Addressing defaulting in tuberculosis management and the role of dispensing pharmacy personnel in Omdurman, Sudan

Dalia Yahia M. El Kheir,[1,2*] Sara Sabhi Al Nufaili [2]

[1]Department of Community Medicine, Faculty of Medicine, University of Khartoum, Khartoum, Sudan; [2]Department of Family and Community Medicine, College of Medicine, Imam Abdulrahman Bin Faisal University, Dammam, Saudi Arabia

ABSTRACT

Background Ending Tuberculosis epidemic by 2030 is a health target for the Sustainable Development Goals set by WHO. Multidrug-resistant-TB is a public concern, with treatment defaulting being an important factor. This study aims to assess the knowledge, attitude, and practice of dispensing pharmacy personnel regarding tuberculosis treatment and defaulting.

Methods A cross-sectional, mixed-methods study was conducted during October 2011 in 7 TB-treatment centers in Omdurman locality, Sudan among 23 pharmacy dispensing personnel. A questionnaire was used to collect the data.

Results National TB program Sudan was the main source of TB management knowledge for 21 (91.3%) of participants. All of them (n=23), correctly knew drug-regimen for new and re-treatment of TB-cases. However, 13 (>50%) displayed inadequate knowledge of medication safety while 21 (91.3%) of participants attributed drug-resistance to therapy interruption. The long-distance between TB-centres and patient home, treatment-related costs, initial recovery, and noncompliance were reported as reasons for defaulting. About 15 (65.2%) of participants believed medication adherence is patient responsibility. None of them believed drug-choice is pharmacist's role. The majority, 21 (91.3%), strongly agreed with TB-program in Sudan. All, 23, strongly agreed and agreed with TB single-pill and attaching the patient's laboratory results with the prescription, respectively. Interestingly, 16 (69.6%) of participants strongly disagreed with DOTS. Five (21.7%) participants stop TB-drug in case of side-effects before referral, and only 1 (4.3%) participant educated patients about TB and its medications.

Conclusion Dispensing pharmacy personnel displayed good knowledge of TB drug-regimen, defaulting causes and the overall TB-care; however, they showed inadequate knowledge of medication safety, deficient practice as compared to knowledge, and negative attitude towards DOTS.

***Correspondence to** dyme@rocketmail.com*

INTRODUCTION

Ending Tuberculosis (TB) epidemic by 2030 is one of the health targets of the Sustainable Development Goals (SDG) set by WHO.[1] In 2015, 10.4 million new cases of TB were reported globally as compared to 9 million cases in 2013[1,2] Although direct comparison of incidence rate might not be appropriate, as multiple factors could affect the rate of disease reporting. In Sudan, TB cases account for up to 15% of the TB burden in the Eastern Mediterranean Region.[3,4] Sudan was categorized as a high burden country of TB and Human Immunodeficiency Virus (HIV) before it was removed from the list in 2015.[3,4]

A recent dilemma in managing TB burden is the treatment of multidrug-resistant-TB (MDR-TB). About 300,000 patients with TB have MDR-TB. Of those, 136,000 patients were eligible for treatment, and only 97,000 of them received the treatment, with a success rate of 51 %.[1,2] Notably, patients with

MDR-TB constitute around 20.5% of previously treated TB cases.[1,2] Among others, MDR-TB could be attributed to the inappropriate drug choice, dose or duration, and defaulting from treatment, creating a resistant strain of *Mycobacterium tuberculosis*.[5] Re-treatment of TB occurs after relapse, failure of treatment, or defaulting. Previous studies found that male gender, younger patient age, unknown or positive HIV status, medication side effects, initial sense of recovery after TB therapy, being a re-treatment case, financial difficulties, lack of family support, heavy drinking, being imprisoned or arrested, miscommunication with health-care providers, lack of access to health-care services, and change in job or residency location were all risk factors for defaulting from TB treatment.[6,7,8] In contrast, female patients, and those on antiretroviral therapy (ART) were less likely to default from treatmen.[6]

All things considered, ending TB necessitates multidisciplinary actions at the team level.[9,10] Pharmacists are usually the first-encountered people in the healthcare system of low and middle-income countries.[11] Pharmacists are thus expected to play a crucial rule in TB detection, MDR-TB prevention, and the overall management of TB in those countries.[11] Nevertheless, there is a paucity of information regarding the current role of pharmacists in TB management and defaulting issue, especially in Sudan. Therefore, this study sought to assess the knowledge, attitude, and practice of dispensing pharmacy personnel about TB management and defaulting in one of Sudan localities.

