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Follow Up Status and Characteristics of Tobacco Users in an Urban Primary Healthcare Setup in Male, Maldives

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Abstract: ***Objective**: To explore follow up status, quit rates, and nicotine replacement therapy NRT usage among tobacco users attending the tobacco cessation clinic at an Urban Primary Healthcare Center Dhamanaveshi from 2017 to 2023. Methods: A retrospective quantitative descriptive survey was conducted using secondary data from 544 tobacco cessation assessment forms. **Results**: Among 544 tobacco users, 90.8% were male, and 52.4% had no follow up visits post initial assessment. About 30% of follow ups were via phone, and 17.6% were physical visits. Less than a quarter of users quit, and a smaller number relapsed. **Conclusion**: Establishing a proper follow up mechanism is crucial for improving quit rates among tobacco users.*

Keywords: follow up, nicotine replacement therapy, behavioral counseling, behavioral education, NRT

1. Introduction

Consumption of tobacco is one of the leading causes of death globally (WHO, 2022) [1]. It is verified that tobacco kills nearly half of its consumers (WHO, 2022) [1]. Tobacco consumption is a growing epidemic and public health concern in most of the low to middle income countries (NCD Alliance, 2022) [2].

Prevention of initiation of tobacco use is equally important as tobacco cessation (Gallert et al., 2012) [3]. Previous literature of research shows that two - thirds of the smokers wanted to stop smoking; however, only a few people consequently succeeded in quit attempts (Yong et al., 2014) [4]. Surveys across several countries and various age groups including Maldives show that approximately 70% of smokers have thought of quitting at some point in time, but only 2 - 3% have successfully quitted without assistance (Smoke free teens, 2017) [5].

Follow up visits are recommended in tobacco cessation guidelines (WHO, 2010) [6]. A clinician can identify the status of tobacco users during their follow up visit including challenges faced during quitting process, coping strategies applied and side effects or difficulties occurred while taking nicotine replacement therapies and prescription medication such as bupropion and varenicline. It is follow - up visits where a health care provider can adjust dosage of nicotine replacement therapy and reassures regarding challenges with further behavioral education and coping strategies.

World Health Organization (WHO, 2024) [7] recommends varenicline, nicotine replacement therapy, bupropion and cytisine as effective treatments for tobacco cessation. In April 2024, Kenvue's nicotine gum and patch became the first WHO - prequalified NRT products (WHO, 2024) [7] WHO recommends behavioral interventions, including brief health worker counselling (30 seconds to 3 minutes) offered routinely in health - care settings, alongside more intensive behavioral support (individual, group, or phone counselling) for interested users (WHO, 2024) [7]. Additionally, digital interventions such as text messaging, smartphone apps and internet programs can be used as adjuncts or self - management tools. Effective tobacco cessation methods include willpower, Nicotine Replacement Therapy (NRT), pharmacotherapy, health education, counseling, and consulting a smoker Quitline (Lancaster & Stead, 2017, Cahill et al., 2016 & Harman Boyce et al., 2018) [8, 9, 10]. Most smokers chose willpower to quit smoking and smokers who used willpower or the cold turkey method were more successful than those who used nicotine replacement therapy as a cessation method (Kim et al., 2021) [11]. Evidence - based smoking cessation methods include a combination of cognitive behavioral support and pharmacotherapy. Among the medication choices, varenicline, nicotine replacement therapies and bupropion are recommended as the first choice (Baker et al., 2021) [12]. Combination of medication and behavioral counselling has been associated with a quit rate of 15.2% over 6 months compared with a quit rate of 8.6% with a brief advice or usual care (Rigotti et al, 2022) [13].

In addition, Agaku et al. (2021) [14] reported that nearly half of the current smokers are aware of smoking cessation programs, 68.2% were about prescription cessation medication and 92% were aware of nicotine replacement therapy. Utilization of cessation aids was also different among current smokers.

A considerable concentration of nicotine is present in all the tobacco products (Avila - Tang et al., 2012) [15]. Cotinine is a main metabolite of nicotine which can be detected easily in numerous body fluids such as urine, blood, saliva (Kulza et al., 2012) [16]. Cotinine is distributed in various body fluids including blood, saliva and urine (Jung et al., 2012) [17].

