

## Hindrances of Accreditation of Eligible Drug Shops in Mtwara District, Tanzania

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### Research Article

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#### ABSTRACT

Tanzania as one of the developing countries, the drug shops plays a key role in the promotion of primary health care by ensuring the availability and accessibility of quality and affordable medicine. However, the trend of misconducts from these shops has increased such as operating without being accredited or registered, lack of qualified personnel for selling or dispensing medicines. Thus, the study explored the hindrances of accreditation of drug shops in Mtwara District. This qualitative study applied descriptive cross-sectional design. The study used purposive and convenient samplings to obtain 35 participants. An in-depth interview was used to collect data, where by an in-depth interview data collection guides for Ward Executive Officers (WEOs), members of Council Food and Drug Committee (CFDC) and ward drug inspectors were prepared and administered to 35 participants from Mtwara District. Content analysis was used to analyses the data with the help of ATLAS.ti software version 7. Regarding the procedural related hindrances for accreditation of drug shops, the study found that Councils do not follow the required procedures during accreditation in which there was little or no involvement of ward levels during accreditation of drug shops. Regarding the standards related hindrances; Majority of drug shops owners had not attended awareness course conducted by the Pharmacy Council and majority of drug shops had no qualified medicine dispensers. Regarding the Service providers related hindrances; the ward levels officers responsible for processing the accreditation of drug shops had limited knowledge on accreditation of drug shops compared to the one at the Council levels. Moreover, it was found that majority of the officers at ward level such as WEOs and drug inspectors were not oriented or trained on the accreditation of the drug shop and lastly One Council did not conduct CFDC meeting in last two years.

Based on the above findings, the study recommends that; ward levels officers responsible for accreditation of drug shops should be oriented on accreditation of drug shops, Pharmacy Council and Councils should strengthen supervision and inspection of drug shops in order to ensure that the regulation and guidelines are followed during accreditation of drug shops.

#### INTRODUCTION

Successful health service delivery systems should always guarantee the provision of quality, reliable and accessible health services at all levels, to achieve this the private sectors are needed as much as the government sectors. Tanzania as one of the developing countries, the private pharmaceutical sector plays a key role in the promotion of primary health care by ensuring the availability as well as accessibility of medicines and related commodities which are affordable and having the required quality [1].

In Tanzania it has been documented that the poor communities prefer self-medication by seeking medical help to private small drug shops over visiting to hospitals. Furthermore, it estimated that over 70 percent of the country population have no

health insurance hence the preferred method of payment for health services in hospitals is by out of pocket for which majority of poor communities cannot afford them hence the only option of getting health services is by visiting the drug shops [2,3]. Unfortunately, most of the drug shops in these communities faces a lot of challenge including dispensing medicine without the qualified personnel's, having infrastructures which are in poor conditions, selling or dispensing medicines which have poor qualities, and also majority of these shops normally operate without being registered by the responsible authorities [4,5].

Various efforts have been done by different countries in Africa in order to improve the conditions of these private drug shops. Tanzania established the Accredited Drug Dispensing Outlet (ADDO) program in 2003 which called for all existing drug shops by then called "Duka la dawa Baridi" (DLDBs) which had a lot of challenges to be improved and accredited. The approaches which were used in establishing the ADDO program included; formulating an accreditation system based on Ministry of Health founded standards and regulations, formulating commercial skills of ADDO shops owners and sharpening the capacity of medicine dispensers by training, education, and supervision. Also, other approaches used were; providing ADDO owners with commercial incentives such as access to loans, improving customer awareness to service and treatment compliance through public education, improving legal access to a limited list of basic, high-quality prescription and non-prescription essential medicines and lastly by concentrating on regulation and inspection through amending regulatory capabilities of Local Governments [6,7].

The number of drug shops operating without being accredited in Tanzania has continue to raise, despite the establishment of the ADDO program in 2003 [15]. The ADDO program requires all drug shops to be accredited and to have a business permit before starting to operate [22]. But the situation is different from the one which was expected after establishment of the ADDO program.

The establishment of this program was thought would eliminate the challenges imposed by the DLDBs which operated without being accredited or registered. The notable challenges which were imposed by these unregistered drug shops included; lack of qualified personnel for selling and dispensing of the medicines and irrational prescribing of medicines [8,9,11]. Those challenges meant that the health of the communities around such drug shops were in serious danger as the medicines were being dispensed or sold by unqualified personnel and more over there was no accountable as they were not registered hence not known by the responsible authority.

