%)
Agree to implement QC testing on raw materials (n=72)	
Yes	20 (27.8)
No	31 (43.1)
Maybe	21 (29.2)
Reason for disagreeing or unsure about the implementation of QC testing (n=51)	
Budget constraint	30 (58.8)
Not cost effective	12 (23.5)
Manpower, facility and/or time constraint	4 (7.8)
Other reasons	5 (9.8)
Time needed to set up a facility to conduct the test (n=67)	
< 1 year	1 (1.5)
1 – 3 years	27 (40.3)
4 – 5 years	14 (20.9)
> 5 years	25 (37.3)
Limiting factors in implementing QC testing on raw materials (n=68) *	
Cost for setting up the facility	66 (97.1)
Insufficient qualified personnel	51 (75.0)
Insufficient technology	43 (63.2)
The product must meet the contracting company's requirement	22 (32.4)
Cost of hiring qualified personnel	2 (2.9)
Delaying production process	1 (1.5)
Difficulty in findings stable suppliers for reagents, and contractors for equipment maintenance.	1 (1.5)
Limited cash flow without improvement in sales	1 (1.5)

* Multiple responses were allowed for these questions.

When responding to an open-ended question about suggestion for implementing QC testing on raw materials, respondents proposed a phased approach, starting with simple testing rather than full-scale implementation. There were also suggestions for a grace period (at least 3 years) to allow time for the manufacturers to establish testing facilities (results not presented in Table 4).

Discussion

In order to establish quality standards and specifications for herbal materials, a guideline of Quality Control Methods for Medicinal Plant Material has been published in 1998 by WHO (3). The majority of adverse events reported in relation to the use of herbal products and medicines are attributable to poor quality of the product. Hence, to promote the safety of herbal medicines, new guidelines pertaining to quality assurance and control have been consistently developed over the years to update existing ones (3). The findings of this study suggested the feasibility of QC testing on raw materials and provided valuable insights into the practices and challenges faced by local natural product manufacturers. The background information indicated that a significant proportion of manufacturers have over a decade of experience in producing natural products, suggesting a well-established local industry with substantial knowledge and operational capacity. The capacity beyond manufacturing, such as providing laboratory services (9.7%) may be driven by the need to control product quality and cater to the registration requirements prior to be marketed. The manufacturers primarily sourced raw materials locally (88.9%) which might imply that local supply chain for raw material is sufficiently mature to support the sustainability and quality of natural products.

The effort to strengthen QC testing for Natural Products falls under Strategic Thrust 3, Strategy 1 (Strengthen Governance and Regulatory Control), Initiative 4 of the Ministry of Health Malaysia (MOH) Pharmaceutical Services Programme (PSP) Strategic Plan 2021-2025 with the objective of strengthening the QC requirement in ensuring raw materials used in natural products manufacturing were identified and authenticated before they were released into market. The initiative included the recognition of private laboratories that were able to conduct identification and authentication tests for herbal raw materials and enforcement on the requirement to submit certificate of analysis (COA) for raw materials from the suppliers and manufacturers of finished product during product registration (11). In preparation for the prospective implementation of QC testing on raw materials for natural product registration, NPRA's Committee on Strengthening Quality Control Testing of Natural Products organised a series of awareness programmes including two virtual workshops in 2021 and one physical workshop in 2023. These workshops attracted a broad audience (approximately 100 participants per virtual session and 150 for the physical session). During the Q&A sessions and post workshop feedback, it became evident that some manufacturers remained unfamiliar with the purpose and requirements of QC testing. Following the awareness programmes, this study was undertaken to assess the feasibility of manufacturers conducting QC testing on raw materials. Many of the manufacturers acknowledged the importance of QC testing to verify raw material authenticity and detect adulterants. When COA for the raw material was not provided by the supplier, a significant portion of them would conduct QC testing on the material, thus displaying their proactivity in quality assurance of the raw material. Additionally, most of the manufacturers were aware of available standard references or methods for herbal raw material identification. These findings indicate that the awareness programmes might have contributed to the improved awareness on quality assurance practices among the industry players.

Looking at the technical aspects for QC testing, even though some manufacturers reported having QC testing facilities, which indicated the availability of technical capability, these facilities may not fully meet the quality standards required by accreditation bodies. This limitation is likely attributed to the high costs associated with obtaining accreditation, which typically involves meeting minimum requirements for equipment, qualified personnel, and facility infrastructure. Such financial and logistical demands can pose significant barriers, particularly for smaller institutions or those operating with limited budgets (12). The survey respondents also highlighted that budget restraints remained the largest challenge in conducting QC tests for raw materials, followed by shortage in qualified personnel and technology deficiency, which both require financial investment as well.

The most common QC tests conducted on raw materials include organoleptic testing, moisture content, microbial limit and heavy metal testing. These are the existing tests required to be conducted on finished product. In contrast, identification test is not made compulsory in the current registration requirements, thus leading to relatively low availability of testing facilities. The implementation of mandatory

regulatory requirement could potentially improve the adherence of the industry to include identification test as part of the raw material QC testing as per the TMHS GMP guideline. Among the facilities that performed identification testing, the most common tests were macroscopic examination and chemical testing, while less than 5% mentioned other methods such as thin layer chromatography or chemical profiling. While macroscopic examination commonly serves as the initial step in identifying an entire plant, variations in phenotypic features can occur due to factors such as growing conditions and the age of the plant at the time of harvesting. Macroscopic examination becomes impractical when dealing with herbal materials in powdered form, necessitating microscopic examination to be supplemented by chromatographic evidence (13).

With respect to the capacity of personnel in conducting QC testing, most manufacturers equipped with testing facilities agreed to put more emphasis on employing skilled personnel to maintain quality product. Majority of them recognised the need for personnel with at least a diploma or bachelor's degree to conduct QC testing. QC personnel in manufacturing facilities should have the expertise to conduct tests to identify the raw materials as well as to detect adulteration, fungal growth, infestations, and non-uniformity when receiving and inspecting the raw materials (10). On the other hand, many of the tests were conducted manually, with only a minority utilising computer-based applications as analytical tools. This may be due to limited financial and technological resources required to implement advanced analytical technologies. In addition, it was concerning that some manufacturers did not provide continuous training to their employee as it is crucial to maintain the competency level of personnel and to enhance the standards of QC testing in the local facilities.

Market feasibility is one of the key determining factors when it comes to developing QC testing workflow and facilities. Despite a strong recognition on the importance of identification testing to ensure the safety and quality of finished products, respondents generally expressed disagreement or uncertainty regarding its value, primarily due to the concerns over cost and resource constraints. Respondents were worried that high testing cost would lead to higher product prices and risks of market loss, especially for products with multiple active ingredients. These concerns may be addressed by having a more extensive cost-benefit analysis to demonstrate the long-term value of QC testing for raw materials in ensuring compliance with regulatory requirements, thereby enhancing the credibility of natural products and facilitating access to new markets. Furthermore, if the implementation of mandatory raw materials QC testing is done in a staged manner, as suggested by the respondents, local manufacturers would have additional time to prepare for the investment of establishing more extensive testing facilities. This would also allow planning in the aspects of budgeting, personnel and other relevant resources, ultimately to comply with the regulatory requirements. The authority may also consider gradual adaptation, beginning with voluntary compliance and progressing toward mandatory enforcement.

One limitation of this study is that the questionnaire was not pilot-tested to assess its reliability, primarily due to time and resource constraints. Expert consultation is a recommended approach to improve the design and content of surveys when pilot testing is not feasible (14). To mitigate this limitation, the questionnaire was carefully reviewed to improve its clarity, comprehensiveness, and suitability. Another limitation includes missing or incomplete data for some questions, particularly those that were not compulsory to be answered and those that allowed multiple responses, which resulted in varied number of responses from the same group of respondents. This may limit the reliability of the findings and complicate the results. In order to address this issue, detailed information on the number of responses was stated in the result tables to clarify the extent of data coverage. Other than that, the low survey response rate may impact the generalisability of its findings on QC testing feasibility. It may also potentially introduce response bias favouring more proactive manufacturers with established testing facilities and higher awareness. However, the responses still reveal significant industry trends, such as the utilisation of locally sourced raw materials and a strong emphasis on quality assurance, which may be valuable for policy planning. Future studies should aim for higher participation rate and broader stakeholder engagement to strengthen the generalisability and quality of evidence.

Conclusion

This study indicated that most manufacturers were generally aware of, and committed to QC testing on raw materials. However, financial and technical restraints continue to pose significant challenges in the process whereby addressing them is crucial for the effective implementation of QC testing on raw material to ensure

safety and quality of natural products. Based on the findings of this study, the implementation of QC testing for raw materials as part of the natural product registration process is considered feasible through a phased approach to facilitate a smooth and non-disruptive transition for all stakeholders. By incorporating industry engagement, targeted training for regulators and manufacturers, and the expansion of testing infrastructure, existing capacity gaps could be addressed.

Acknowledgement

The authors would like to thank the Director General of Health Malaysia for his permission to publish this article. The authors would also like to thank NPRA's Research and Development Committee as well as Committee on Strengthening Quality Control Testing of Natural Products for their valuable input during the development of survey questionnaire.

Conflict of interest statement

The authors declare no conflict of interest. This research did not receive any specific grant from funding agencies in the public, commercial or not-for-profit sectors.

