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LANDSCAPE ASSESSMENT OF RESEARCH, DEVELOPMENT, AND TECHNOLOGY TRANSFER PRACTICES IN THE LOCAL PHARMACEUTICAL MANUFACTURING INDUSTRY: A DESCRIPTIVE CROSS-SECTIONAL STUDY

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ABSTRACT

Globally, the pharmaceutical industry has indispensable contribution in public health and sustainable economic growth. However, its technological complexity and finance-intensive nature limited most developing countries, particularly those in sub-Saharan Africa from keeping pace and get benefited from the sector. In Ethiopia, despite its over six decades operation, the local pharmaceutical manufacturing sector could not apparently contribute in the national healthcare, research capacity, technology transfer and overall economic growth. This study explored the state of R&D and technology transfer practices by the local pharmaceutical industry. A descriptive cross-sectional study involving purposively selected technical experts from all 15 actively operating local pharmaceutical companies was conducted between 15 December 2024 and 15 January 2025. Data were collected with structured survey questionnaire and observational checklist. Data were entered into Epi-Data version 4.7 and analysed using SPSS version 25. The study participants disclosed varied level of engagement in technology transfer but only one-third (33.3%) maintained R&D units for conventional formulation development. Conversely, the experts indicated strong R&D and technology transfer understanding; several of them mentioned engagement in practical implementations. Technical capacity limitations, exclusion of R&D investment from regular government support schemes, and joint venture arrangements by considerable number companies that have foreign affiliates for R&D and technology transfer, and financial constraints were reported major challenges. Extensive reliance on foreign partnerships for technology transfer was found to significantly hamper their competitiveness and capacity utilization. The technical experts appreciated the positive impact of technology transfer on innovation, quality management, productivity and regulatory compliance. Yet, most companies lacked resources and technical expertise for effective research and technology transfer which is necessary for sustainable growth and competitiveness. R&D and technology transfer practices in the local pharmaceutical companies were found to be weak and restricted. Addressing critical bottlenecks and leveraging opportunities requires strategic interventions through a concerted effort from all stakeholders to ensure sustainable growth and competitiveness of the sector.

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INTRODUCTION

For over the millennia, medicines play indispensable global public health and socioeconomic development; many of the debilitating and difficult to manage diseases have been prevented or treated by medicines [1]. The value of the global pharmaceutical market was projected to grow at about 4.9% annually to reach approximately $1.3 trillion by 2020 [2]. This industry is known investing heavily in research and development (R&D), and is among the top sectors that spend significant amount of its earnings on R&D [3]. However, in many developing countries, access to safe, effective and quality essential medicines has remained a major challenge [4]. In Africa, for example, over 70% of medicines are imported, and the contribution of the local industry in access, production, R&D, and technology transfer is still limited [5]. With significant disparity among countries, close to 70% medicines manufactured in Africa are sourced from only three countries: South Africa, Algeria and Egypt. South Africa could establish an R&D supported industry which has been contributing to the national economy through enhanced access to medicines, entrepreneurship along the value chain and research spending [6,7].

In Ethiopia, the pharmaceutical industry has been in operation for over six decades but could make very limited contributions for the national health system and economic growth [8]. Over the past 15 years, the sector recorded commendable growth through some commendable incentive support and incentive schemes by the government and stakeholders. Nevertheless, the capabilities of the sector in production capacity, R&D, technology transfer, innovation and market outreach has remained very limited and the country still heavily relies on import for essential medicines [9]. Many challenges have been cited for the restricted growth of the sector including lack of sustainable financing, operation under low economy of scale, limited technology utilization, reliance on import for the supply of input materials, weak quality management system implementation, policy incoherencies, shortage of qualified workforce and regulatory hurdles [10].

The Ethiopian pharmaceutical market estimated to reach $1.8 billion by 2025 with a growth rate of 25% over the past 10 years and projected to worth $3.6 billion by 2030 [11]. Cognizant of the sector contribution, the government has identified pharmaceutical sector among priority areas for industrialization; several initiatives have implemented including development of ten years strategy and plan of action, establishment of pharmaceutical industry development and support institute, development of a dedicated pharmaceutical industry park with one-stop administrative services, implementation of commendable incentive schemes, and restructuring of the regulatory system [12,13].