But the above challenges have continued to exists despite of establishment of the ADDO program in Tanzania. it has been documented that these ADDO shops have more challenge compared to the DLDBs [11]. Hence this study explored the hindrances associated with accreditation of eligible drug shops in Mtwara District. Then based on the study findings to recommend the ways in which those hindrances can be eliminated or minimized.

## **METHODS**

### **Study design**

This qualitative study which used descriptive cross-sectional design was conducted in Mtwara District which is one of 6 Districts in Mtwara region. According to the Population and Housing Census of 2012, the District had a total population of 342,982 including 181,102 women and 161,880 men and by 2017 the total population was estimated to be 358,866 [16]. This district which consists of 3 Councils namely; Mtwara-Mikindani Municipal Council, Mtwara District Council and Nanyamba Town Council was selected because is the one of the districts which implement the ADDO program and also meets both the rural and peri-urban status as recommended by the ADDO regulation of 2019 and guideline of 2014 to establish drug shops.

### **Study subjects and sampling**

This study was conducted from January to March 2020 and included a total of 35 participants. The study participants were selected among ward executive officers from the wards where there were drug shops, drug shop owners, ward inspectors, district pharmacists and other members from Council Food and Drug Committee (CFDC). The participants from ward executive officers, drug shop owners, ward inspectors and district pharmacists were purposively selected because of their roles in the implementation of the program while other members of CFDC were selected based on convenience that is based on being available during the day of the interview.

### **Measurements**

We examined the procedural, those responsible for accreditation of drug shops at different levels in the Councils (service providers) and the standards related hindrances of accreditation of drug shops. The procedural related hindrances were examined in the following categories; the accreditation procedure at the Councils, report submission from the Councils to the Pharmacy Council (PC) and feedback from the Pharmacy Council after submission of reports. The service providers related hindrances were examined based on the knowledge of service providers, capacity in terms of training, inspection of drug shops and lastly if the Councils food and drug committee (CFDC) conducted meeting as part of accreditation of drug shops. Finally, the

standards related hindrances of accreditation of eligible drug shops examined by interviewing the participants from the drug shops about the location and also about the capacity of Personnel in term of training of drug shop owners and medicine dispenser as one of the requirements for drug shops to be accredited.

The study used an in-depth interview during collection of data from the study participants. The interview guides with open-ended questions were prepared and pilot tested before starting the actual data collection in order to recognize and getting rid of any errors or complications associated with the tools or procedures of data collection. An in-depth interview guides prepared were administered to ward executive officers, drug shop owners or their representatives, ward inspectors, district pharmacists and other members from Council Food and Drug Committee (CFDC). Furthermore, all the interviews were translated from English to Swahili during administration for easy understanding. And also, all the interviews were recorded by using recording device.

### Data analysis

All the audio files recorded from an in-depth interview of study participants were transcribed verbatim, on the same day after being collected. Also, after the data collection all transcripts were counter checked for any errors which might have occurred during transcription. Furthermore, all the audio interviews which were in Swahili were translated to English during transcription. All transcripts were imported into the qualitative analysis software (ATLAS.ti version 7) and coded by creating different themes which occurred during coding then similar themes were grouped into three families namely; procedural related hindrances, standards related hindrances and service providers related hindrances. Moreover, the content from the ATLAS.ti software containing quotations, codes and families were exported into a Microsoft word file and was used in writing the final report in which the findings were presented in forms of themes and quotes from the participants.

### Ethical consideration

The study was conducted after obtaining the written approval from the Directorate of Research, Publications, and Postgraduate Studies (DRPPS) of Mzumbe University. Furthermore, the verbal and written consent was obtained from all study participants before an in-depth interview. Additionally, all the participants were explained about the aim of the study and also, they were given a choice of not to answer any question asked if they felt so or to withdraw from the study at any time without being restricted. Lastly, all the information obtained during the interviews was kept anonymous and handled with high confidentiality.

## RESULTS

### Characteristics of Study Participants

A total of 35 participants were interviewed from the three Councils in Mtwara. The participant distribution according to the Council were; Nanyamba Town Council had 14, Mtwara District Council had 8 and Mtwara-Mikindani Municipal Council 13 participants. The study participants distribution according to gender and type; overall the female participants were 20 (57%) and male were 15 (43%) also the total number of female participants who were also drug shops owners was 14 (74%) while the male participants who were the drug shop owners were 5 (26%), male participants had a large number of representation among the Ward Executive Officers having a total number of 4 participants (67%) while female were 6 (33%). Majority of ward inspectors were female having a total number of 4 participants (57%) while male participants were 3 (43%) lastly all district pharmacists interviewed were male 3 participants (100%) (Table 1).