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Appendix

Complete responses for Domain 2 and Domain 3 of the questionnaire

Domain 2: Manufacturers' awareness on QC testing of raw material

Awareness on QC testing of raw materials	n (%)
1. Is it important to test the raw materials? (n=72)	
Yes, it is important as to ….. (n=47)*	47 (65.3)
ensure the supply of correct raw materials.	38 (80.9)
adhere to regulatory requirement.	31 (66.0)
ensure no adulterant.	28 (59.6)
ascertain the content of raw materials.	27 (57.4)
ensure free from contamination by heavy metals, microbes, or chemicals.	2 (4.3)
No, it is not important because ….. (n=18)*	18 (25.0)
it incurs cost.	17 (94.4)
suppliers have provided sufficient documentation.	13 (72.2)
it will delay manufacturing plan.	12 (66.7)
wastage of raw materials.	6 (33.3)
finished product will be tested.	5 (27.8)
it is not a regulatory requirement.	4 (22.2)
Unsure	7 (9.7)
2. Do the suppliers of raw materials provide CoA? (n=72)	
Yes	55 (76.4)
No	12 (16.7)
Occasionally	5 (6.9)
For responders who answered "No" and "Occasionally", what documents are received? (n=17)	
Delivery order, receipt and/or invoice	8 (44.4)
No document	6 (33.3)
Safety data	1 (5.6)
Raw material specification	1 (5.6)
In-house QC testing	1 (5.6)
3. Details included in the CoA of raw materials provided by suppliers: (n=66)*	
Organoleptic test	55 (83.3)
Heavy metal test	52 (78.8)
Raw materials details	51 (77.3)
Microbial limit test	45 (68.2)
Moisture content	44 (66.7)
Extraction ratio	31 (47.0)
Extraction solvent	28 (42.4)
Test for identification and comparison to standard reference	26 (39.4)
Assay of standardised compound	23 (34.8)
Ash content	21 (31.8)
Not applicable because not receiving CoA	10 (15.2)
Pesticide and herbicide residue	9 (13.6)
Aflatoxin	5 (7.6)

Awareness on QC testing of raw materials	n (%)
4. If no CoA is provided by the supplier, do respondents conduct QC testing on the raw materials? (n=72)*	
Yes	54 (75.0)
No, QC testing is not conducted because … (n=18)*	18 (25.0)
Costly	13 (72.2)
Limited quantity of raw materials	8 (44.4)
Not a regulatory requirement	7 (38.9)
Unable to find a suitable lab for testing	5 (27.8)
Others: Unaware of the specific tests required for raw materials	1 (5.6)
Others: Wastage of raw materials	1 (5.6)
Others: Refrain from procuring from suppliers who do not provide CoA	1 (5.6)
Others: Testing on finish products are more important	1 (5.6)
Others: Time consuming	1 (5.6)
5. Are the respondents aware of the standard methods available for identifying herb? (n=72)	
Yes	53 (73.6)
No	19 (26.4)

Domain 3: Feasibility for conducting QC testing on raw material

Aspects considered for conducting QC testing on raw materials	n (%)
A) Technical Aspect	
1. Are tests for raw material available in the respondents' setting? (n=72)	
Yes	46 (63.9)
No	26 (36.1)
2. Are the respondents' QC testing facilities accredited? (n=41)	
Yes	8 (19.5)
Name of the accreditation body (open ended response) (n=6)	
MS ISO/IEC 17025	2 (33.3)
Standard Malaysia	2 (33.3)
Name of laboratory	2 (33.3)
No	33 (80.5)
3. Type of QC testing available in the manufacturing plant? (n=39)*	
Organoleptic testing	38 (97.4)
Moisture content	21 (53.8)
Microbial limit test	12 (30.8)
Heavy metal test	9 (23.1)
Identification testing	6 (15.4)
Assay of standardised compound	2 (5.1)
Ash content	2 (5.1)
Pesticide and herbicide residue	1 (2.6)
Aflatoxin	1 (2.6)
4. Do respondents outsource the QC testing of raw materials? (n=72)	
Yes	48 (66.7)
No	24 (33.3)
5. Is the outsourced lab accredited? (n=48)	
Yes	45 (93.8)
It is accredited by … (open ended response) (n=43)*	
Department of Standard Malaysia, SAMM	31 (72.1)
ISO 17025	8 (18.6)
NPRA	4 (9.3)
Name of the outsourced laboratory	1 (2.3)
Malaysian Institute of Chemistry	1 (2.3)
Malaysian Palm Oil Board	1 (2.3)
No	3 (6.3)

Aspects considered for conducting QC testing on raw materials	n (%)
6. Types of testing available in the respondents' facilities to identify raw material? (n=72)*	
Physical or macroscopic examination	49 (68.1)
Chemical testing	6 (8.3)
Thin layer chromatography	3 (4.2)
High performance layer chromatography	3 (4.2)
Chemical profiling	2 (2.8)
Others: Fourier-transform infrared spectroscopy	2 (2.8)
Others: Moisture test	1 (1.4)
Others: Identified by expert and/or according to encyclopaedia	1 (1.4)
Not applicable as the manufacturer doesn't have a laboratory	25 (34.7)
7. Does the identification test methods follow a standard reference procedure (n=72)?	
Yes	23 (31.9)
No	2 (2.8)
Unsure	14 (19.4)
Not applicable as the manufacturer doesn't have a laboratory	33 (45.8)
8. What is the standard reference used in the respondents' setting? (n=28)*	
British Pharmacopoeia	15 (53.6)
In-house standard	13 (46.4)
US Pharmacopoeia	7 (25.0)
The Pharmacopoeia of the People's Republic of China	7 (25.0)
Malaysian Herbal Monograph	5 (17.9)
Ayurvedic Pharmacopoeia	1 (3.6)
9. What is the reason for not having access to the available standard references for identification testing? (n=8)	
High cost of the reference materials	2 (25.0)
Never conducted identification tests	1 (12.5)
Lack access to the appropriate standard reference	1 (12.5)
Manufacturing small quantities of products	1 (12.5)
Unable to perform it; only perform organoleptic tests	1 (12.5)
Not familiar with it	1 (12.5)
Lack lab facilities and expertise	1 (12.5)
10. Can the respondents follow the methods specified in the standard reference for identification testing? (n=72)	
Yes	23 (31.9)
No	11 (15.3)
Not applicable as the manufacturer doesn't have a laboratory	38 (52.8)
11. What are the reasons of unable to follow methods specified in the standard reference? (n=21)*	
Lack of equipment	16 (76.2)
Lack of personnel	15 (71.4)
Expensive	14 (66.7)
Lack of chemical substance needed	13 (61.9)
Lack of competency	13 (61.9)
Unfamiliar with the identification tests	1 (4.8)
B) Personnel Competency	
12. What is the minimum qualification level required for personnel conducting QC testing? (n=49)	
Bachelor degree	17 (34.7)
Diploma	17 (34.7)
SPM level or equivalent	14 (28.6)
Below high school	1 (2.0)
13. What is the minimum qualification level needed for personnel to analyse/verify QC test results? (n=49)	
Bachelor or Degree	32 (65.3)
Diploma	12 (24.5)
SPM level or equivalent	5 (10.2)
Below high school	1 (2.0)
14. How are QC results analysed? (n=42)	
Manually by human analysts	28 (66.7)
Both manually and through computerisation	12 (28.6)

Aspects considered for conducting QC testing on raw materials	n (%)
Computerised through applications or tools	1 (2.4)
Based on the CoA from Allied Chemists Laboratory	1 (2.4)
15. How frequently are personnel involved in QC testing provided with continuous training? (n=62)	
Never	11 (17.7)
1 – 2 times yearly	47 (75.8)
3 – 6 times yearly	4 (6.5)
C) Market Demand	
16. Is it necessary to conduct identification testing for raw materials used in natural products? (n=72)	
Yes	52 (72.2)
No	20 (27.8)
17. The reasons for above responses are ….. (n=72)*	
Positive reasons	
To ensure the product safety (e.g. adulteration can be avoided)	28 (38.9)
To increase the quality of finished products	16 (22.2)
To prevent use of raw material contaminated by heavy metal	1 (1.4)
Required for finished product testing	1 (1.4)
Neutral or negatives reasons	
Important for quality, but lack of resource to enforce it	1 (1.4)
Identification test is crucial, but unwilling to conduct it	19 (26.4)
Delay production and increase cost	4 (5.6)
Important for quality, but lack of resource to enforce it	1 (1.4)
Use natural materials	1 (1.4)
No benefit of testing raw materials as the testing of the finished product is the conclusion.	1 (1.4)
18. What is the estimated duration to complete an identification test of a raw material? (n=35)	
⩽1 day	3 (8.6)
1 – 2 days	2 (5.7)
3 – 7 days	6 (17.1)
5 – 7 working days	4 (11.4)
10 – 20 working days	5 (14.3)
1 – 3 weeks	9 (25.7)
1 month	2 (5.7)
Based on form of raw materials	1 (2.9)
Unsure	1 (8.6)
19. What is the current cost for conducting an identification test on a raw material? (n=59)	
< RM 100	5 (8.5)
RM 101 – RM 200	7 (11.9)
RM 201 – RM 500	24 (40.7)
RM 501 – RM 1,000	12 (20.3)
>RM 1,000	11 (18.6)
20. Are the time and cost required for raw material identification testing justified to ensure safety and quality of natural products? (n=72)	
Yes	19 (26.4)
No	21 (29.2)
Maybe	32 (44.4)
21. The reasons for Question 20 reply. It is … (n=33)	
Justified because….	
To ensure the manufactured finished products are safe and high quality for consumers to use	2 (6.1)
To ensure the quality and safety of raw materials	2 (6.1)
Purchase from reliable source that save cost and waiting-time	1 (3.0)
Not justified because …..	
High testing costs raise product prices, risking market loss	9 (27.3)
Testing raw materials is unnecessary because the conclusion is drawn from testing the finished product, which has a Certificate of	3 (9.1)

Aspects considered for conducting QC testing on raw materials	n (%)
Analysis (CoA)	
Too many raw materials used in 1 finished products	3 (9.1)
The raw materials are limited, in crude form, have a CoA, lack identification testing for local herbs	5 (15.2)
Technical constraints such as insufficient technology, manufacturing delays, unavailability of external labs covering all compounds, and the requirement to comply only with GMP and DRGD	4 (12.1)
Unsure	2 (6.1)
Depending on the dosage form, may not be necessary for oil-based products	1 (3.0)

Assessment of Patients' Satisfaction towards Drive-Through Pharmacy Service in Sandakan Health Clinic

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Abstract

Introduction: Drive-through pharmacy is one of the pharmacy value-added services (VAS) in Ministry of Health Malaysia facilities to ease the collection of follow-up medication. While previous studies have studied the awareness, attitudes, barriers and challenges related to drive-through pharmacy, this study aimed to explore a different aspect.