METHODS

This was an observational, cross-sectional study. It was conducted in all of the functioning TB treatment centres (7 in total) in Omdurman locality in Sudan during October 2011. The targeted population included all dispensing pharmacy personnel working in these 7 centres (23 persons). Study variables were the knowledge, attitude, and practice in TB management and defaulting. A questionnaire consisting of 27 questions was designed, and its items were subjected to expert review. The knowledge and practice regarding TB medications and their side effects were assessed using a multiple-choice format. The attitude was evaluated with a 5-point Likert Scale. Other questions, 1 in knowledge, and 2 in practice sections, were qualitative for open responses.

Ethical approval was obtained from the Department of Family and Community Medicine Institutional Review Board (IRB) in the University of Khartoum, Sudan. All dispensing pharmacy personnel in the 7 centres were invited to voluntarily participate in the study, and informed verbal consent was taken. Data was collected through face-to-face interview, and participants' responses were filled in the study questionnaire. The data was analyzed manually. Frequency tables and figures are used to present the quantitative responses, and common answers were selected to represent the qualitative responses.

RESULTS

All of the 23 dispensing pharmacy personnel targeted in this study agreed to participate (response rate=100%). As illustrated in (Table 1), females constituted 15 (65.2%) of the study population. Nine (39.2%) of the 23 participants have from 1 to 4 years of practice experience, and the majority (n=14, 61%) of dispensing personnel are assistant pharmacists.

The knowledge of dispensing pharmacy personnel

The main source of most participants' (n=21, 91.3%) knowledge about TB management was the National TB program Sudan. All participants (n=23) answered correctly regarding the first-line drugs to be used in new and re-treatment TB cases (Table 2). Nevertheless, 13 (>50%) of them did not know the safety profile of TB medications (rifampicin, isoniazid, ethambutol, pyrazinamide, and streptomycin) in pregnancy, breastfeeding, use of contraceptive pills, children, hepatic or renal failure (Table 3). About 21 participants (91.3%) attributed drug resistance among other causes in TB management to therapy interruption by patients (Table 4). Furthermore, in the qualitative question concerning participants' knowledge about

defaulting causes, common answers were a long distance between TB centres and patient home, unaffordable treatment-related costs, patient sense of recovery after therapy initiation, and patient non-compliance (Table 4).

As shown in Table 5, on promoting patient adherence to TB medications, the majority of the dispensing personnel, 16 or more (>65%), reported that one or a combination of the following would be effective in increasing patient compliance: patient education about the disease and the importance of drug adherence, giving instructions about the proper timing to take the medications to avoid food-drug interactions, and patient follow-up during treatment course. Moreover, to directly assess for patient compliance, 15 of the participants (65.2%) would directly ask the patient about it, nonetheless, 15 (65.2%) of them believe that medication adherence is the patient responsibility.

The attitude of dispensing pharmacy personnel

About 18 participants (78.3%) believed that drug choice is the responsibility of the physician alone, and none of them reported it as the pharmacist role (Table 6). The majority of the dispensing personnel (n= 21, 91.3%), strongly agreed with the current TB treatment program in Sudan. Furthermore, all of them (100%) strongly agreed and agreed with converting TB medications into a single pill and attaching the patient's laboratory results with the prescription, respectively. On the other hand, 16 (69.6%) of the participants strongly disagreed with the DOTS strategy (Directly Observed Treatment Short-course) as shown in Figure.

The practice of dispensing pharmacy personnel

In managing the side effect of TB medications, only 5 participants (21.7%) said that they would stop the medication and then refer the patient to a physician. In contrast, the majority of them, 18 (78.3%), would directly refer the patient to a physician. Upon medication dispensing, all participants (100%) reported that they routinely advise TB patients not to stop their medications, and to use tissues to cover their cough, maintain good nutrition and keep their surrounding environment healthy and clean. Nevertheless, only 1 participant (4.3%) used this opportunity to educate the patients about TB and its medications as summarized in Table 7.