The present study explored R&D and technology transfer practices by the local pharmaceutical manufacturing industries envisioning to provide valuable insights to guide policy updates for investment priorities and stakeholders' engagement towards building a sustainable and competitive sector that could ensure self-reliance for essential medicines in the long run.

MATERIALS AND METHODS

Description of the study setting

Ethiopia is the second largest populous country in Africa with over 120 million inhabitants with increasing burden from triple burden of diseases [13]. The capital, Addis Ababa hosts the African Union Headquarter and many regional and international diplomatic missions. Most of the local pharmaceutical manufacturing companies included in this study are concentrated in Addis Ababa and its environs. Fourteen of the companies produce generic medicines in conventional dosage forms while the remaining one is engaged in the production of empty hard gelatin capsules for the local and export market.

The companies manufacture not more than a quarter of medicines included under the National Essential Medicines List, and could contribute to only 15 to 20% of the national essential medicines demand [12].

Study design

A descriptive cross-sectional study design was employed to assess the state of R&D and technology transfer practices by the local pharmaceutical manufacturing companies.

Sampling method and sample size

All the 15 actively operating pharmaceutical manufacturing companies were included in the study. Purposive sampling procedure was followed to recruit technical experts from the respective companies. Technical managers, technical experts and R&D unit leaders were included to participate in the study.

Ethical considerations

Informed verbal consent was obtained from all survey participants before data collection. In addition, responses were anonymized and confidentiality was strictly maintained during data analysis and reporting of the findings.

Data collection and quality assurance

A researcher administered structured survey questionnaire, and an observational checklist comprising both close-ended and open-ended questions were employed to collect data. The survey questionnaire comprised three sections: general participant information section, R&D practice assessment section, and technology transfer practice assessment section. The data were collected through face-to-face interview and direct observation of different departments of the manufacturing companies from December 15, 2024 to January 15, 2025. Six data collectors with Bachelor's Degree in Pharmacy qualification who oriented about the tools and the objectives of the study and two supervisors participated during data collection. Close supervision and daily data cleaning and verification were made to check accuracy and completeness.

Statistical Analysis

The collected data were entered into Epi-Data version 4.7 and exported to SPSS version 25 and MS-excel for descriptive analysis.

Ethical considerations and confidentiality

Permission to conduct the study was facilitated by a support letter from Armauer Hansen Research Institute. Informed verbal consent was obtained from each of the study participants following presentation of the study objectives. To ensure anonymity and confidentiality, no personal identifiers were used in the study process or results.

RESULTS

Participant characteristics

A total of 15 technical experts (one expert from each company) were approached and kindly provided the data to fill out the survey questionnaire along with the observation checklist. Among the participants, 60% were male; about 60% had a master's degree; and close to have (53.3%) had over 10 years of work experience in the industry (Table 1).

Table 1: Socio-demographic characteristics of study participants' (N = 15)

Category	Characteristics	Number	Percentage
Gender	Male	9	60.0
	Female	6	40.0
Highest level of education	Bachelor's Degree	5	33.3
	Master's Degree	9	60.0
	Doctor of Vet. Medicine	1	6.7
Work experience	Less than 5 Years	2	13.3
	5 to 10 years	5	33.3
	Over 10 years	8	53.3

The state of research and development capacity and practice

Figure 1 presents the existing state of R&D capacity and activities of by the local pharmaceutical manufacturing companies. Two-thirds (66.7%) of the companies reported that they do not have a dedicated R&D department; only a third reported some level of structured engagement. From the one-third of manufacturers with dedicated R&D departments, over half reported that they do not engage in critical areas such as advanced formulation development, new drug discovery, or excipient development research underscoring the urgent need for strategic interventions. Further, the study revealed inadequate resource allocation even by those companies with dedicated R&D unit. Technical capacity limitations, exclusion of R&D investment from regular government support schemes, and joint venture arrangements by considerable number companies that have foreign affiliates for R&D and technology transfer, and financial constraints were reported major challenges.