Objective: This study aimed to assess patients' satisfaction with the drive-through pharmacy service and to determine the association between socio-demographic characteristics and the patients' satisfaction level towards drive-through pharmacy service at Sandakan Health Clinic.

Methods: This cross-sectional study was conducted from April 2022 to April 2023. Patients, including their caregivers or family members, who registered for drive-through pharmacy service at Sandakan Health Clinic were invited to participate in the study. An adapted questionnaire was used to evaluate patient's satisfaction with the drive-through pharmacy service. The satisfaction score was categorised using Blooms' cut-off point. Meanwhile, the association between socio-demographic characteristics and patients' level of satisfaction was assessed using Mann-Whitney U test and Kruskal Wallis Test.

Results: The result showed that 96% of patients had a good satisfaction towards the drive-through pharmacy service, while 3.6% had moderate satisfaction, and 0.4% reported poor satisfaction. The median total satisfaction score was 16, indicating that most patients were fully satisfied with the service. No significant association was observed between socio-demographic characteristics and patients' satisfaction level, except for education level (p=0.034).

Conclusion: Most patients showed great satisfaction towards the drive-through pharmacy service provided by Sandakan Health Clinic, with education level demonstrated a significant association with patient's satisfaction. Several key areas for improvements were identified in this study and may be considered for implementation to provide a better service for patients in the future.

Keywords: Drive-Through Pharmacy, Pharmacists, Pharmacy Value-Added Services, Satisfaction

NMRR ID: NMRR-22-02064-U8V

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Introduction

Pharmacies in many countries have adopted new services such as pharmacy value added services or extended pharmacy services to improve medication accessibility for patients with chronic diseases. These services had become more popular in the pandemic era, as they reduce congestion in healthcare facilities (1). In Malaysia, the Ministry of Health (MOH)'s Pharmaceutical Services Programme introduced Pharmacy Value Added Services (VAS) to address long waiting times in public healthcare facilities. The types of VAS available in MOH health facilities include Medicines by Post (*Ubat Melalui Pos* - UMP), Appointment Card, Integrated Drug Dispensing System (*Sistem Pendispensan Ubat Bersepadu* - SPUB), Drive-Through Pharmacy and a few others (2).

Drive-through pharmacy service offers a convenient alternative for the collection of refill medications. Once registered, patients, caregivers or family members can collect their refill medicines at the drive-through pharmacy counter on appointment date. The refill medicines will be prepared in advance, eliminating the need for patients to park their car and wait in line. The first drive-through pharmacy service in Malaysia was first implemented as a pilot project in Pulau Pinang in 2008 (3). At the Sandakan Health Clinic, drive-through pharmacy service was introduced in 2014 as an initiative to reduce waiting times at the outpatient pharmacy. Eligible patients or their representatives may register at the pharmacy screening station of the outpatient

pharmacy counter. Eligible criteria include prescription with more than one-month supply and the absence of dangerous drugs. Once registered, the original prescription will be kept by the pharmacy, while the patients or representatives will receive a copy of the prescription and the drive-through pharmacy card. The subsequent month's medication can then be collected at the drive-through pharmacy counter.

The drive-through pharmacy counter in Sandakan Health Clinic is located behind the outpatient pharmacy which enables registered patients or representatives to drive through and remain in their vehicles during medicine collection and exit via a designated one-way roundabout after collecting their medications. The service operates from 8.30am to 4.30pm, every Monday to Friday, with a pharmacist assistant on duty every month. Since its establishment, the average number of prescriptions served in drive-through pharmacy has grown substantially from an average of 200 per month in 2015 to 800 per month in 2021. In view of this increment, it is essential to review this service for further improvement. In healthcare setting, patient satisfaction surveys serve as one of the tools to assess the quality of healthcare service delivery (5). Therefore, in this study, our aims were to assess patients' satisfaction towards drive-through pharmacy service and determine the association between socio-demographic characteristics and the level of satisfaction towards drive-through pharmacy service at Sandakan Health Clinic.

Method

Study settings

This single-centre cross sectional study was carried out at Sandakan Health Clinic, Sabah, Malaysia for a duration of one year, from April 2022 to April 2023. This study was registered with the National Medical Research Registry (NMRR ID-22-02064-U8V) and was approved by the Medical Research Ethics Committee, Ministry of Health Malaysia.

Study population

The study population consisted of patients who registered for drive-through pharmacy service at Sandakan Health Clinic. All patients, caregivers or family members who registered for drive-through pharmacy service at Sandakan Health Clinic during the study period were invited to participate in this study. Patients who did not understand English or Malay were excluded from the study.

Sample sizes were determined using a sample size calculator by Raosoft Inc. The total population size was 1279 (patients who registered for drive-through pharmacy service in Sandakan Health Clinic). The accepted margin of error was set at 5% with a 95% confidence interval. Sample size estimation was based on our estimation that at least 50% of patients using drive-through pharmacy service are satisfied with our service. This resulted in a sample size of 296 patients.

Data collection

The candidates of this study were identified at the outpatient pharmacy counter when handing in their prescriptions. Patients who met the inclusion criteria were approached by the investigator. Those who agreed to participate were asked to provide informed consent. Interviews were then conducted using a researcher-administered questionnaire.

Study instruments

The study adapted a validated questionnaire by Liew et al., with prior permission acquired (6). All items that assess patient satisfaction in the original questionnaire were retained with minimal rephrase. Therefore, factor validity test was not conducted. Face and content validation was conducted by two senior pharmacists from Sandakan Health Clinic, a pharmacist who are in-charge of the drive-through pharmacy, and four junior pharmacists. The percentage of agreement across the seven experts for face validation was 98%, while the scale content validity index based on universal agreement (S-CVI/UA) value for content validation was 0.86.

The original English version of the questionnaire was translated to Malay. The translation process followed a forward and backward translation method where the forward translation was performed by two independent native Malay speakers with good command in English. Their translations were then harmonised and re-conciliated into a single harmonised version. Subsequently, another two expert language translators performed the backward translation into the original language independently. All the translators involved were not aware of the existence of the original version of the questionnaire to prevent any information bias.

The questionnaires comprised three components. The first component collected basic demographic information such as gender, age, distance between home and the drive-through pharmacy, occupation and level of education. The second component consisted of 16 items designed to assess patient satisfaction on the various aspects of the pharmacy drive-through service using 4-point Likert scale, with 1 being Strongly Disagree, 2 is Disagree, 3 is Agree, and 4 is Strongly Agree. The third component included four open-ended questions that asked patients about the overall performance and suggestions to improve the drive-through pharmacy service.

Data analysis

To derive the level of satisfaction, responses in the second component of questionnaire were group into two categories, in which Strongly Agree and Agree were classified as being satisfied, while Disagree and Strongly Disagree were classified as not satisfied. Scores were assigned to the responses using a binary scoring method. A score of one was assigned if the response was Strongly Agree or Agree while score zero was given if the response was Disagree or Strongly Disagree. The scores of the levels of satisfaction were derived by adding up the scores of 16 items, resulting in a minimum possible score of zero and a maximum possible possible score of 16. Based on Bloom's cut-off point, the total scores were categorised as good satisfaction (score 13-16), moderate satisfaction (score 10-12), and poor satisfaction (score 0-9) (7-11).

Incomplete questionnaires were excluded from data analysis. Data were analysed using IBM Statistical Package for the Social Sciences (SPSS) version 28.0. All socio-demographic categorical data were presented as frequencies and percentages. The median of total satisfaction scores was calculated to summarise the overall satisfaction level across all patients. The association between patients' sociodemographic characteristics and satisfaction levels was assessed using Mann-Whitney U-test and Kruskal Wallis test. A p-value of less than 0.05 was considered statistically significant.

Topic analysis was used in analysing the responses of the four open-ended questions. All responses were listed and grouped by themes.

Results

A total of 350 patients were approached, out of which 303 patients consented and were enrolled in the study. Table 1 presented the socio-demographic characteristics of the respondents and the satisfaction scores. Majority of the respondents were female (57.8%), aged more than 65 years old (31.4%), lived within a distance range of 1 to 10 kilometres (75.9%), unemployed (55.4%) and had a background with secondary education (49.5%).

The overall median satisfaction score was 16. Most respondents (n=291, 96.0%) had scores between 13 and 16, which were categorised as good satisfaction, and 3.6% (n=11) of the respondents scored between 10 to 12 (moderate satisfaction). Only one respondent (0.4%) scored 9 in satisfaction score (poor satisfaction).

As shown in Table 1, there were no statistically significant differences in satisfaction levels across all socio-demographic characteristics except education level, with a p-value of 0.034. To explore this further, Mann-Whitney U tests were conducted to compare the patients' satisfaction scores between: (i) primary and secondary education group, (ii) secondary and tertiary education group, and (iii) primary and tertiary education group. The tertiary education group showed a statistically significant difference when compared to the primary education group ($p<0.01$) and the secondary education group ($p=0.018$). The comparison between primary and secondary education groups was not statistically significant ($p=0.063$).

Table 2 showed the satisfaction levels on the 16 aspects of the drive-through pharmacy service. All respondents (100%) were satisfied that the dispensers were knowledgeable. In contrast, only 261 respondents (86.1%) reported being satisfied with the adequacy of direction sign board.