Table 1. Demographics of study participants (n= 23)

Variable	Frequency (%)
Gender	
Female	15 (65.2)
Male	8 (34.8)
Years of practice	
1-4	9 (39.2)
5-10	7 (30.4)
>10	7 (30.4)
Qualification	
Clinical pharmacist	1 (4.3)
Pharmacist	6 (26)
Assistant pharmacist	14 (61)
Medical assistant	2 (8.7)

Table 2. Participants' knowledge of TB treatment and source of their information

Variable	(%) Frequency
Knowledge on first-line drugs in new TB cases (CAT I & III)	
Correct regimen	23 (100)
Didn't know	0 (0)
Knowledge on first-line drugs in re-treatment TB cases (CAT II)	
Correct regimen	23 (100)
Didn't know	0 (0)
Information source about TB treatment	
National TB program Sudan	21 (91.3)
Informative presentations	0 (0)
Others	2 (8.7)

CAT I: New sputum smear-positive or smear-negative with excessive lung involvement; severe non-pulmonarydisease should receive INH_RIF+E+PZA[12]; CAT II: patients with sputum smear-positive after relapse, treatment failure, or interruption should receive INH_RIF+E+PZA+S according to 2010 WHO recommendation.[12]In 2017 update, CAT II is no longer used in patients requiringTB re-treatment and drug-susceptibility testing should be conducted to inform drug choice[13]; CAT III: New smear-negative and less severe non-pulmonary disease should receive INH_RIF+E+PZA[12]

Table 3. Participants' knowledge of TB medications' safety

Item-drug	Safe (%)	Unsafe (%)	Don't know (%)	Item-drug	Safe (%)	Unsafe (%)	Don't know (%)
Children				Hepatic failure			
Rifinah*	8 (34.8)	2 (8.7)	13 (56.6)	Rifinah*	2 (8.7)	7 (30.4)	14 (60.9)
Ethambutol	5 (21.7)	5 (21.7)	13 (56.6)	Ethambutol	5 (21.7)	4 (21.4)	14 (60.9)
Pyrazinamide	7 (30.4)	3 (13)	13 (56.6)	Pyrazinamide	6 (26.1)	3 (13)	14 (60.9)
Streptomycin	7 (30.4)	3 (13)	13 (56.6)	Streptomycin	5 (21.7)	4 (17.4)	14 (60.9)
Pregnancy				Renal failure			
Rifinah*	4 (17.4)	4 (17.4)	15 (65.2)	Rifinah*	5 (21.7)	3 (13)	15 (65.2)
Ethambutol	5 (21.7)	5 (21.7)	13 (56.6)	Ethambutol	5 (21.7)	4 (21.4)	14 (60.9)
Pyrazinamide	6 (26.1)	3 (13)	14 (60.9)	Pyrazinamide	5 (21.7)	2 (8.7)	16 (69.6)
Streptomycin	4 (17.4)	6 (26.1)	13 (56.6)	Streptomycin	3 (13)	6 (26.1)	14 (60.9)
Breas-feeding				Contraceptive pills			
Rifinah*	5 (21.7)	3 (13)	15 (65.2)	Rifinah*	3 (13)	4 (17.4)	16 (69.6)
Ethambutol	5 (21.7)	4 (21.4)	14 (60.9)	Ethambutol	3 (13)	4 (17.4)	16 (69.6)
Pyrazinamide	6 (26.1)	3 (13)	14 (60.9)	Pyrazinamide	6 (26.1)	2 (8.7)	16 (69.6)
Streptomycin	6 (26.1)	3 (13)	14 (60.9)	Streptomycin	6 (26.1)	2 (8.7)	15 (65.2)

Ideal answer is underlined, and it reflects the rate of correct responses. ***:** Rifinah: rifampicin and isoniazid

Table 4. Causes of resistance to TB medications and defaulting from TB treatment (according to study participating dispensing pharmacists)

Causes of resistance to TB medications	Frequency (%)
Inappropriate drug choice	9 (39.1)
Incorrect drug dose	9 (39.1)
Interruption of treatment by patients	21 (91.3)
Causes of defaulting from TB treatment	Frequency (%)
Patient lives faraway from TB center	23 (100)
Patient stops the medication when he/she feels better	23 (100)
Patient stops the medication due to financial difficulties	23 (100)
Patient non-compliance to treatment	23 (100)

Table 5. How to increase medication adherence and ensure compliance among TB patients (according to study participating dispensing pharmacists)