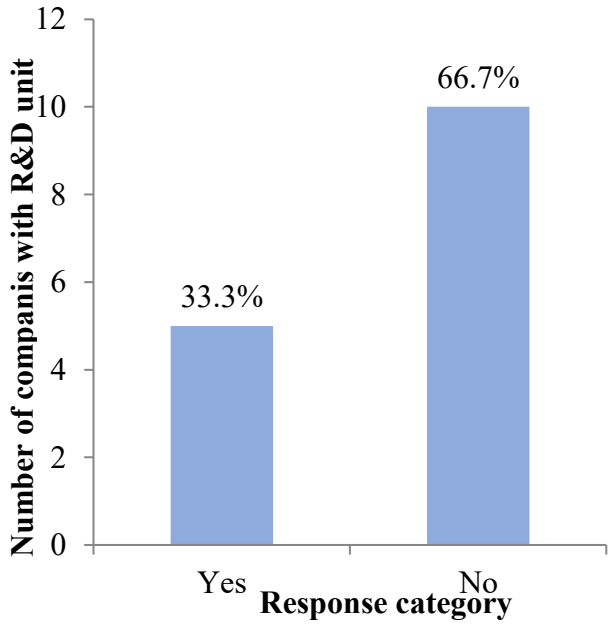

Figure 1: The state of R&D activities in the local pharmaceutical companies (N = 15)

The state of technology transfer practices

With regard to awareness and familiarity on technology transfer, the findings indicated that the majority of the participants (86.67%) were "Very Familiar" with the concept of technology transfer (Figure 2). The overall distribution pointed out that most respondents had a strong understanding of technology transfer process from foreign sources.

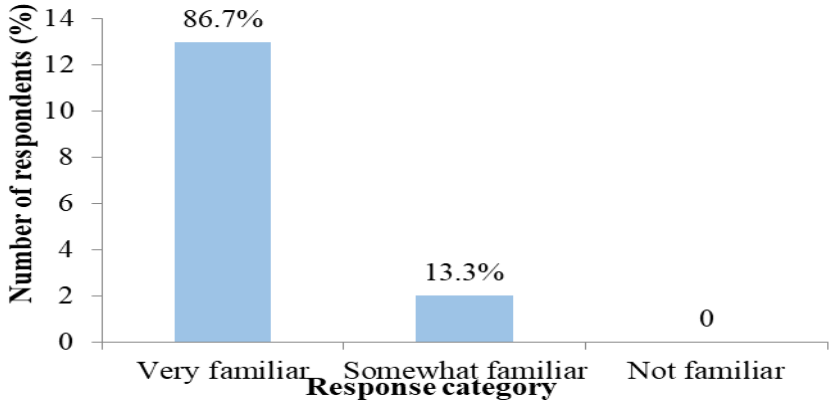

Figure 2: Level of awareness and understanding on technology transfer among technical experts from local pharmaceutical companies (N = 15)

The practices of technology transfer in the pharmaceutical industry had been illustrated across four key areas (Figure 3): production techniques, quality control methods, research methodologies, and compliance with regulatory requirements. All the technical experts had claimed that production techniques had been successfully transferred in their respective companies. To the contrary, divided results were observed in relation to quality control methods; with approximately half of the respondents answering 'No,' accounting merely for moderate accomplishments. Overall, technology transfer practices in production techniques had been reported to be more effective than in other areas.