Table 1: Socio-demographic characteristics of the respondents and satisfaction score towards drive-through pharmacy service (n=303)

Socio-demographic characteristic		n (%)	Total satisfaction score, Median (IQR)	p-value
Gender				
	Female	175 (57.8)	16 (1)	0.815*
	Male	128 (42.2)	16 (1)	
Age				
	18 - 25 years old	0 (0)	-	0.209**
	26 - 35 years old	17 (5.6)	16 (1)	
	36 - 45 years old	31 (10.2)	16 (1)	
	46 - 55 years old	73 (24.1)	16 (1)	
	56 - 65 years old	87 (28.7)	16 (1)	
	> 65 years old	95 (31.4)	16 (1)	
Distance				
	1 - 10 Kilometres	230 (75.9)	16 (1)	0.204**
	11 - 20 Kilometres	70 (23.1)	16 (1)	
	21 - 30 Kilometres	3 (1)	16 (1)	
	> 30 Kilometres	0 (0)	-	
Occupation				
	Employed	135 (44.6)	16 (1)	0.264*
	Unemployed	168 (55.4)	16 (1)	
Education				
	Primary	74 (24.4)	16 (1)	0.034**
	Secondary	150 (49.5)	16 (1)	
	Tertiary	79 (26.1)	16 (1)	

Abbreviations: IQR = interquartile range

** Mann Whitney U test, **Kruskal Wallis test*

Table 2: Satisfaction level on the 16 aspects of the drive-through pharmacy service (n=303)

No.	Item	n (%)	
		Satisfied	Not Satisfied
1	I am satisfied with the operation hour.	298 (98.3)	5 (1.7)
2	I am satisfied with the interaction between dispenser and patients/caregiver.	302 (99.7)	1 (0.3)
3	The location of drive-through pharmacy is convenient.	265 (87.5)	38 (12.5)
4	The drive-through pharmacy is easily accessible.	263 (86.8)	40 (13.2)
5	I can easily obtain my medications at the drive-through pharmacy even in bad weather.	267 (88.1)	36 (11.9)
6	I am satisfied with the problem identification.	303 (99.3)	2 (0.7)
7	I wait less than 30 minutes to get my medication.	300 (99.0)	3 (1.0)
8	The dispensers are knowledgeable.	303 (100)	0 (0)
9	The dispensers are helpful.	302 (99.7)	1 (0.3)
10	The drive-through pharmacy has adequate direction sign boards.	261 (86.1)	42 (13.9)
11	I am happy with the way the medications being dispensed (5R criteria).	301 (99.3)	2 (0.7)
12	I am satisfied with the quantity of medications being dispensed until next refill date.	301 (99.3)	2 (0.7)
13	I am satisfied with the medications label.	302 (99.7)	1 (0.3)
14	I am satisfied with the way medications were packed.	302 (99.7)	1 (0.3)
15	The drive-through pharmacy provides flexibility in setting up appointment date.	298 (98.3)	5 (1.7)
16	I am satisfied with the procedure in obtaining medication if missed the appointment date.	300 (99.0)	3 (1.0)

Abbreviations: 5R = the right patient, the right drug, the right time, the right dose, and the right route

On the four open-ended questions about the performance and suggestions for drive-through pharmacy service, only 10 responses were received. Three themes were derived from these responses, which were presented in Table 3.

Table 3: Responses about the overall performance of drive-through pharmacy service

Theme	Quote	Comment
1. Accessibility	...limited space to have one-way flow of driving, sometimes need to reverse the car then only can drive out from the DTP area (Patient 97and Patient 181)	The respondents expressed dissatisfaction with the restricted accessibly due to narrow roundabout.
	...lorry from other clinic also park here, it's hard for me to enter the DTP area to get the medication (Patient 17, Patient 153 and Patient 210)	The DTP reserved area was frequently occupied by lorry who delivered medication stock, Poslaju or vehicles from other clinic due to the proximity of DTP to the pharmacy sub store.
2. Operation hours	I work 8am-5pm on weekdays. During lunch DTP also closed then it is hard for me to collect the medications (Patient 8, Patient 19, Patient 167 and Patient 188)	Respondents commented about the DTP service operation hours that were not convenient for the working group.
3. Small awning size	The small awning sometimes makes us difficult to collect the medications on rainy days without getting wet (Patient 11)	Patients found it quite difficult to take the medications on bad weather such as raining heavily due to small awning at DTP area.

Abbreviations: DTP = drive-through pharmacy; SHC = Sandakan Health Clinic

Discussion

Our findings demonstrated a high level of satisfaction with the drive-through pharmacy service at Sandakan Health Clinic. This finding aligned with the results of a study by Chung et al. which reported that the majority of the patients demonstrated the highest level of satisfaction with the drive-through pharmacy service with an average score of 4.40 (SD=0.70) (12). This implied that the drive-through pharmacy service users were satisfied with this innovative method of follow-up medication dispensing, due to its convenience, efficiency, time-saving nature, and reduced waiting time when compared with the conventional dispensing service at the outpatient pharmacy counter. Additionally, the study conducted by Chan et al. has shown that drive-through pharmacy service achieved a higher satisfaction level of value-added service as compared to mail pharmacy services (13). This possibly due to its greater convenience in dispensing medications that are not restricted to certain medications or required refrigeration (13).

According to our study, education level was significantly associated with patient's overall satisfaction with drive-through pharmacy. This finding coincided with a study conducted by Lagu et al. who found that there was a significant relationship between satisfaction level and individual education level (14). Another study that supported this finding was a study conducted by Hekkert et al. where patient's education significantly influenced the satisfaction outcome (15). This could be attributed to the fact that individuals with higher education levels were generally more conscious of their environment and were aware of consumer rights (16). As a result, they tend to seek higher quality services including public healthcare.

Our study highlighted the satisfaction with many aspects of drive-through pharmacy service provided, particularly in relation to the dispenser's performance. Specifically, all patients were satisfied with the dispenser's knowledge, while most respondents showed satisfaction with the dispenser's interaction with patients or caregivers, their helpfulness, and the clarity of medication labels and packaging. These results indicated overall satisfaction with the pharmacists and pharmacy assistant who were overseeing the drive-through pharmacy. Similarly, a study conducted by Liew et al. found that a high number of patients were "very satisfied" with the service, particularly due to convenience in collecting refill medications, short waiting time, timely rectification of problems and helpful personnel (6).

Out study found a notable percentage of dissatisfactions towards the adequacy of direction sign boards (13.9%), accessibility concerns (13.2%), and inconvenient location (12.5%). These concerns were further expressed in the responses to the open-ended questions. The drive-through pharmacy in Sandakan Health Clinic was situated beside the lobby area of the clinic with which may restrict vehicle access. Placing a “strictly no parking” sign may help to prevent obstruction of the drive-through pharmacy area. The existing narrow roads and space limitations have been acknowledged. Any future expansion or restructuring in healthcare facilities should consider accessibility and convenience for patients, depending on budget availability.

The open-ended responses from patients also highlighted several suggestions for service improvement. One suggestion was to extend the operation hours to accommodate the patients who faced difficulties in collecting medication during normal working hours. Moreover, the medication expiry dates should be clearly placed on the medication envelopes to increase the patient awareness. Also, adequate drive-through pharmacy sign boards and a bigger awning were required to ease the medications collection on rainy days.

There are several limitations in this study. A pilot study was not conducted prior to the study as the questionnaire was adapted from a validated tool with minor changes. Regarding the open-ended questions, data saturation could not be confirmed because only ten responses were received. Furthermore, the study was limited to patients attending the Sandakan Health Clinic drive-through pharmacy service, making it a single-centred study. Hence, the results may not be generalised to other healthcare facilities in Malaysia. Future studies should include more healthcare facilities for a more comprehensive view of the satisfaction level of drive-through pharmacy service and other value-added services. Additionally, the exclusion of patients who could not understand English or Malay may have introduced selection bias. Thus, further study was recommended to include a more variety of patients, particularly those who understand Chinese or native Sabahan languages as well.

Conclusion

Majority of patients have good satisfaction level towards the drive-through pharmacy service provided by Sandakan Health Clinic. This study found that patient satisfaction was significantly differentiated by education levels. The suggestions provided by patients can be used to improve the drive-through pharmacy service so we can continuously cater to patient needs**.** In the future, it would be beneficial to expand the study population to include value-added services in more healthcare facilities which could provide additional insights to explore.

Acknowledgement

The highest gratitude to the Director General of Health for his permission to publish this paper. We would also like to express our appreciation to Liew et al. for allowing us to use their questionnaire. In addition, we want to thank Dr Johari Awang Besar, the Sandakan District Officer, Dr Zaiton Yahaya, the family medicine specialist in Sandakan Health Clinic and Puan Masturah Bt Hj Abd Rajik, Head of Pharmacist in PKK Sandakan for their endless support throughout this study. Last but not least, we would like to thank Mr James Voo Hon Yau for his guidance and encouragement.

Conflict of interest statement

The authors declared no conflict of interest in this study.

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Medication Reconciliation: A Qualitative Analysis of Healthcare Professionals' Perceptions

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Abstract

Introduction: Medication discrepancies occur intentionally or unintentionally between a patient's medication list and medication administration. Medication reconciliation (MedRec) is a process to attain a complete patient's medication list with the aim of reducing the occurrence of drug discrepancies.

Objective: This study sought to explore healthcare professionals' perceptions and perceived barriers and facilitators of MedRec at Hospital Tuanku Ampuan Najihah (HTAN), as well as their feedback on a proposed MedRec Form.

Methods: This qualitative study used a purposive sampling method. Semi-structured interviews were conducted. The interview guide consisted of three domains: (1) perceptions on MedRec, (2) barriers and facilitators to the implementation of MedRec, and (3) feedback on the proposed MedRec Form. Interviews were recorded and transcribed verbatim. Data were analysed using thematic analysis approach.

Results: Five medical officers and five pharmacists were interviewed. The interview data yielded 62 codes and seven themes. The themes were (1) Perceptions of the MedRec process, (2) Challenges and barriers, (3) Safety and drug management, (4) Technology and documentation, (5) Medication review and accuracy, (6) Collaboration and responsibility, (7) Awareness, education, and experience. All respondents agreed that MedRec is beneficial for patients as it could reduce medication error, increase medication safety and optimise treatment regimen. The respondents suggested that time, poor medication history taking and workloads were the barriers in conducting MedRec. Overall, the respondents had contrasting views on the proposed MedRec form.

Conclusion: The implementation of MedRec remains challenging. Healthcare professionals in HTAN had mutual understanding on the benefits and barriers of MedRec, but with different views on the implementation of the new MedRec tool. Hence, addressing these barriers might improve MedRec implementation and clinical outcomes.

Keywords: Medication Reconciliation, Perceptions, Barrier, Facilitators

NMRR: NMRR-22-00633-PAW (IIR)

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Introduction

The World Health Organization (WHO) recognised medication reconciliation (MedRec) as a solution to reducing the occurrence of drug discrepancies. Many medication errors and adverse drug events can be prevented and facilitated by implementing MedRec in the healthcare systems (1). MedRec can be described as the process of creating a comprehensive and accurate list of a patient's current medications. The list is then compared with the medication orders prescribed by physicians during each transition of care, from admission to discharge. The primary objectives of MedRec are to ensure that the patient receives the correct medications and to prevent any discrepancies or errors in drug administration (2).