**Table 1.** Participant distribution according gender.

Participan	Male	%	Female	%	Total
Drug Shop	5	26	14	74	19
Ward	4	67	2	33	6
Ward	3	43	4	57	7
District	3	100	0	0	3
Total	15	43	20	57	35

### Procedural related hindrances of accreditation

The study found that none of the three Councils visited in Mtwara District adhered to the procedure of accreditation during accreditation of drug shops instead each Council had its own procedure for accreditation; one of the Council didn't involves the village and the ward level during accreditation, instead all the process were conducted by the District pharmacist and District health officer as one of the Ward Executive Officer confirmed:

“mmmh, since I have been here for about four years I have never handled any application for accreditation of drug shops

these issues usually are handled by the District Pharmacists and District Health Officer, usually I interact with drug shops owners when they are dealing with Tanzania Revenue Authority (TRA) as they have the form which am supposed to sign" (WEO 2).

Another Council only the ward health officers were responsible for inspection of drug shops and the Ward Executive Officer was responsible for signing the application forms, which the respondents confirmed:

"The owner of the premise, is the one who comes with the application form I think the forms comes from the district pharmacist, and after that I usually go to his / her drug shop in order to inspect the shop and after inspecting the shop I usually sign the part of the form for ward inspector. After that the owner of the particular shops returns the form to the district pharmacist" (Ward Inspector 3).

And also, none of the wards in this Council had conducted the Ward Health Committee (WHC) for the purpose or in which the accreditation of the drug shops was one of agenda in the meeting.

"We have never conducted WHC in order to discuss the accreditation of drug shops what we do is that after a particular shop has been inspected by health officer and signed by WEO we tell the owners to submit the form to district pharmacist" (WEO 3).

Regarding the report submission and feedback, the results show that two out of three Council visited who managed to conduct the CFDC meeting and submit the report to Pharmacy Council did not get any feedback or certificate of accreditation of the drug shops from the Pharmacy Council on time as explained below:

"You know brother... there was a case in which we sent the report to Pharmacy Council but we did not get any feedback or certificates from them... so I had to go myself to their office in Dar es salaam, so when I reached there I found out that the Pharmacy Council had not yet prepared the certificates and also there was no any effort to prepare them, one of the Officer there advised me to prepare another report... you know I was very disappointed because the customers here thought the problem was on my side" (Dpharm3).

### **The standards related hindrances of accreditation**

The study findings indicated that the locations in which the drug shop owner established their shops were either approved by the District pharmacist or health officer of particular Council as explained by the study participants below;

"You know this is my home, so when I decided to start this business, I told the pharmacist the intention to open the business, so he told me to use the skills I got during the training... such as not to open near the garage, so then I decided to build this shops based on the education I got during the ADDO training.. after I have finished, I called him in order to get other input. After that I completed this shop" (Drug Shop Owner 6).

The findings of this study indicated that the drug owners in the Councils visited have not attended the training or any awareness course conducted by the Pharmacy Council as indicated below:

"No, I have not attended any training issued by The Pharmacy Council except my dispenser who has attended ADDO and owner training" (Drug Shop Owner 1).

Also, this study revealed that, most of the drug shops owners who are also medicine dispensers in their shops have also attended owners training as this training are provided during ADDO training as explained below:

"Yes, during ADDO training, there was an option to attend owners training after finishing the ADDO training so, I joined and completed" (Drug Shop Owner 5).

Regarding the dispenser training the results of the study shows that only one Council out of 3 Councils visited majority of the drug shops had medicines dispenser who had attended training provided by the Pharmacy Council while the other 2 Councils most of the drug shops did not have qualified medicine dispensers as explained below by the respondents:

"I attended one-month ADDO training in 2018 but I failed in the examination which was provided at the end of the training, that's why I have no certificate, but I intend to apply again as soon I get that chance" (Drug Shop Owner3).

### **The service providers related hindrances**

Regarding the knowledge of service providers, the results revealed that the providers at the Council levels such as the pharmacists and the health officers are more knowledgeable about the accreditation of drug shops and the ADDO program compared to the providers at ward level such as Ward Executive Officer (WEO). As explained below by the respondents of this study;

"You know this program... mhhh as I remember we used to have "Maduka ya dawa Baridi" which had a lot of challenges so that's why ADDO program was established! Also, the program is very important as you know our Council is very scattered so not all the place have the Health facility so...if it was not for these shops, the people would not have the opportunity to get the medicines services" (DPharm 2).