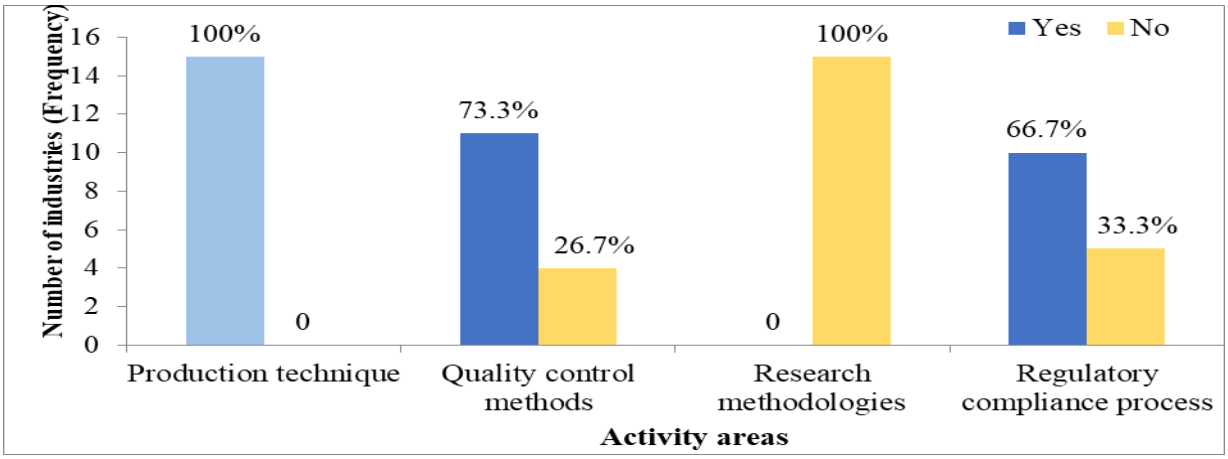

Figure 3: Technology transfer activities by local pharmaceutical manufacturing companies (N = 15)

The participants indicated that Figure 4 depicts the different technology transfer sources are commonly employed by the local pharmaceutical companies (Figure 4). Most of the respondents (66.66%) cited foreign partnerships as the most frequently used source conforming the over-dependence on international collaborations to access advanced technology and expertise. In contrast, the contribution from local universities and research institutions was reported to be minimal. It was also perceived that industry associations had a lower contribution underscoring the potential underutilization of such platforms for technology transfer and innovation efforts.

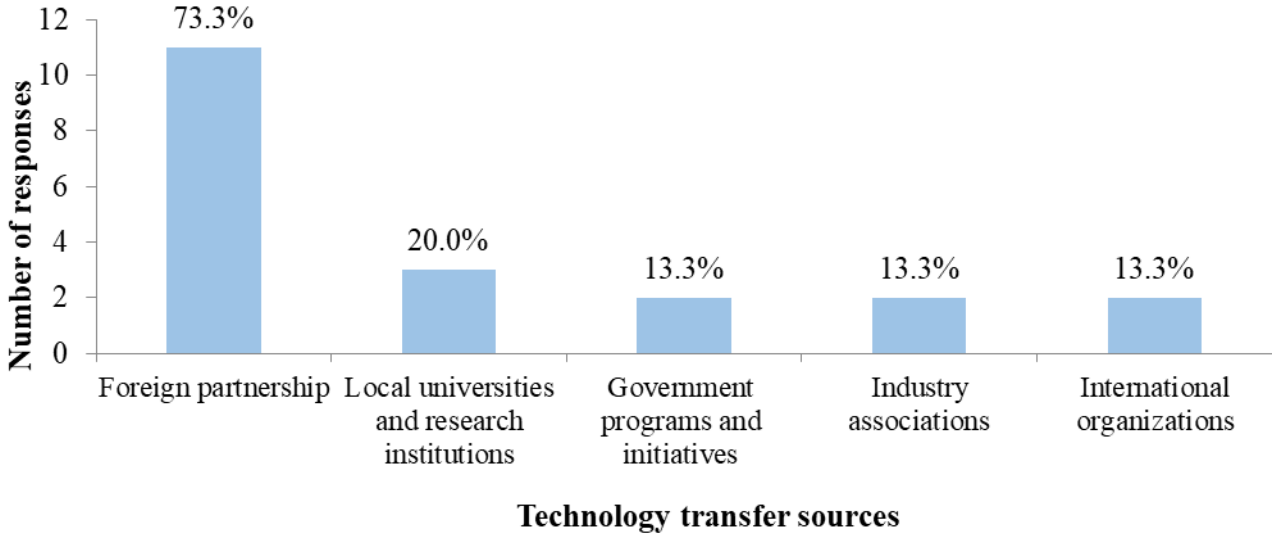

Figure 4 Common sources for technology transfer by local pharmaceutical industries

Direct investment, joint ventures, and licensing agreements were the different technology transfer models utilized by the local companies (Figure 5). Half of the experts indicated direct investment as the most commonly utilized model citing it multiple benefits including possibility for full ownership, greater control opportunities, and mechanisms for long-term commitment to the technology transfer process. The second frequently cited model was joint venture arrangements (41.7%) accounting for benefits including risk-sharing, resource pooling, and promoting collaborative partnerships.