A systematic review and meta-analysis study by Choi & Kim (3) reported that MedRec reduced the proportion of patients with medication discrepancies and the number of medication discrepancy events by 68% and 88%, respectively. An unpublished clinical audit was done at Hospital Tuanku Ampuan Najihah (HTAN) to identify the prevalence of medication discrepancies before hospital discharge in 2020 (4). The study reported that four of the total 50 patients had discrepancies in their medication orders. In particular, 20% of the medication discrepancies were unintentional with omissions being the most common form.

Collectively, these findings indicated the potential benefits that effective implementation of MedRec could contribute in medication discrepancies and medication error prevention, and improving patient safety.
The implementation of MedRec in Malaysia, however, was observed to be relatively low pertaining to challenges such as interprofessional collaboration, increased workload for healthcare professionals, and the need for significant resource allocation for workflow redesign. Moreover, there were lack of standardised MedRec tools and protocol within the Ministry of Health Malaysia (MOH) healthcare facilities to streamline the MedRec process, from patient admission to discharge. Therefore, this study aimed to explore the insights from healthcare professionals in HTAN on their perceptions and the perceived barriers and facilitators to implement MedRec service in public hospitals. Additionally, it sought to explore the feedback on a proposed Medication Reconciliation Form that was created to be implemented in HTAN.

Method

Study design

This qualitative exploratory study was conducted over a four-month period from May to September 2022 at Hospital Tuanku Ampuan Najihah (HTAN). It is a major specialist hospital and the second largest public hospital in Negeri Sembilan, located in the Kuala Pilah district. HTAN is equipped with 314 beds and provides outpatient services, inpatient wards and up to 13 specialist services.

This study was registered with the National Medical Research Register (NMRR) and approval from the MOH Medical Research and Ethics Committee (MREC) was obtained.

Study instrument

A semi-structured interview guide in English was developed based on the existing literature and a monograph entitled “The Physician's Role in Medication Reconciliation” (5). It was further refined through discussion with the research team. Each participant was interviewed alone by two interviewers. The interview questions focused on three main domains: (1) Perceptions on medication reconciliation, (2) Barriers and facilitators to the implementation of medication reconciliation, and (3) Feedback on the MedRec Form.

At the point when this study was carried out, MedRec was generally conducted at the point of discharge by ward pharmacists in MOH hospitals. It was usually based on three separate documents used by the ward pharmacists, namely the Medication History Assessment Form (CP1), Pharmacotherapy Review Form (CP2) and Patient Referral Note (CP4). To streamline and facilitate the MedRec process in HTAN, a MedRec Form was created by our research team. The form differs from CP1 as it gathers data on the patient’s medications in the Emergency and Trauma Department (ETD), ward, and at discharge, whereas CP1 solely collects information about the patient’s previous medications. The proposed MedRec Form was intended to focus on the reduction of medication discrepancies from the point of hospital admission to discharge. The form was adapted from the UMass Memorial Medical Centre Medication Reconciliation Project led by Professor Dr. Eric Alper with permission from the authors (6). Some parts of the original form that were deemed not applicable in our setting were removed, such as “last dose date/time”. Subsequently, a section on "withhold" was added to the form, as this information is crucial throughout the patient's course of treatment.

A pilot study was conducted to ensure mutual understanding of the interview questions and identify any potential issues before actual data collection. Two participants were recruited for a pilot study, which involved a clinical pharmacist and a MO from the medical ward. A repetitive question was identified in the interview guide whereby the question was removed. The finalised list of interview questions was then constructed. The result from the pilot study was excluded from the results of this study.

Data collection

The targeted respondents were pharmacists and physicians working in HTAN. This study used a purposive sampling technique which is often employed in qualitative research when there is a limited number of people with experience or expertise in the research area and to ensure variation in participants' professions (7). An individual, face-to-face interview session was conducted in the Medication Therapy Adherence Clinic (MTAC) room for each participant to discuss their perceptions on MedRec in HTAN. This approach facilitated open and candid discussions, allowing participants to express their opinions freely and without hesitation.

The researchers set an appointment with each participant to conduct the interview session. All interview sessions were conducted face-to-face and audio recorded using an electronic recorder. All participants were interviewed alone by two interviewers. Written consent was given by the participants before the interview. The interviews lasted between 10 and 30 minutes.

The audio recording was de-identified, and there was no mention of personal identifying information during the interview, such as names and IC numbers. The audio recording was only for transcription purposes and was neither copied nor sent to any other individual. After the transcription of each interview session was done, the audio recording was disposed of securely.

A total of 10 interviews were conducted, as data analysis indicated thematic saturation—no new themes, perspectives, or insights emerged from additional responses. This decision was based on a thorough review of recurring patterns across the dataset, ensuring that further interviews were unlikely to contribute novel information. Guest, Bunce, & Johnson's Saturation Model (2006) suggested that saturation often occurs within 6–12 interviews in studies with a homogeneous sample (8).

Data analysis

The interviews were transcribed verbatim, producing 29 pages of 1.5-spaced text. Content analysis began with the interviewer carefully listening to the recordings and extracting raw-data quotes. Common themes were identified, coded, and grouped into categories, which were then organised into overarching themes. These themes were further synthesised into broader conceptual frameworks, offering a comprehensive view of the participants' collective experiences. Data analysis was conducted manually.

Results

Demographic characteristics of interviewed participants

A total of 10 participants were included in this study, comprising two medical officers (MOs) from the medical ward, three MOs from ETD and five clinical pharmacists. Half of the participants had five to 10 years of working experience in their current position, followed by less than five years of experience (n=4) while one participant had over 10 years of working experience. Table 1 below summarised the demographic characteristics of participants.

Table 1: Demographic characteristics of interviewed participants (n=10)

Characteristics	n (%)
Gender	
Male	2 (20)
Female	8 (80)
Age group	
<30 years old	6 (60)
31-40 years old	4 (40)
Profession	
Specialist	0 (0)
Medical Officer	5 (50)
Clinical Pharmacist	5 50)
Years of experience	
< 5 years	4 (40)
5-10 years	5 (50)
> 10 years	1 (10)

C*odes, categories and themes*

The interview data yielded 62 distinct raw-data codes, which were abstracted into 7 themes. The themes were (1) Perceptions of the MedRec process, (2) Challenges and barriers, (3) Safety and drug management, (4) Technology and documentation, (5) Medication review and accuracy, (6) Collaboration and responsibility, (7) Awareness, education, and experience.

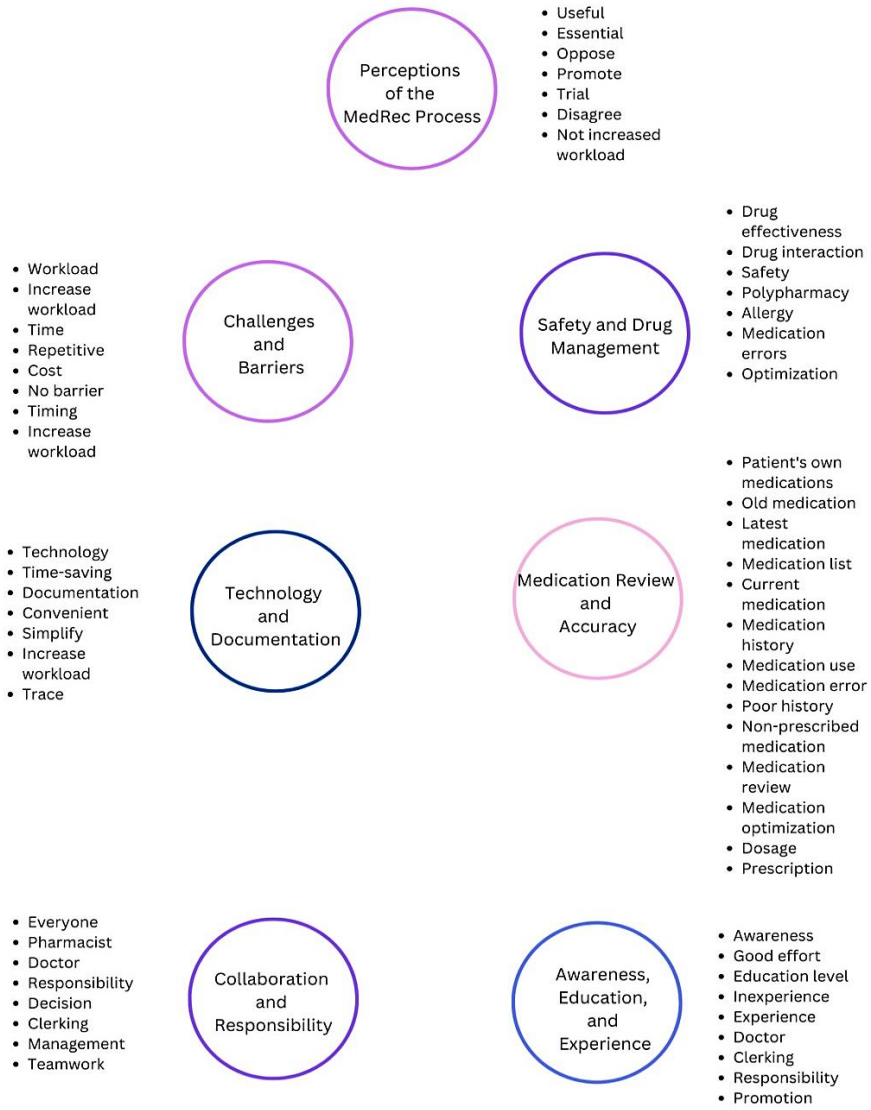

Figure 1: Codes that generate themes

Theme 1: Perceptions of the MedRec process

This theme captured healthcare providers' perception towards the MedRec process. Although the participants were from different professions, they had similar ideas and perspectives on MedRec. Most participants mentioned that MedRec is a process to ensure the updated list of patient's medications.