Also, from the finding, the participants from the Council level were able to explain the importance of the ADDO program as explained below by one of the participants;

"The program is important as you know these shops helps to provide medicines service to the society, so hence by accrediting them, make easy for the authority to control and regulate them" (DPharm 1).

The finding also, revealed that, because WEOs had not been oriented about the accreditation of drug shops, so they depend on ward health officer on the issue pertaining the accreditation of drug shops. As explained below;

“mhhh... I only depend on the Ward health officer but most of the times we usually look at the distance between one drug shop to another” (WEO 1)

The findings also indicated that one service provider at the Council level who is also District pharmacist had received both accreditation and inspection of drug shops training the other service providers from 2 Councils who are also the District Pharmacists had been trained on inspections of drug outlet only.

“Yes, I first received the training on accreditation of drug shop when I was in Nanyumbu District before I shifted here and then I attended Tanzania Medicines and Medical Devices Authority (TMDA) training on inspections of drug shops last year in Mtwara” (DPharm 1)

Another District pharmacist explained the following when asked if he had attended any training on accreditation of drugs shops;

“Ahh... I only attended the training on inspection last year which was conducted by the TMDA but regarding the accreditation of the drug shops, I haven't attended such training... I only read different document to get the knowledge and also, I ask the people with experiences” (DPharm 2).

Furthermore, the finding of this study shows that the service providers at the ward level in three Council visited have never been oriented or trained about the accreditation of drug shops or about the program as described below;

“No, I haven't received any training about ADDO, so it is real challenge when handling the application of drug shops, as sometimes we are not sure what to do. So, I suggest to the responsible authority to establish such training as we are the one who are near to the society” (WEO 1).

Regarding if training or orienting ward level officers on accreditation of drug shops was necessary. One participant responded that;

“You know, I think the pharmacy Council, should also train the ward personnel especially we drug inspector because we have important role to play in the improvement of the program, as these shops are found in the wards so without proper training it will be just the business as usual” (Ward Inspector 2).

The results about the inspection of drug Outlets show that all three Councils conducts the inspection of both new and existing drug shops though the quality of inspection at lower level is questionable compared to the one conducted by the Council level as described below;

“Normally we have different stage of inspections but the problem we have here is that the ward drug inspector, do not have the skills and have not been trained so when they provide the inspection reports... we have to counter check in order to be sure if the shops meets the standard” (D Pharm 2).

The results of this study also, revealed that two out of three Councils visited conducted at least 2 meetings per year as described below:

“The last time we conducted the CFDC meeting I think it was in September last year (2019) ... I think we have conducted four CFDC meetings since I have been in this position for about two years” (Dpharm 3).

Another Council use the CFDC meeting to allow the drug shops which have been approved by the committee to operate while waiting for accreditation certificate from the Pharmacy Council;

“we normally discuss at our Council Food and Drug Committee meeting, then after discussing we allow them to continue with the business, as the permit and accreditation certificate may takes more than 3 months, for instance last time I sent the report to the pharmacy council in August last year (2019) in order to issue the certificates, but up to now in February 2020 no certificates have been received! So, if you don't allow these people to continue with the business, first the District Council will not get the revenues and also these people tend to get the loans from the bank in order to start the business, so they may be in trouble” (D pharm 2).

Moreover, the findings revealed that there was one Council that did not conduct CFDC meeting for more than 2 years even though there are drug shops which have not been accredited in the Council;

“For now, we haven't conducted such meeting as there is no any drug shop which have met the recommended standard...you know here you may have the new drug shops which have qualified medicine dispenser but do not meet other important standards, e.g. they don't have the door, no ceiling fan so, you cannot process the registration, also you know the people here do not always agree with our advice as you may inspect the premise even for more than five times but they don't improve so if we conduct CFDC meeting it will be just a waste of resources” (Dpharm 1).

## **DISCUSSION**

We found that none of the three Councils visited in Mtwara District followed the procedure for accreditation at ward level. It was found that the Councils did not involves the village and the ward level during accreditation, also it was found that the councils do not conduct the Ward Health Committee (WHC) meeting for the purpose of accreditation of the drug shops. By not involving the ward level in accreditation of drug shops could lead to the following consequences; first the drug shops owners with bad behaviour their shops may be approved as the districts or Councils might not know them also as the ward level is tasked to scrutinize the behaviour of the applicants during accreditation <sup>[17]</sup>, also the drug shops may be established in the area where the particular ward doesn't want to have any shops, the drug shop may not be approved hence not accredited by the PC

and also by not involving the ward level the drug shops may lack close supervision as the wards leaders are the one who are close to these drug shops hence undermining the whole aim of accrediting the drug shops.