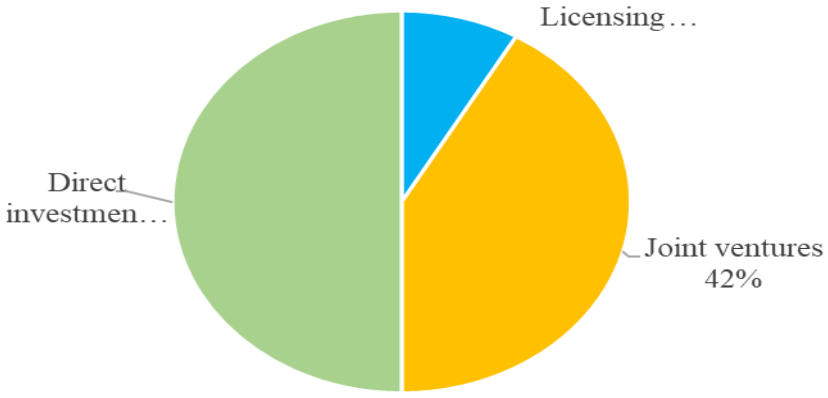

Figure 5: Type of technology transfer models used by the local pharmaceutical companies

The demonstrated varying levels of involvement in technology transfer activities by the local companies. Close to half of the respondents (46.7%) reported frequent participation, while approximately a quarter (26.7%) indicated occasional involvement and only 6.7% had never engaged in technology transfer activities. The contribution of in-house R&D for technology transfer was very minimal which was worth noticed for considerable intervention. On the other hand, most of the experts (86.67%) rated the technology transfer practices in their companies as "Very Effective," linking the initiatives contribution in enhancing workforce skills, professional development, and overall productivity. By contrast, 13.33% considered technology transfer related initiatives "not effective" citing very limited or no tangible benefits derived from such programs.

The experts identified several limiting factors including lack of clear policies and procedures for technology transfer, misalignment between R&D activities and sector policies, lack of sustainable financing, inadequate physical infrastructure, shortage and high turnover of qualified experts, inadequate collaboration between companies, and weak linkage and collaboration between the industry and academic and/or research institutions.

DISCUSSION

Research and innovation are the lifeline for pharmaceutical manufacturing industries; development and commercialization of new and better products is critical for competitiveness and sustainable growth [14]. Conversely, lack of dependable programs and investment in R&D significantly impacts overall performance and innovation capacity; a common challenge for low-income countries. This study identified the bleak state of R&D activities in the local companies. In addition to internal financial and technical limitations by companies, lack of streamlined R&D financing and support system compounded the already strained sector competitiveness. The ten years sector strategy and plan of action rightly identified as a critical

element for sustainable growth [15]; however, aligned support systems have not yet been implemented in terms of R&D related tax incentives, research grants, and context specific financing. Despite the well-recognized benefits, joint venture and full FDI-based arrangement by companies that have foreign affiliates might have restricted in-house R&D investee efforts as the companies obtain optimized formulation and processes from their affiliates possibly with additional royalty fees [9].

In this study, among one-third of manufacturers with dedicated R&D units, majority did not engage in critical areas such as formulation development, drug discovery, or excipient research; underscoring the need for strategic interventions to improve R&D capacity and foster innovation. With the dynamic global shift towards biopharmaceuticals and advanced therapeutic modalities, such a weak R&D practice by the local companies will not be helpful for sustainable growth. Policy updates and streamlined technology transfer procedures need to be instituted to strategically address the challenge. With the large population size and increasing communicable and non-communicable diseases prevalence, Ethiopia cannot afford continuing such a heavy reliance on import for the supply Active Pharmaceutical Ingredients (APIs), pharmaceutical excipients, packaging materials and production process technologies [16–18].

According to this study, several factors contribute to the existing weak state of R&D including lack of commitment from top company managers, lack of preferential support system for R&D investment, lack of R&D financing, technical capacity limitations and broader economic challenges of the country. The local companies hence focus primarily on formulation development and minor modifications to existing products [19]. This is a common trend by companies in low-income countries tend to prioritize formulation modification on generics due to the capital intensive and complex nature of advanced formulation development and drug development research [10]. Moreover, weak university-industry linkages and overreliance on foreign partners for formulation research further exacerbate the challenges. The shortcomings in R&D have resulted in a limited product portfolio, low economies of scale, underutilized production capacity, minimal export market penetration, and inadequate compliance with regulatory and quality standards [20]. Aligned interventions from key stakeholders including the industry, the government, academic and research institutes, financing sector and development partners are required to address the challenge in a phased approach to tap the sectors immense potential and leveraging leapfrogging opportunities.