> "*… Medication reconciliation is a process to get the up-to-date patient's medication list. Usually when a patient admitted to ward, we will try to find patient's latest medication."* (Pharmacist A)

> *"... Medication reconciliation is a process to ensure the latest medication list for every transition of care when patient admitted to ward ...*" (Doctor E)

Theme 2: Challenges and barriers

This theme reflected the challenges faced by healthcare professionals during the MedRec process. These included the pressure of workload, time constraints, and additional tasks that could lead to barriers in performing MedRec properly. Both doctors and pharmacists think that the main barriers to implementing MedRec were time restrictions and heavy workloads in their workplaces.

> *"I feel like time factor because we do see a lot of patients but we are restricted in time. So, in order to rush the time, we would actually not do certain things. So, I think one of it is this medication reconciliation, because I think it takes up more time."* (Doctor B)

> *"I think time and heavy workload. I work in medical ward, so we have many things to do in wards. So, I think that would be barrier for us to do this process. That is why we usually ask helps from pharmacist to trace patient's medication list."* (Doctor D)

> *"I think time. In ward there is only one to two ward pharmacists. Sometimes it is impossible to complete the CP one for every patient before round started. ... Heavy workload also could be a barrier for me."* (Pharmacist A)

Other than that, poor history given by patients was also identified as one of the barriers to conducting MedRec which may be due to the patient's poor health literacy level and old age.

> *"... We have patients who come in with no documentation or no memory of what they are on. So, in that way, we can't really guess the medication because that's going to be harmful."* (Doctor B)

> *"… If let's say the patient's old or the patient cannot explain well of himself and in nowadays if the family support not so good, like nobody bring the medication come to the ward then it will be hard for the for everyone in the ward to know the medication."* (Pharmacist C)

> *"… Different educational level. If you ask patient what are the medications they took, they only tell you they took diabetes and hypertension medication, round and white in shape. Patients don't know what is the drug they took, the name of the drug."* (Pharmacist E)

Nevertheless, some participants highlighted that there were no barriers to conducting the MedRec process.

> *"Basically, basically, it's not an issue because nowadays, okay, if last time it was hard a bit, because you have to depends on patients, whether they bring their KK book, their prescriptions, their POMS. And also, certain patients if let's say they cannot take care of themselves, you need to base on caretaker and all that. But because nowadays most facility actually using computerised system, so actually, it's not a big problem. anytime, as long as you know where the patients follow up, actually, you can just call up and then you get a history, or else you just call up the caretakers. ... So, in overall is not a problem."* (Pharmacist B)

Theme 3: Safety and drug management

This theme highlighted the role of MedRec in ensuring patient safety, preventing drug interactions, managing polypharmacy, and addressing allergies or other risks in the medication regimen. In conducting MedRec, doctors and pharmacists shared the same opinions about the importance of conducting MedRec, which included ensuring patient's safety and to ensure that their treatments were effective.

> *"… For a better patient management. From the medication list, we can manage patient better based on the patient condition."* (Doctor E)

> *"It's to know the patients, it's to relate to the patient's current medication of course. Okay, and it's for us to also know what kind of medication they're on? We cannot just simply treat a patient merely on their symptoms that they're presented with."* (Doctor C)

> *"For patient's benefit. To reduce error and to ensure patient's safety like to prevent polypharmacy and to take extra cautious if patient has any allergy. Patient's safety purpose and to save medication."* (Pharmacist E)

> *"Probably to ease the treatment, to reduce medication error, to ensure medication safety, to optimise treatment regimen, something like that*." (Pharmacist B)

Theme 4: Technology and documentation

This theme reflected some possible concerns regarding the complexity or redundancy of the new documentation tool. Pharmacists and doctors had distinct views on the MedRec form and its process due to their individual experiences in clerking patient cases. Most doctors mentioned that the new form would be helpful and might help to save time.

> *"Okay, if you look at the form as a full thing, okay, it has patients' credentials, name, diagnosis, IC number, okay, which is the identity confirmation, okay. And then there's the source of medication list. Okay, so it also very well divided into certain categories, which will make us you know, like patient medication list, patient's own medication pharmacy records, I mean, if you're going to take on pharmacy records, we can say for sure that okay, this is the current medication that they're on, okay? Or if you're gonna see the patient OTC, we can be like, okay, is this right? Is this a correct one getting in that sense of medication is gonna help? Medication name, dose, frequencies is very important. And then there's this term C for continue, discontinue, newly started, I guess this is gonna be very helpful medication history recorded. Now it's going to be very helpful for us to know what are the exact medication that they own. And it will be easy for us to decide whether we need to continue the medication, withhold, or discontinue and there's also an option which is newly started."* (Doctor C)

> *"… It will make jobs easier. First, we do it at ED and then when patient admitted to the ward. Okay, the medical officer in the ward we refer back to this list. It will shorten the time."* (Doctor A)

> *"I think this form is useful."* (Doctors D and E)

> *"I think this form helps physician to monitor patient's medication from each transition of care until patient is discharge."* (Pharmacist A)

In contrary, some pharmacists had different views on the MedRec form as it was perceived to be similar to the existing CP1 form for medication history taking upon admission.

> *"… This form is almost similar to CP1. I don't see any extra things. It is almost similar to CP1."* (Pharmacist B)

> *"Disagree, because I think this form & CP1 is the same."* (Pharmacist C)

The two professions had different perspectives on the implementation of the form. Most doctors were supportive to utilise the MedRec form in daily routine.

> *"I think is a good effort … because I think it can make things easier. … I think that's a very good idea to go about."* (Doctor A)

> *"… I think it is useful actually… because from here (form) we can compare, because when we admit patient maybe got some acute issue then not all the medication can be restarted back at that moment. So, when patient already stabilised, already fit to be discharged, it's a good way that, because our BHT is so thick. So, this page/form is already simplified. So, we can recall back what is the medication that can be prescribed back or restarted after patient fit to be discharged. So that we won't forget what are the medications patient needs but we don't restart back. I think it is useful actually."* (Doctor D)

However, the pharmacists were not agreeable to implementing the MedRec form due to redundancy with current form.

> *"No, you only need one. You only need the baseline. Then upon discharge, you just use the prescription. After review the medication you just use prescription discharge. And you don't need to do reconciliation using this form anymore".* (Pharmacist D)

> *"No to me is no. Very obvious my answer. Because like the current one, one CP1 is enough, because we only cut the medication history. But if you are going to use this one, you need to update every change. So, for sure there is workload one and second one, for sure there will be error when someone's going to update this thing. And the existing system I think is already much sufficient. No need to do another form."* (Pharmacist B)

Theme 5: Medication review and accuracy

This theme focused on the importance of reviewing and maintaining a patient's medication list accurately, thereby ensuring the correct medications and dosages were documented to avoid errors and discrepancies. All doctors and pharmacists concurred with the necessity to conduct MedRec in all healthcare facilities to support precise decision making in the final discharge medications list.

> "*Actually it is important to conduct this process. We want to review the medication and ensure the medication is safe and indicated to be used based on patient's current condition. Apart from that, we want to avoid polypharmacy. From this medication list we also can continue the medication in ward. … When a complete and correct medication history is obtained, we can reduce medication error by not prescribe unnecessary medication thus ensure patient safety."* (Dr E)

Theme 6: Collaboration and responsibility

This theme centred on the collaborative nature of MedRec and highlighting the involvement of various healthcare providers, such as physicians, pharmacists, and nurses, and the distribution of responsibilities to promote patient safety. Most participants agreed that both pharmacists and doctors played a significant role in conducting MedRec.

> *"... By right is both doctor and pharmacist for confirmation from, to make sure that all the medication has been checked properly for all including the traditional and also the medication prescribed by hospital or KK."* (Doctor D)

> *"… As a clinical pharmacist, we are responsible to do medication reconciliation for every patient admitted in ward. We usually use CP one to conduct this process. Which mean this our job to conduct medication reconciliation. … I think doctor also responsible in this process. If the ward has no clinical pharmacist, or patient admitted to ward during weekend or after office hours, doctor also need to trace patient's latest medication. So, from this, they are also responsible to do medication reconciliation."* (Pharmacist A)

On the other hand, two participants expressed that MedRec should be considered a shared responsibility among patients, caregivers and all providers.

> *"If you ask me, I would say actually, it's like apart from everybody, including the patient itself. Because if I was a patient, and if I am started on any medication, I would want to know the use of the medication. And I want to know what medication I'm on. So, I think I should remember my medications. If I'm unable to remember, maybe my family members. Second, there should be documentation from the hospital side doesn't matter from doctors, pharmacist, staff nurse, anyone, but I think there should be documentation in order to make it easier for them to have the medication."* (Doctor B)

> *"I guess, everyone, starting from the medical assistants, staff nurse, doctors, pharmacists. Everyone plays a role in that."* (Doctor C)

Theme 7: Awareness, education and experience

This theme examined the significance of education, clinical experience, and awareness in the effective implementation of MedRec. While all doctors and pharmacists reported different levels of experience in conducting MedRec, not all doctors were actively involved in the process. Conversely, all ward pharmacists carried out MedRec as part of their daily routine. Generally, they would review the patients' old medications upon admission, often referencing to previous prescriptions or the treatment record books from health clinics.

> "*Actually, from my experience so far for my clerking patient, usually, I tend to see both the prescription and also the medication brought by the patient to the hospital. And also when clerking we tend to ask regarding the social. So we tend to also ask whether patients taking any extra medication other than prescribed by hospital."* (Doctor B)

> "*It is my practice when I do clerking for new admission, I will check the medication that patient brought and prescription. So from that we can list out the medication that patient currently on. Sometimes we also will ask if patient consume any extra medication or supplement."* (Dr E)

The importance of elevating patients' awareness and effort in managing their own medications without relying fully on caregivers or healthcare professionals was also highlighted.