Cotinine is the most commonly used marker to distinguish between tobacco users and non - users due to its greater sensitivity and specificity than other biochemical tests (Balhara & Jain, 2013) [18] and cotinine reflects the extent of tobacco exposure (Binowitz et al., 2008) [19]. Urine cotinine level is more frequently used biomarker as cotinine concentrations are four to six times higher in urine than in blood or saliva (Balhara & Jain, 2013) [18]. There is correlation between daily usage of tobacco and urinary cotinine. A value of cotinine in urine ranges from 20 - 550 ng/ml. A change in the cut - off value is directly proportional to the sensitivity of detection (Balhara & Jain, 2013) [18].

Longer half - life of cotinine makes it a useful short - term marker of nicotine exposure. During tobacco smoking its level fluctuates relatively to lesser extent than other tobacco products (Nuca et al., 2012) [20].

Another measurable and valuable motivational tool for smokers is Carbon Monoxide (CO) monitoring. Co presents visible evidence of harm caused by tobacco use or smoking and provided a measure to chart their progress after they quit smoking. Smokers are more likely to make a successful quit attempt if a CO breath monitor is used as part of a supported and structured quit plan (Shahab et al., 2011) [21].

Exhaled breath CO monitor measures CO level in the blood. CO is toxic gas found in tobacco smoke and binds hemoglobin in red cells 200 times more readily than O2 in the blood. Carbon monoxide has a short half - life. It is usually undetectable around 24 hours after last smoking, which makes it a useful marker for regular smoking. When smokers report their smoking status by their shelves or it is self - reported, it can be unreliable and if they claim to have not smoked in the past 24 hours, exhaled air test or CO level can confirm tobacco exposure (Baxter, 2016) [22].

CO monitors are handled, portable and easier to use. The patient inhales deeply, holds their breath for 15 seconds, then exhales slowly aiming to completely empty the lungs. The results are instantly available on the monitor's screen and can be interpreted with the charts supplied (Baxter, 2016) [22].

All CO monitor devices give a CO reading in parts per million (ppm).9 ppm is generally considered to be the highest acceptable level of CO in the exhaled breath of an individual who reports not smoking. (Baxter, 2016) [22]. Those who have remarkable experience of using CO monitors says that any value above 5ppm usually suggests tobacco smoking exposure (Baxter, 2016) [22]. NICE guideline recommends CO monitor reading less than 10ppm at the four week point after the quit date should be used to validate the success in stop smoking (NICE, 2008) [23].

Jarvish et al (1987) [24] define non - smokers as those with an exhaled carbon monoxide reading below 10 parts per million (ppm). Wu et al (2014) [25] categorized smoking status based on CO level results in ppm as non - smoker, light smoker and heavy smokers. The results were arranged as 0 - 6ppm suggestive of non - smoker, while 7–10 ppm was indicative of light smoker and who scored 11–72 ppm was considered heavy smokers.

The exhaled CO concentration is related to the average number of cigarettes smoked daily and the duration of smoking. When the average number of cigarettes smoked per day is less than 10 or the duration of smoking is less than 5 years, the exhaled CO concentration may still be within the normal range of 0–6 ppm (Wenlong et al., 2009) [26], thus monitoring CO level in exhaled breath cannot be used as a basis for determining the success of smoking cessation.

Although, tobacco cessation clinic at UPHC (Dhamanaveshi) was the first clinic to open in Maldives, no researches have been conducted to analyze already collected secondary data through tobacco cessation assessment forms, thus this study was aimed to explore follow up status including frequency, type of follow up, quit and relapse status during follow up visit and assessing NRT usage with the method used for quitting amongst tobacco users who attended the selected tobacco cessation clinic from 2017 to the end of 2023.

Aims

The aim of the actual research project was to identify the characteristics of tobacco users such as, (1) demographic characteristics, (2) practice of tobacco uses, (3) history of previous quit attempts (4) nicotine dependence (5) status of follow ups (6) status of quit and relapse among tobacco users who attended tobacco cessation clinic at one of the Urban Primary Healthcare Center (Dhamanaveshi) in Male' Maldives, from 2017 to the end of 2023. Moreover, the actual project also analyzed (7) variation in nicotine dependence amongst tobacco users. Yet, this paper is majorly focused on 5th and 6th objectives of the actual research project.

