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Identifying Challenges and Possible Ways to Improve the Effectiveness and Efficacy of Plant-Based Drugs in Traditional Medicine in Sri Lanka

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Abstract— According to the World Health Organization (WHO), approximately 80% of the global population relies on traditional medicine for their primary healthcare needs. Even in developed countries, there's a growing popularity of complementary or alternative medicine. A worldwide survey on national policies and regulations for traditional medicine and herbal medicines reveals that around 50 countries, including China, Japan, and Germany, have already established their own regulations and policies for traditional medicinal practices. Traditional medicine encompasses a range of health practices, beliefs, and knowledge that involve using plant, animal, and mineral-based remedies, spiritual therapies, manual techniques, and exercises to diagnose, treat, prevent, or maintain well-being. In Sri Lanka, there are four established traditional medicine systems: Avurveda, Siddha, Unani, and Deshiya Chikitsa. This study aimed to identify challenges and propose solutions to enhance the effectiveness of herbal drugs in Sri Lankan traditional medicine. Qualitative analysis was conducted using both primary and secondary data sources. Primary data was gathered through 52 qualitative interviews involving various traditional medical practitioners, employees in Ayurvedic drug production in the Kandy district, and the general public. The quality issues surrounding herbal preparations were classified into external and internal categories. External issues encompassed problems like contamination (such as toxic metals, pesticide residues, and microbes), adulteration, and misidentification. Internal issues revolved around the complexity and non-uniformity of herbal medicine ingredients. Moreover, challenges were pinpointed in the regulatory and licensing processes for practitioners and products, product composition, quality control, manufacturing methods, stability, safety, and preclinical and clinical studies. To address these challenges, modern technology methodologies and guidelines can play a crucial role. Given the intricate nature of ensuring guality and safety in traditional medicine preparations, appropriate measures need to be established for the assessment and standardization of these methodologies and drugs. The insights provided by discussing various issues and drawbacks related to herbal drug production in Sri Lankan traditional medicine can serve as valuable guidance for industries, practitioners, and regulatory authorities, enabling them to understand the present landscape and take appropriate actions.

Index Terms- herbal drugs, plant-based drugs, Sri Lanka, Traditional medicine

1 INTRODUCTION

Traditional medicine has deep historical roots and holds a significant place in global healthcare practices. According to the World Health Organization (WHO), a substantial 80% of the global population relies on traditional medicine as their primary source of healthcare [1], a trend not limited to developing countries. Even in developed nations, complementary or alternative medicine is gaining traction, signaling a growing interest in exploring diverse healthcare approaches. Notably, a global survey on national policies and regulations highlights the increasing recognition of traditional medicine and herbal remedies. Approximately 50 countries, including influential players like China, Japan, and Germany, have established their own regulatory frameworks, affirming the relevance and potential of these traditional practices [2]. Traditional medicine encompasses a wide array of health practices, each rooted in unique cultural theories, beliefs, and experiences. This rich tapestry includes the utilization of plant, animal, and mineral-based remedies, spiritual therapies, manual techniques, and exercises. These practices are often employed individually or combined to address various health needs, ranging from treating and diagnosing illnesses to maintaining overall well-being. Prominent examples include traditional Chinese medicine (TCM),

Ayurveda, Kampo, traditional Korean medicine (TKM), Unani, and Deshiya Chikitsa in Sri Lanka.

One compelling facet of traditional medicine is its profound relationship with the botanical world. The World Health Organization defines herbal medicines as finished labelled products containing active ingredients derived from plants, encompassing various plant parts or combinations. Plants are akin to living factories, producing an intricate array of chemical compounds, including both primary metabolites essential for growth (such as amino acids and carbohydrates) and secondary metabolites like alkaloids, terpenoids, phenylpropanoids, polyketides, and flavonoids. Notably, certain herbal medicines provide a level of polypharmacology that orthodox drugs often cannot replicate. In fact, from the mid-20th century to recent years, nearly half of FDA-approved chemical drugs trace their origins or inspiration back to natural products. These medicinal agents often feature relatively low concentrations of active ingredients, which, coupled with the complex and time-consuming extraction process, underscores the challenges inherent in their development and application [2, 3].