> "*Most of the time, some patients are very well aware what kind of medication took, you know, some, they might not remember the name, but they can at least recall the dosing, whether they took BD dosing or TDS dosing. And, you know, certain, some, some of them, they could barely remember anything. You know, they will just say, Oh, I pergi klinik, the Doctor gave me the medicine and I took that. You know, I feel like there's also lack of what's the interest in them to know what kind of medications they're on?*". (Doctor C)

Discussion

Healthcare providers in HTAN demonstrated a shared understanding of MedRec and they were in agreement that the process is beneficial for enhancing patient safety and minimising medication errors. Healthcare providers' perceptions are vital in determining the successful implementation of MedRec (9). The state of being neglectful in the understanding of MedRec process can present challenges such as disengagement or underutilisation of the process, inaccurate reconciliation, poor interdisciplinary collaborations, and fragmented implementation. Therefore, there is a need to receive routine feedback on the challenges perceived by health providers regarding MedRec process. In reality, the difficulties commonly faced by providers are heavy workload, time constraint, insufficient manpower, and repetitive work that render the process tiresome. To illustrate, MedRec was believed to add on extra burden on the existing hectic work routine in the wards as the process requires comprehensive and thorough medication review of patients (10). The process becomes even more time-consuming when the patients present with multiple comorbidities that necessitate the use of a wide range of medications. Repetitive tasks, such as verifying medications and continuously updating records, contribute to stress and burnout among healthcare providers. These factors contribute significantly to the resistance to adopt MedRec as part of patient care and superficial implementation of MedRec.

Reducing resistance among healthcare professionals toward MedRec requires a multifaceted approach. A key challenge lies in balancing direct patient care with administrative responsibilities and enhancing acceptance of providers to adopt MedRec. For example, solving staffing shortages, allocating dedicated time for medication review, and streamlining work procedures should be considered (11). Essentially, a standardised MedRec workflow would lead to a more effective process with clear delineation of responsibility among the healthcare professionals. Other potential strategies to reduce resistance include staged implementation with constant feedback for system improvements, providing real-world data on its benefits as well as targeted education or training. The successful implementation of MedRec is largely dependent on the education, experience, and awareness of health professionals (12). Through continuous education and training, the benefits of having a standardised MedRec process could be emphasised, such as how it impacts patient safety and reduces medication errors. These efforts could help to shift perceptions and encourage integration of the MedRec process into the routine workflow. By addressing both practical and perceptual barriers, healthcare institutions can enhance acceptance on MedRec, promote consistent and effective implementation of MedRec, and ultimately improving patient outcomes and reducing medication-related errors.

It is important to constantly validate an updated list of medications to avoid medication discrepancies and medication errors. In fact, the findings from this study illuminate the mutual agreement between doctors and pharmacists that MedRec is crucial for patient safety, as it helps to manage risk factors such as drug interactions, allergies, and polypharmacy. Vira and colleagues reported that the MedRec

process prevented the potential for harm in 75 percent of cases (13). According to the American Academy of Family Physicians, a prominently displayed and up-to-date medication profile in each patient's chart serves as a crucial safety measure in patient care and should be updated at every clinical encounter (9). Poor history-taking, improper recording of medications, and lack of consistency between old and new prescriptions are some of the common factors leading to medication errors. More structured process of drug review, such as focusing on verifying current patient's medications and dose, can help in optimizing patient care and avoiding errors. A detailed and comprehensive MedRec is able to flag the information on allergy and adverse reactions, detect polypharmacy and drug-drug interactions through displaying the most updated medication list (prescribed and non-prescribed medications) to facilitate the identification of all regimen modification across transitions of care that may not be apparent otherwise.

In our study, the pharmacists and doctors had contrasting views on a proposed MedRec form. While the prescribers perceived the new form to be helpful, pharmacists viewed it as a duplication of existing form. Therefore, the work process and tools of MedRec should be carefully considered to avoid redundancy of workflow and adding unnecessary burden to the healthcare providers. On the other hand, technology is potentially an invaluable resource for enhancing the implementation of MedRec, such as with the use of electronic health records (EHR) (14).

EHR system needs to be designed to ensure accuracy, efficiency, and safety throughout the patient care continuum. An optimal EHR system that supports medication reconciliation should provide a comprehensive, accurate, and accessible medication list that integrates data from multiple sources. Specifically, it should have clear distinction between active, withheld, discontinued, and new medications, user-friendly interface, flagged discrepancies for review, automated alerts for allergies, drug-drug interaction and polypharmacy. When effectively implemented, technology can reduce human error, save time, and improve the overall accuracy of MedRec. However, concerns remain regarding the issues of governance regulation, data privacy, poor scalability and cost-effectiveness of electronic documentation (15). Thus, striking a balance between technological integration and practical workflow considerations is essential to optimise the effectiveness of MedRec in current clinical settings.

MedRec is a team effort, with the involvement of different healthcare providers such as pharmacists, physicians, and nurses (1). Successful medication reconciliation relies on the collective action of all the providers. Effective communication and role definition are essential to effective MedRec implementation. Poor coordination or unclear roles can lead to lapses in the process. Specifying the roles of every profession in MedRec implementation can reduce role ambiguity, which often contributes to internal conflicts, stress, and resistance in coordinating among each other (11). Mutual responsibility ensues all professionals contribute towards patient safety. A good relationship among the healthcare providers is the foundation to create a climate of trust to ease communication, thus optimising team work and ensuring better patient outcomes eventually.

There were certain limitations within this focused analysis that must be acknowledged. Firstly, this study was unable to recruit HOs and specialists for the interview session, which may have influenced the comprehensiveness of the findings. Specialists, due to their expertise and decision-making roles, could have provided valuable insights into the clinical and administrative challenges of MedRec. Similarly, HOs, who often serve as the first point of contact in patient clerking, might have had unique perspectives on the practical difficulties and workflow constraints associated with the process. However, their unavailability during the study period, primarily due to time constraints and work schedules, restricted their participation. Future studies should consider strategies such as scheduling flexibility or alternative data collection methods (e.g., online interviews or surveys) to include these key stakeholders. Secondly, the study was exploratory in nature and was only conducted at a single site, limiting the generalisability of the findings to other healthcare settings. Practices, workflows, and challenges related to MedRec may vary across different hospitals, regions, and healthcare systems. A multicentre study would provide a more comprehensive understanding by capturing a broader range of experiences and institutional policies.

Despite these limitations, purposive sampling ensured recruitment of a targeted group of healthcare professionals, representing different roles within the MedRec process. This helped to capture a wide range of perspectives, enhancing the depth of the findings. However, future research should aim for a larger and more diverse group of respondents and include multiple study sites to strengthen the robustness and applicability of the findings.

Conclusion

The MedRec process is pivotal to ensure medication use optimisation and patient safety. The findings from this study suggested that healthcare providers generally had a mutual understanding about MedRec and agreed that MedRec is beneficial in improving health outcomes, reducing medication errors, and ensuring patient safety. Nevertheless, the healthcare providers might have different views on a feasible MedRec tool. Time restraints, suboptimal information gathering with patients and increased workload were the main barriers to conducting MedRec in real clinical practice. Addressing these barriers while increasing providers' self-efficacy might improve medication reconciliation and its outcomes.

Acknowledgment

The authors would like to thank the Director General of Health Malaysia for his permission to publish this article. In addition, the authors would also like to thank all the respondents for their kind cooperation.

Conflict of interest

No funding was received to assist in the preparation of this study. The authors have no conflict of interest to disclose.

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Retrospective Study on Potential Cost Savings of Medications after Implementation of “Order What You Need” (OWUN) at Labuan UTC Health Clinic

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Abstract

Introduction: "Order What You Need" (OWUN) is an initiative that encourages patients to only collect the medicines they require at the pharmacy. OWUN might help to avoid unnecessary medicine wastage.
Objective: This study aimed to estimate the potential cost savings of medications after the implementation of the OWUN practice at the outpatient pharmacy of Labuan UTC Health Clinic.
Methods: This was a retrospective analysis on the record of OWUN unwanted medicines from April to September 2023. Unwanted medicines referred to medicines that patients or caregivers indicated as not needed during prescription refill at the outpatient pharmacy counter. The cost savings of medications were calculated based on the latest cost prices.
Result: Of 235 patients who joined the OWUN programme, 58% were female, and the mean age was 60.1 ± standard deviation 12.8 years old. A total of 9,572 units of medicines were identified as unwanted, resulting in an estimated cost savings of RM2,636. Medicines from the respiratory group accounted for the highest proportion of cost (41.0%), followed by the endocrine group (27.1%) and the cardiovascular group (17.6%). The three most common unwanted medicines were metformin (40%), atorvastatin (14%) and gliclazide (6%).
Conclusion: The study showed cost-saving potential of the OWUN practice. Similar initiatives may be replicated in other healthcare facilities.
Keywords: Order What You Need, Medication saved, Unwanted medicine, Cost savings, Pharmacy

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Introduction

In Malaysia, there was nearly RM2 millions disposal of expired medicines at government facilities from 2014 to 2016 (1). At Hospital Canselor Tunku Muhriz, approximately RM174,369 worth of expired medicines were returned by patients annually from home between 2015 and 2017 (2). Similarly, the Malaysia National Cancer Institute recorded RM133,473 worth of returned medicines from home within four months period from January to April 2019 (3). The common reasons for returning medicines at the pharmacy included stockpiling at home, change of medication or discontinuation, allergies or side effects, non- compliance and death of patients (2,3). Medications returned from households cannot be reused and must be disposed of appropriately. The disposal of medicines has not only caused economy loss due to wasted medications and associated disposal costs, but also environmental threats if these medicines were not disposed properly (4,5). Improper disposal of medicines may lead to polluted water as mentioned in the Research by the World Economic Forum, for example, improper disposal of antibiotic may leak into water system and contribute to antibiotic resistance (5), which may then result in ineffective treatment, increased difficulty to treat patient, and even mortality (6).

A report by the Department of Health, United Kingdom estimated that unused medicines cost the National Health Service (NHS) around £300 million annually (7). The "Order What You Need” and “Not Dispensed” programme was carried out in the United Kingdom since 2012 to reduce medication wastage. Under these programmes, pharmacists were encouraged not to dispense medicines to patients or caregivers who informed that they no longer require the medicines, and patients or carers were advised not to refill prescriptions unnecessarily if they still have adequate supplies at home (7,8). A similar OWUN

project was implemented as Quality Improvement Initiative project by Mazlan et al. at the Malaysia National Cancer Institute to reduce the return of analgesics from patients' homes (3). The project also included awareness campaign to inform patients about the importance of checking their balance of medicines before refills, and create awareness that the returned medicines cannot be reused and must be disposed by the pharmacy. By implementing these strategies, the project resulted in a 21% reduction in the cost of returned medicines and a saving of RM5,944 (4).