Discipline and items	Frequency (%)
1. Promoting patient adherence to medication	
TB education, importance of taking medications	18 (78.2)
Instruction on correct time for taking medications	17 (73.9)
Patient follow up during treatment course	16 (69.5)
2. Ensuring compliance	
Direct questions to patient about compliance	15 (65.2)
Asking patient to bring medication blister packet to TB center	7 (30.4)
Believe compliance is mainly patient responsibility	15 (65.2)

Table 6. Attitude towards whose responsibility is to choose the appropriate TB medication

Responsible party	Pharmacist	Physician	Patient	Physician & patient
Frequency (%)	0 (0)	18 (78.3)	0 (0)	5 (21.7)

Table 7. Practice of participant dispensing pharmacy personnel in TB care

Discipline and items	Frequency (%)
1. Approaching a patient with medication side effects	
Stop medication and refer to a doctor	5 (21.7)
Refer to a doctor	18 (78.3)
2. Advices/Instructions given to patients	
Education about TB	1 (4.3)

Education about medication-related information	1 (4.3)
Do not stop medications	23 (100)
Education on usual side effects of medications	1 (4.3)
Stop smoking and alcohol during treatment	1 (4.3)
Maintain good nutrition	23 (100)
Maintain healthy environment, use tissues to cover cough	23 (100)

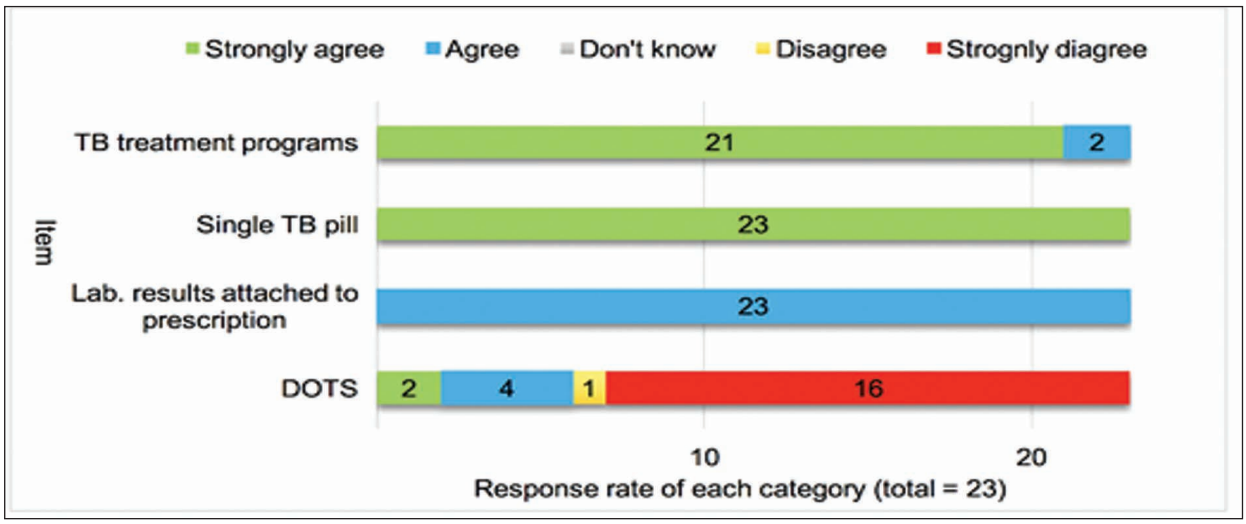

Figure. Attitude of pharmacy dispensing personnel towards different measures to stop TB and promote medication compliance among patients (n=23). DOTS: Directly Observed Treatment Short-course.

DISCUSSION

Knowledge

This study revealed that the majority of drug dispensers have acquired their knowledge of TB care from the National TB Program Sudan, which is based on WHO recommendations. All of them displayed good knowledge of TB medications drug choice. Previous research showed contrary results, though most of these studies were conducted among other healthcare workers. Alene et al.[12.] showed that only 44.6% of the involved Ethiopian healthcare workers correctly answered about nationally recommended MDR-TB treatment regimen. Another study in Southern Mozambique, reported deficient knowledge of intensive and maintenance phase TB drugs among healthcare workers.[13] These results might, however, be influenced by the question format; whether recall or multiple-choice questions were used.