With regard to technology transfer, most of the participants reported adequate knowledge and experience which should have served as a foundation and exploited to establish procedures for effective technology transfer. Effective technology transfer programs can enhance business viability through consistent product quality, efficient productivity, reduced waste, better customer satisfaction, improved regulatory compliance, and extended market outreach [21]. However, the level of technology transfer and its subsequent application in the local pharmaceutical companies was fund to be inadequate and inconsistent; the sector experts cited minimal gains from its application which companies should have utilized the most. Effective technology transfer programs require prior experience, strong R&D foundation, sustainable financing, and advanced level training which all are still limited in Ethiopia. Similar challenges have comparably been reported in many low-income countries [20, 22].

The successful utilization of foreign collaboration and partnerships in attracting sector investment and fostering technology transfer by many of the emerging pharmaceutical economies can be benchmarked. The impacts have been manifested in terms of co-developed projects, improved local production capability, reduced import dependence, increased export market share, and enhanced access to essential medicines [22, 23]. For pharmaceutical companies in Ethiopia, effective international collaboration through balanced mutual benefits can be a strategic path to progressively build their R&D and technological capacity. It is worth noticing for the companies that competitiveness in the sector entails the presence of strong effective technology transfer and strong R&D programs. Improved capacity utilization, consistent product quality assurance, demonstrated compliance with regulatory requirements, dependable quality management system, extended market outreach and customer trust, and competitive staff attraction environment are all dependent of strong research and technological innovation programs.

On the other hand, extensive and long-term reliance on foreign support and collaboration for R&D and technology should not be taken as a granted path for sustainable growth. Local companies and the government need to give due attention for in-house R&D and home-grown innovation as drivers for sustainable growth. The findings underlined the need for improved communication, workforce development, and policy updates to foster a more comprehensive understanding on the role of local R&D and technology transfer for sustainable growth and competitiveness in the sector [23, 24]. Capacitating industry associations and strengthening industry-academia linkages can support the initiatives through resource mobilization, information exchange, networking, and advocacy activities. In addition, strategies need to be formulated to maximize the effectiveness of joint ventures in technology transfer and R&D capacity building through aligned policies, well-defined governance structure, clear intellectual property agreement protocols, and effective communication channels along with monitoring and evaluation mechanisms. For Ethiopia, the existing over deepened on import for the supply of essential medicines, the growing population size with increasing unmet needs, and potential opportunities to participate in the untapped regional market can serve as rational reasons for strengthening R&D and technology adoption capabilities. programs might be imperative. All key stakeholders need to work in abreast to enhance local technical capability, and

promote innovation for the pharmaceutical industry to make a meaningful contribution to national healthcare and socioeconomic development.

CONCLUSION

The study explored the existing context of R&D activities and technology transfer practices by the local pharmaceutical manufacturing companies. While the experts reported adequate understanding on R&D and technology transfer concepts, with some claiming successful application, significant challenges remained in the sector. Most companies lacked dedicated R&D units and primarily relied on foreign partnerships for technology transfer. These challenges were evidently high in areas such as quality control, capacity utilization, new products development, market competitiveness, and regulatory compliance. In-house capacities and collaboration with local universities, research institutes, government programs, and industry associations were very limited.

The situation was further complicated by several barriers such as lack of practical R&D training, limited access to advanced technology, financial constraints, insufficient investment in training and capacity building, shortage of skilled workforce, and regulatory hurdles. Nevertheless, commendable agreement was observed on the potential benefits of R&D and technology transfer in driving innovation in key areas such as new product and process development, product quality improvement, capacity utilization, market expansion, and sustainable growth were still weak.

Strong collaboration and coordinated efforts from all stakeholders are needed, with a focus on policy alignment, resource mobilization, capacity building, advocacy, and networking towards building a sustainable and competitive local pharmaceutical manufacturing industry in the long run.

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AUTHORS CONTRIBUTIONS

WLL, MD, SF and AA identified the study area, designed the project and formulated research questions, objectives and methods. All the authors contributed in data analysis and writing the draft manuscript. TMW and WLL made the final critical review and necessary editions. All authors read and agreed to the submitted version of the manuscript.

CONFLICT OF INTEREST

Authors declare no conflict of interest

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