Our study also showed that the Councils do not get any feedback and the accreditation certificates on time from the Pharmacy Council and thus this could leads to the increase of number of drug shops operating without being accredited or having the permit to do so hence this may cause the drug shops owner to loses the benefits which are associated with being accredited such as being registered to provide services to NHIF customers these findings are in line with the studies conducted by Kakanda, which indicated that NHIF services have been attached to the accredited drug shops hence confirming that accreditation is one of the requirements for the drug shops to provide NHIF services [7,13,14].

We also found a number of drug shops in the Councils visited had never been accredited or given permit to run the business despite being operating for more than 3 years. This correspond with the study conducted in Bangladesh where it was documented that the registrations of drug shops were difficult and took a long time to complete hence causing the owners to incurs addition costs [18].

Regarding the standard related hindrances, we found that the location in which the drug shops were established was either approved by the district pharmacist or health officers of the respective ward. This finding agrees with the study which reported that the owners of drug shops usually establish their shop based on the need of the community such as shortage of medicine in the nearby public health facility [19], also it is in line with the ADDO regulation of 2019 which directs to establish the drug shops in the location which is approved by the authority [22].

Furthermore, our study showed that majority of the drug shop owners had not attended the ADDO awareness course provided by the PC in contrary to the ADDO regulation of 2014 and 2019 which requires that all drug shops owner to attend such course before permitted to operate the drug shops. The awareness course is important as the drug owners get to learns important things such the drug shops regulations and other business skills related to the drug shops hence signifying its importance to the management of the shop.

The study also shows that most of the drug shops did not have qualified medicine dispensers, this is in contrary to the ADDO regulations which does not permit any drug shop to operate without having a qualified medicine dispenser. This finding agrees with the study which documented that the owners of drug shops normally hire the qualified medicine dispenser during registration and after registration they substitute them with unqualified one [20]. Also concurs with the study by Minzi and Manyilizu which stated that majority of qualified medicine dispensers were not working in their original shops instead unqualified medicine dispenser were working in those shops [11]. It was also observed that, the frequency of not having a qualified medicine dispenser was more prominent in rural areas than in town and the availability of qualified dispenser was related to the shop being accredited as the Councils in which majority of the drug shops did not have qualified medicine dispenser also had few accredited drug shops. The findings agree with the study in Nigeria which documented the link between the registration of drug shop and qualification of dispenser [21].

Regarding the service providers related hindrances, we found that the providers at the ward level such as Ward Executive Officer (WEO) had less knowledge on the accreditation of drug shops and the ADDO program. furthermore, the findings indicated that majority of CFDC members and all members of WHC have neither been trained nor oriented about the accreditation and ADDO program in general thus undermining their capabilities in making decision on the matter pertaining the accreditation of eligible drug shops in the respective Councils and also this evaluation data depicted that the quality of inspection conducted by the WHC is questionable as they lack appropriate inspection skills.

Moreover, according to the ADDO regulation all CFDC committee must conduct their meeting at least once every quarter which means at least 4 meeting per year, but the data shows that the trend in these three Council it is not satisfactory as these committee do not meet as required and others do not conduct meeting at all. Hence this creating the hindrances for accreditation as according to the regulations all the drug shop must be approved by the CFDC committee of respective Council in order to be accredited and permitted to operate by the PC.

## **CONCLUSION**

The study conclude that the accreditation of drug shops is largely hindered by low involvement of ward level by the council level, inadequate knowledge of service providers at ward and LGAs levels on accreditation of drug shops, lack of training of service providers especially at ward levels, inadequate understanding of drug shop owners about the whole process of accreditation which is contributed by not attending owners awareness courses conducted by PC, lack of feedback from the PC to the Councils about the accreditation of drug shops and weak management and regulations of drug shops at the councils level. There fore more emphasis should be placed on orienting or training of ward levels officers responsible for accreditation of drug shops, the drug shops in which their owners have not attended awareness courses conducted by the PC should not be accredited and also the Pharmacy Council (PC) and local government authorities (LGAs) should start exercising the re-accreditation of drug shops every three years as indicated by the ADDO regulation of 2019 in order to ensure that all drug shops adhere to the guideline and regulation.

## **LIMITATIONS**

The study was based on registered and unregistered drug shops, where by the list and address of the drug shops was obtained from district pharmacists. So, there might be some unregistered drug shops which might have been omitted from the list used either knowingly or because they are not known by the district pharmacist of the particular Council. So, the participants from those omitted drug shops might had a different story or view regarding the accreditation of drug shops in general.

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#### CONFLICT OF INTEREST

The authors declared no competing interests.

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