This study also demonstrated the level of knowledge of dispensing personnel in regard to individual TB drugs safety profile in multiple conditions, which is an original addition to the existing literature. It showed that more than 50% of the participants lacked sufficient knowledge to recognize or deal with adverse events in TB patients. Noe et al.[13] reported similar results where the majority of healthcare workers in the study failed to recognize jaundice as a side effect of TB treatment.

Inappropriate drug choice and or drug dose was reported in the present study as the cause of resistant TB by only 39.1% of the participants, as compared to another study where the majority (94.7%) of participating healthcare workers related MDR-TB to improper administration of TB treatment.[13] Dispensing pharmacy personnel showed good knowledge of TB-treatment defaulting, comparable

to those commonly described in literature.[5-8] Most of drug dispensers were also aware of the effective strategies to promote patient compliance; however, it was regarded by the majority as being the patient's responsibility.

Attitude

Although dispensing personnel in this study were aware of MDR-TB and its causes, they still thought that it is, solely, the physician's responsibility to determine the appropriate medication for TB patients. This passive attitude is not unusual in the Sudanese community as it could be explained by the unwelcoming response that pharmacists receive from physicians if the former interfered with the treatment plan, as physicians would feel threatened to lose patient confidence.[10] The majority of the participants showed a supporting attitude for the use of a single TB pill and attaching the laboratory result of the patient to the prescription. These results could include patient sputum status, liver and renal function test, and other important information that would inform pharmacist practice in managing TB patients.

In contrast, the DOTS approach was negatively perceived by most of drug dispenser in this study. This result was unexpected as this strategy is widely applied per WHO recommendation. It was demonstrated that community-based DOTS are more effective and accessible to the patient than clinic-based DOTS.[14,15] which emphasizes the role of community pharmacists in the management of TB cases. The scope of the present study did not allow for further elaboration in the issue; yet this might be attributed to lack of knowledge about DOTS, structural or procedural barriers to DOTS; including increased workload as perceived by dispensing personnel if DOTS is to be conducted by pharmacists. Previous research reported that younger pharmacists, who are involved in TB meetings and workshops and have prior knowledge of DOTS, are more likely to participate in DOTS programs than others.[16]

Practice

The minority of study participants would discontinue the medications prior to referral in cases of adverse events. This might be due to the lack of proper knowledge about TB medications safety as was shown earlier; or more importantly, unclarity of job responsibility as stated in one study; "… I believe the first step in developing our practice is to establish practice standards… I need to know the responsibilities and duties that I should commit to…"[10] Furthermore, there is a discrepancy between dispensing personnel knowledge and their practice regarding medication adherence-promoting strategies.

Linking theory to practice

Low and middle-income countries are in need of effective strategies to control TB. Giving that pharmacist care is usually cheaper and more accessible than physician care; healthcare leaders are encouraged to activate the role of pharmacists in their communities. Previous studies recommend involving community pharmacists in TB case detection, education, and management.[11,17] As was shown in this study, drug dispensers are inadequately trained regarding the safety of TB medications and patient education. A Nigerian study reported improved pharmacy personnel practice in HIV/AIDs and TB cases after engaging stakeholders, changing the infrastructure standards, providing job aids and tool, and pharmacist training.[18] Those included better practice in terms of patient counseling, adverse effects monitoring and patient compliance tracking.[18] Therefore, future interventions should focus on training drug dispensers and establishing collaboration strategies between community drug dispensers and physicians in healthcare institutions.

Limitations and future directions

All dispensing pharmacy personnel in Omdurman locality were surveyed; however, the inherently small sample size might not enable generalizability of our study results. The study, nonetheless, revealed interesting findings such as inadequate knowledge of safety of TB drugs and disagreement about DOTS among study participants, all of which are potential areas for future studies aimed to improve knowledge about these issues and establish the role of pharmacists in TB care.

CONCLUSION

Although dispensing pharmacy personnel displayed good knowledge of TB drugs-regimen, defaulting causes and the overall TB-care, they showed inadequate knowledge about drugs' safety, deficient practice as compared to knowledge, and negative attitude towards DOTS.

Authors' Contributions

DYME has a role in choosing study design and implementing the study and data collection, analysis and interpretation of data, she contributed substantially to the writing of this article, read, edited and approved its final version; SSA has a role in data analysis and interpretation, she contributed substantially to the writing of this article, read, edited and approved its final version.

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