Since July 2022, the pharmacy outpatient department at the Labuan UTC Heath Clinic has implemented the OWUN initiative. All patients or caregivers who presented a prescription for medication refill will be interviewed by the pharmacist about existing medicine supplies at home before dispensing the refills. All unwanted medicines by patients or caregivers during the prescription screening and dispensing process were recorded to serve as evidence for internal audits (9). By assessing the remaining supplies, pharmacists can evaluate patients' medication adherence and determine the appropriate quantities to be dispensed after discussing with the patients or caregivers. This study was conducted to estimate the potential cost saving of OWUN practice at the outpatient pharmacy of Labuan UTC Health Clinic.

Method

This retrospective study utilised secondary data extracted from the record of OWUN unwanted medicines from April to September 2023. This study employed universal sampling, including all records of unwanted medicines during the study period. Medicines returned from home were excluded from this study.

Unwanted medicines referred to medicines that are voluntarily declined by patients or caregivers during the screening or dispensing process at the pharmacy outpatient counter. The amount of dispensed medicines was adjusted to ensure sufficient medication until the next scheduled prescription refill date, based on patients or caregivers' agreement. These medications were classified according to the classification index based on pharmacological groups in the British National Formulary (11).

The cost savings of medications was the cost of unwanted medicines not dispensed to patients or caregivers, which was calculated based on the latest unit cost price obtained from the Pharmacy Information System (PhIS). To standardise the calculations, medication quantity was calculated as the number of units of inhalers, tablets, capsules, bottles, or insulin pens (11).

Microsoft Excel was used to collect information, analyse data and generate descriptive result. Descriptive statistics including frequency and percentage and mean with standard deviation (SD) were used in this study. This study was registered in the National Medical Research Register (NMRR ID-23-03636-SXU) and ethical approval was obtained from the Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia.

Results

During the study period, 235 patients utilised the OWUN initiative. More than half of these patients (62.5%, n=147) were 60 years old and above, and 136 (58%) were female.

Table 1: Demographic characteristics of study population (n=235)

Variable	n (%) / Mean (SD)
Age, year, mean (SD)	60.1 (12.8)
Age range (year), n (%)	
18-29	6 (2.6%)
30-39	6 (2.6%)
40-49	25 (10.6%)
50-59	51 (21.7%)
≥60	147 (62.5%)
Gender, n (%)	
Male	99 (42.1%)
Female	136 (57.9%)
Origin of prescription, n (%)	
Hospital Labuan	35 (14.9%)
Labuan Health Clinic	73 (31.1%)
Labuan UTC Health Clinic	127 (54.0%)

Abbreviation: SD = Standard deviation; UTC = Urban Transformation Centre

As shown in Table 1, half of the refilled prescriptions were from Labuan UTC Health Clinic (n= 127, 54%), followed by prescriptions issued from Labuan Health Clinic (n=73, 31%) and Hospital Labuan (n=35, 15%). A total of 46 types of medicines were reported as unwanted by patients or caregivers. The total quantity of unwanted medications was 9,572 units, amounting to a total cost of RM2,634.

Table 2: The quantity and cost of unwanted medications at outpatient pharmacy by pharmacological groups

Pharmacological Group	Medication quantity (unit)	Cost, RM (%)
Respiratory system	90	1,080 (41.0)
Endocrine system	4,343	714 (27.1)
Cardiovascular system	3,201	465 (17.7)
Nutrition	1,322	199 (7.6)
Gastro-intestinal System	310	77 (2.9)
Other	306	99 (3.8)
Total	9,572	2,634

Abbreviation: RM = Malaysia Ringgit

As shown in Table 2, respiratory group medications had the highest proportion of cost (41%), followed by endocrine group (27.1%) and cardiovascular group (17.6%). Among these, antidiabetic drugs (metformin and gliclazide) and antihyperlipidemia drugs (atorvastatin and simvastatin) were the most frequently reported unwanted medications (Figure 1).

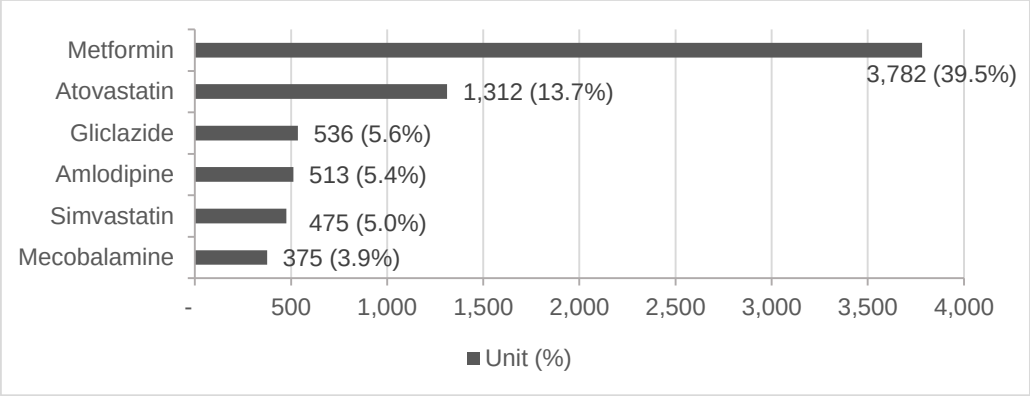

Figure 1: Top six types of unwanted medicines by quantity (unit)

Discussion

This study was conducted to estimate the potential cost saving of OWUN practice at the outpatient pharmacy of Labuan UTC Health Clinic. Among the refilled prescriptions, almost half of them were from Hospital Labuan and Labuan Health Clinic. Due to the strategic location of Labuan UTC Health Clinic, which is situated next to a morning market and located within a building that houses multiple government agencies, it is considered a convenient choice for patients to refill their medicines.

In this study, an average of 1,595 units of unwanted medications were identified at the pharmacy outpatient counter each month, which was higher than the 921 units of home-returned medications per month in a previous study (11). However, the average monthly cost of unwanted medications in this study (RM439) were lower than the monthly cost of home-returned medications in the mentioned study (RM1,133) (11). This difference in costs may due to the nature of the prescriptions at Labuan UTC Health Clinic, which mainly consists of non-specialist medications that were generally less expensive than specialist medications. Bekkers et al. found that approximately 39% of returned medications were classified as preventable waste, as they were unopened, undamaged, and had at least six months remaining before expiry (12).

This study identified that metformin and gliclazide were the most frequently unwanted antidiabetic medicines. This could be attributed to non-compliance or side effects. Complex dosing regimens requiring multiple doses per day, which can sometimes cause patient to forget to take their medicines (3,11). On the

other hand, antihyperlipidemic drugs such as atorvastatin and simvastatin, were the second most common unwanted medicines. Possible reasons included patients' concern about the side effects like muscle pain and stiffness, as well as reluctant to take (11). In addition, some patients may mistakenly believe that atorvastatin must be taken at night like simvastatin, which was a leading cause of poor adherence as certain patients tended to forget to take the medicines at night. In such cases, pharmacists may play a role by discussing with prescribers to simplify the regimen, such as to prescribe atorvastatin with instruction for once daily dosing at any convenient time to improve compliance (11).

This study found that the highest cost of unwanted medicines originated from the respiratory group, accounting for nearly half of the total cost, followed by the endocrine and cardiovascular groups. Notably, despite having the lowest quantity of returned units, respiratory medications imposed the greatest financial burden due to the high unit prices of inhalers such as salbutamol and budesonide metered dose inhalers (MDI). In another study by Jamaluddin et al. (2022), the authors reported substantial wastage in the endocrine and cardiovascular categories, particularly due to the high cost of insulin (11).

A major potential contributor to respiratory medication wastage was the inability to visually assess the remaining doses in inhalers (13). As a result, patients or caregivers may refill prescriptions unnecessarily, leading to medication stockpiling. To address this, it is essential for patients to bring their inhalers to the pharmacy during refills. Pharmacy staff can estimate remaining doses based on dispensing records and typical usage patterns, while also educate patients on proper tracking methods. Labelling the date of opening and explaining the total dose capacity, such as the 200-dose content in a typical salbutamol inhaler, can help patients avoiding unnecessary refills (15). The availability of fully subsidised medications under the Malaysian public healthcare system may inadvertently lower patients' motivation to monitor their existing medication supplies. Educating patients about the value of medications, such as displaying cost prices on medication packaging, is a promising step taken by the Ministry of Health to foster appreciation and responsible use (2). Pharmacy staffs also need to educate patients or carers that medication returned from home cannot be reused by pharmacy, therefore, they must avoid wastage cause by stockpiling medication at home. To further reduce medication wastage, pharmacists should emphasise the importance of adherence and encourage patients and caregivers to bring their remaining medications when refilling prescription.

A limitation of this study was the potential for recall bias, as some patients or caregivers may not have accurately remembered or checked their remaining medicine supply before refilling. In some cases, patients were unaware of the need to verify their stock. Introducing a simple take-home form for recording the quantity of remaining medicines could support more accurate dispensing and minimise recall bias. This strategy would not only improve inventory management but also saving time during pharmacy visits (2). Implementing structured documentation of home medicine inventories can enhance future studies and strengthen interventions aimed at minimising unnecessary medication supply.

Conclusion

The findings demonstrate potential cost savings of medications through the implementation of OWUN, with the highest savings observed in respiratory, endocrine, and cardiovascular group of medications. Similar initiatives can be replicated in other healthcare settings. Active participation from patients and caregivers was essential in reducing medication waste and supporting environmental sustainability.

Acknowledgement

The authors would like to thank the Director General of Health Malaysia for his permission to publish this study.

Conflict of Interest

No funding was received for this study. The authors have no conflict of interest to disclose.

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eISSN 2637-1332