In light of the complexities within traditional medicine, this study seeks to address pertinent challenges and propose ways to enhance the effectiveness of plant-based drugs in Sri Lankan traditional medicine. By conducting qualitative analysis based on primary and secondary data sources, we aim to shed light on the intricacies of traditional medicine and its potential modern applications. Through a comprehensive exploration of the issues and suggestions for potential solutions, this research contributes valuable insights for the improvement and advancement of traditional medicinal practices in Sri Lanka and beyond.

The objectives of this study are to identify the issues and drawbacks of plant-based drugs in traditional medicine in Sri Lanka and to suggest possible ways to improve their effectiveness and efficacy.

2 LITERATURE REVIEW

Traditional medicine encompasses diverse health practices incorporating plant, animal, and mineral-based remedies, spiritual therapies, manual techniques, and exercises, with applications spanning from illness treatment and diagnosis to well-being maintenance [2]. Notable traditions include traditional Chinese medicine (TCM), Ayurveda, Kampo, traditional Korean medicine (TKM), Unani, and Deshiya Chikithsa.

The World Health Organization (WHO) defines herbal medicines as finished products containing plantbased active ingredients [1]. Plants serve as "living factories," producing an array of chemical compounds, including primary metabolites like amino acids, and secondary metabolites such as alkaloids, terpenoids, and flavonoids. The complexity and diverse bioactivities of certain herbal medicines offer polypharmacology, a characteristic distinct from orthodox drugs [2]. Historical records reveal that from the 1940s to 2014, nearly half of FDA-approved chemical drugs originated from or were inspired by natural products [2, 3]. However, extracting active ingredients from natural sources is a labor-intensive process [2], necessitating the development of effective, selective methods for bioactive natural product extraction and isolation.

The objectives of this study encompass identifying issues and suggesting enhancements for the efficacy of plant-based drugs in Sri Lankan traditional medicine. Employing qualitative analysis, the research draws

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from primary and secondary data sources.

2.1 Traditional Medicine

The WHO defines traditional medicine as encompassing knowledge, skills, and practices rooted in unique cultural theories, beliefs, and experiences [1]. Traditional systems vary, with some supported by extensive literature and others passed down through oral tradition [3]. Throughout the world, many continue to rely on traditional medicine for primary healthcare needs, with some systems evolving into complementary or alternative medicine when integrated with modern practices. Prominent systems are widespread in countries like China, India, Korea, and Africa, while Sri Lankan traditional medicine gains global recognition due to its positive outcomes [2].

2.2 Traditional Medicine in Other Countries

Traditional Chinese medicine, drawing from millennia of practice, offers techniques for dosage, drug preparation, and timing [2, 3]. Japan's traditional medicine, influenced by historical logic, has unique theories and practices distinct from Western medicine [4]. Korea's traditional medicine, often referred to as "Korean medicine," adapts Chinese theories and practices to suit Korean needs [5]. India's Ayurveda, with a history spanning over 2,000 years, boasts ancient theories that have transcended borders and cultures [6]. Unani medicine, originating in Greece, evolved through contributions from Arab and Persian healers [1].

2.3 Traditional Medicine in Sri Lanka

Sri Lanka embraces four traditional systems, including Ayurveda, Siddha, Unani, and Deshiya Chikitsa [7]. Colonial influences initially challenged these systems, yet they endured and even integrated over time [2]. While traditional medicine has not played an active role in primary healthcare, it remains popular among the population [8]. Government-supported Ayurveda facilities exist, despite Western medical establishments' reservations. Traditional practitioners are now being encouraged to contribute to health promotion and disease prevention [9].

Emerging health hazards and the burden of communicable and non-communicable diseases prompt a renewed focus on traditional medicine in Sri Lanka. Medicinal preparations, such as Mellum and Kenda, showcase the diverse forms of traditional treatment [10, 11].

3 METHODOLOGY

The qualitative analysis in this study draws upon both primary and secondary data sources. Primary data was acquired through 52 qualitative interviews involving diverse traditional medical practitioners and personnel from the Ayurveda drug production sector in the Kandy district. Additionally, a representative subset of 10 adults, spanning genders and aged between 50-80 years, was randomly selected from the general population and interviewed. The primary data collection aimed to provide a concise understanding of traditional practitioners' knowledge, perceptions, treatment methods, and the process of manufacturing plant-based medicines. Through this, it also aimed to uncover challenges within the traditional medical sector. Insights into drug production were obtained through employee interviews, while the perceptions of the general public towards the traditional medical system were captured through their interviews. In parallel, secondary sources were reviewed to furnish historical context on medical systems and to pinpoint potential technological avenues for advancing contemporary traditional medicine practices in Sri Lanka.

The study encompassed 27 traditional practitioners (covering Ayurveda, Unani, and Deshiya Chikithsa) within the Kandy district, along with 15 staff members from Pallekele Ayurveda Pharmacy, individuals from private clinics or dispensaries, and an additional 10 individuals undergoing treatments at Ayurveda medical centers in the Kandy district. To gather data, qualitative techniques such as in-depth interviews, key informant interviews, and observations were employed. These methodologies were leveraged to capture insights from practitioners and employees regarding challenges faced by traditional medical systems, particularly concerning plant-based drug manufacturing, contemporary health hazards, and the intricacies of drug production processes.

4 RESULTS AND DISCUSSION

Evidence indicates that humans have long utilized natural sources like plants, animals, microbes, and marine organisms for disease alleviation and treatment [12]. Traditional medicine evolved alongside human development, yielding diverse orthopedic and other treatments worldwide [1, 11].

Interest in traditional medicine, especially herbal remedies, has surged globally in the past decades. Herbal products, deriving compounds from whole plants or parts, stand as a valuable pharmaceutical resource [12]. The World Health Organization (WHO) notes that over 80% of the world's population relies on traditional medicine for primary healthcare [13].

This study encompassed 16 Bachelor of Ayurveda Medicine and Surgery practitioners, 2 Bachelor of Unani Medicine and Surgery practitioners, 6 Diploma in Ayurveda Sasthri practitioners, and 3 Deshiya Chikithsa practitioners practicing within their family tradition. Among them, 59% operate within government healthcare, while 41% exclusively provide services in private clinics, all having their own clinics. Additionally, a group of 10 individuals aged 50-80, equally split between genders, seeking treatment for over a year from such clinics were included.

Regarding staff, 04 individuals work within the government sector, while 11 are employed by private clinics, largely involved in drug manufacturing. This group primarily comprises males (10 out of 15), with educational qualifications ranging from G.C.E. O/L to G.C.E. A/L.

The study proceeds to discuss identified challenges, weaknesses, strengths, threats, and opportunities within traditional medicine (TM), along with suggestions for enhancing plant-based drugs using modern technological methods, bolstered by prior research.

4.1 Why Traditional Drug Production Should Be Improved?

Interview findings highlight the need for new strategies to address challenges in drug development and clinical treatment within the traditional medicine (TM) sector. Key challenges include toxicology, clinical procedures, documentation, and herbal preparation identification. Addressing these necessitates an audit process for potential contaminants. Concerns encompass communication of uncertainty, pharmacovigilance, the addition of harmful components like heavy metals, unapplied GMP/GAP regulations, and the absence of efficacy assessment methods beyond conventional clinical trials.

In response to rising chronic diseases and multiple drug prescriptions, there's a growing demand for polypharmacy targeting various disease aspects. Notably, plant-based medicines, often complex mixtures with multiple active compounds, align well with this approach. However, current evaluation methods predominantly employ single-target compounds.

Sri Lanka's traditional medicine field is rich in knowledge and resources, facilitated by dedicated institutions. Despite strengths, challenges include limited composition information, bulk supply of

unprocessed materials, contamination risks, and deficient pharmacovigilance. Contamination by heavy metals is especially concerning due to agricultural practices and pollution. Additionally, philosophical therapies without clinical bases pose issues.

Drawbacks include misdiagnosis, incorrect dosages, and poor hygiene standards. Lack of technology utilization, research, and quality maintenance further undermine the sector. The potential decline of traditional knowledge due to lack of documentation and competition from other traditional systems raises threats. Moreover, pollution-induced contamination and changes in cultivated plants' chemical composition impact efficacy.

Incorporating modern technology emerges as a solution to improve traditional medicine's efficacy and safety. Yet, few studies explore this field comprehensively

4.2 Application of Technology

Considering the challenges and drawbacks within Sri Lanka's traditional medical system, it's evident that technological integration could yield substantial improvements. Novel medical practices often incorporate technology across various stages of herbal drug preparation [13].

Per insights from interviewees, a comprehensive safety assessment for herbal products is recommended. Safety evaluation methods vary and may encompass measures from the inception of plant cultivation. Implementing good plant husbandry principles, choosing suitable plants, and employing Conservation Agriculture (CA) techniques where needed can enhance product quality. Measures to prevent air, soil, and water pollution are vital [14].

Accurate botanical identification is fundamental. Acquiring data such as taxonomy, distribution, phenology, and genetic diversity prevents misidentification. Herbaria authentication aids species verification. Analyzing growth conditions requires data on topography, geology, soil, and climate. Rigorous collection, transportation, and handling practices safeguard product quality, with bioinformatics and statistical tools aiding data analysis. Good Agricultural and Collection Practice (GACP) guidelines are key for cultivating quality medicinal plants [3, 15].

Toxicity issues arise from inherent toxic compounds or manufacturing contaminants. Technology can assess toxic effects through detailed phytochemical and pharmacological studies. Government support through increased funding for herbal product research utilizing modern technology is crucial [16].

Implementing Good Laboratory Practices (GLP), Good Manufacturing Practices (GMPs), and Good Agricultural Practices (GAP) enhance medicinal product quality (WHO). DNA microarray technology aids in pharmacodynamics, pharmacogenomics, and pharmacognosy for authentication and standardization [13].

Quality assurance methods ensure consistent chemical composition and bioequivalence across batches. Quantitative analysis using a single marker (QAMS) addresses standard material scarcity. Chromatographic techniques (GC, LC, MS) along with ultrahigh-performance liquid chromatography (UPLC) coupled with mass spectrometry can analyze herbal medicine composition. Mass spectrometry imaging enables ingredient proportion assessment [13].

Controlled organic cultivation curbs the depletion of wild plants. Techniques like tissue culture, grafting, organic farming, and chemical analysis ensure that cultivated crops mirror wild species' chemical makeup [3].

To tackle microbial and chemical contamination, biochemical tests (Table 4.1) can be conducted for raw materials, final products, and shelf-displayed items.

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Additionally, chemical analysis can determine herbal drug shelf life, addressing practitioners' concerns and preserving effectiveness. Ancient preservation methods could be revisited.

4.3 Quality Assurance Assessment Methods

Efficient separation methods and robust spectrometric techniques, supported by extensive genomic, proteomic, and chemical data repositories, aid in identifying active compounds. The Fig. 4.1 shows a process of evaluating safety and standardising the herbal drug preparations that can be applied to ensure the product's quality [22]. The fig, 4.2 shows assessment procedures for quality assurance that can be implemented.

4.4 Isolation and Purification of Bioactive Molecules from Plants

Plant material selection and collection are the initial steps. Ethno-botanical knowledge guides bioactive molecule exploration. Extracts are prepared using diverse solvents. Active compounds are isolated and purified via paper thin-layer and column chromatography. High-Pressure Liquid Chromatography (HPLC) expedites purification, while UV-visible, Infrared (IR), Nuclear Magnetic Resonance (NMR), and mass spectroscopy confirm compound identity [12].



Fig. 4.1: Process of evaluating safety and standardizing the herbal drug preparations

Fig. 4.2: Assessment procedures for quality assurance [17]

4.5 Structural Elucidation of Bioactive Molecules

UV-visible, IR, NMR, and mass spectroscopy techniques are pivotal in determining molecule structures [18].

4.6 Chemical Compound Identification

UV-visible, IR, NMR, and mass spectroscopy techniques aid in identifying chemical structures. Mass

spectrometry identifies compounds in medicinal herbs, facilitating the removal of unwanted and toxic molecules to enhance drug efficacy [17].

In conclusion, traditional medicine, with its historical roots deeply embedded in cultures around the world, offers a treasure trove of knowledge and remedies for addressing various health issues. However, the traditional medical sector, particularly in Sri Lanka, faces a range of challenges that necessitate innovative solutions. The utilization of modern technology presents a promising avenue to enhance the quality, safety, and efficacy of herbal drugs used in traditional medicine.

2º metabolite	Name of The Test	Results	References
Alkaloids	Dragendorff's test	Orange spot	[19]
	Wagner test	Brown red precipitate	[16]
	TLC	Orange spot	[22]
Anthraquinone	Borntrager's test	Pink/ deep red coloration of aqueous layer	[19]
Cardiac Glycosides	Kellar - Kiliani test	The green-blue coloration of the solution	[16]
	TLC method	spots can be recorded under UV254 nm light	[20]
Flavonoid	Shinoda test	Pink-red or red coloration of the solution	[19]
	TLC method	spots can be recorded under UV254 nm light	[20]
	NaOH test	A yellow solution with NaOH turns colorless with dilute HCl	[21]
Phenol	Phenol test	Blue coloration of the spot	[19]
Phlobatannin	Boiling with 1% HCl.	Formation of red precipitates	[23]
Reducing Sugars	Fehling test	Brick red precipitate	[23]
Saponin	Frothing test / Foam test	Persistence of frothing	[16]
	TLC method	The colour (yellow) and hRf values of these spots	[20]

Table 4.1. Biochemical tests that can be performed to identify the presence of secondary metabolites.

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		can be recorded by	
		exposing chromatogram to	
		the iodine vapors	
Steroid	Liebermann-	Dark green coloration	[19]
	Burchardt test		
	TLC method	The color (Greenish black	[20]
		to Pinkish black) and	
		hRf values of these spots	
		can be recorded under	
		visible light	
Tannin	Braemer's test	Dark blue or greenish grey	[19]
		coloration of the solution	
Terpenoid	Liebermann-	Pink or red coloration	[19]
	Burchardt test		
	Salkowski test	Reddish brown color of	[23, 24]
		interface	
Volatile Oil	Dilute NaOH and	Formation of white	[23, 25]
	small quantity of	precipitates	
	dilute HCl. Shake the		
	solution.		

5 CONCLUSION

The insights gathered from qualitative interviews with practitioners, employees, and patients underscored the pressing need for technological interventions in the traditional medical landscape. Challenges such as toxicological concerns, lack of standardization, inadequate documentation, and contamination issues highlight the importance of embracing technology to ensure the safety and efficacy of herbal preparations. By integrating novel approaches into different stages of herbal drug production and clinical treatment, traditional medicine can be elevated to new heights.

The application of technology can begin at the earliest stages of plant cultivation, focusing on practices that ensure the growth of high-quality, contaminant-free raw materials. Advances in DNA microarray technology, pharmacodynamics, and pharmacogenomics offer opportunities to assess the safety and efficacy of herbal products comprehensively. Additionally, the adoption of Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP), and Good Agricultural Practices (GAP) can elevate the quality and consistency of medicinal products.

The isolation, purification, and structural elucidation of bioactive molecules are integral to the modernization of traditional medicine. Techniques such as High-Pressure Liquid Chromatography (HPLC) and spectroscopic methods like UV-visible, Infrared (IR), Nuclear Magnetic Resonance (NMR), and mass spectroscopy provide precise tools for identifying and verifying active compounds. These methods enable the elimination of undesired components and contaminants, ensuring that herbal preparations meet stringent

quality standards.

While embracing technology presents a clear path toward improvement, it's important to maintain the unique characteristics and holistic principles that define traditional medicine. The coalescence of ancient wisdom and modern advancements can lead to the development of safer, more effective, and scientifically validated herbal products. Moreover, the support of governmental bodies, increased research funding, and collaboration with academic institutions will be vital in realizing this transformation.

In a world increasingly affected by chronic diseases and changing disease patterns, the time is ripe for traditional medicine to regain its prominence as a complementary and alternative healthcare approach. The successful integration of modern technology into traditional medical practices not only addresses current challenges but also opens up new possibilities for innovative treatments and a stronger global healthcare ecosystem. As traditional medicine continues to evolve, embracing technology will undoubtedly play a pivotal role in its renaissance, ensuring its relevance and efficacy for generations to come.

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