However, this paper is mainly focused on the 5th & 6th objectives of actual research project. Previously, two articles were published assessing various objectives from actual research project. One article was based on first 3 objectives and published by A. A. Hameed (2024) [27] in peer reviewed journal titled "Characteristics of tobacco users who visited the tobacco cessation clinic in an urban primary healthcare center in Male' Maldives from 2017 - 2023: A retrospective, descriptive cross - sectional study". Another article was published in peer reviewed journal by A. A. Hameed (2024b) [28] which was focused on objective 4th and 7th of actual research projected titled as "Nicotine dependence and its variation among tobacco users who visited the tobacco cessation clinic in an Urban Primary Healthcare Center in Male' Maldives".

2. Objectives

1) To determine follow up status of tobacco users who attended the selected tobacco cessation clinic.
2) To assess last documented quit status of tobacco users who attended the selected tobacco cessation clinic.
3) To analyze last documented relapse status of tobacco users who attended the selected tobacco cessation clinic.
4) To explore NRT usage and methods used to quit tobacco amongst tobacco users who attended the selected tobacco cessation clinic.

3. Methods

This is a quantitative retrospective cross - sectional study conducted using secondary data stored at the tobacco cessation clinic (TCC), in one of the Urban Primacy Healthcare (UPHC) setup "Dhamanaveshi" located in Greater Male' Area (GMA). The study analyzed secondary data of TCC starting from 2017 till the end of 2023. During the given 7 - year period of time, a total of 693 clients attended the clinic; nevertheless, 544 study subjects were sampled with the exclusion of those who came repeatedly and cases or forms of clients which were misplaced or unreachable during data analyzing phase. The study utilized

census sampling; thus, the total sample size was equal to the total target population which was 544.

A data transfer sheet was developed by primary researcher as an instrument after reviewing the tobacco cessation assessment form, which comprises of 5 sections starting with (1) demographic characteristics followed by (2) practices of tobacco users, (3) history of tobacco cessation among tobacco users, (4) nicotine dependency and (5) follow up status of tobacco users, usage of nicotine replacement therapy and methods used to quit by tobacco users. The data was then transferred from tobacco cessation assessment form to the data transfer sheet by primary researcher. However, this paper is focused on 5th section only, which included follow up status among tobacco users.

Prior to data transfer or data collection, no objection letter was obtained from urban primary health care center (Dhamanaveshi) and ethical approval was attained from National Health Research Council (NHRC) at the Ministry of Health, Maldives. The NHRC approval number for actual research project is NHRC/2023/18. Data was analyzed by utilizing SPSS software version 21.0. Simple descriptive statistics such as mean, median, mode, frequency and percentages were used.

Table 1: Follow up characteristics based on last documented status

Variable		
Documented follow up status	**N**	**%**
Yes	259	47.6%
No	285	52.4%
Follow up type		
F/U not done	285	52.4%
Physical	96	17.6%
Phone	163	30.0%
Frequency of follow up		
Once	185	34.0%
Twice	46	8.5%
Thrice	10	1.8%
4 or more times	18	3.3%
F/U not done	285	52.4%
Team member who did follow up		
F/U not done	285	52.4%
F/U by CHO	163	30.0%
F/U by Doctors	96	17.7%
Last documented Relapse status on follow up		
Yes	68	12.5%
No	186	34.2%
I don't know	290	53.3%
Last documented quitting status on follow up		
Yes	94	17.3%
No	164	30.1%
I don't know	286	52.6%
NRT usage		
Yes	539	99.1%
No	4	0.7%
Don't know	1	0.2%

4. Results

Sociodemographic characteristics

According to the present study 39.6 years is the mean age for tobacco users who attended tobacco cessation clinic at UPHC (Dhamanaveshi) and 18 to 80 years were the age ranges of the study subjects. Less than half (49.1%) of the tobacco users who attended the clinic belonged to the age group 36 - 64 years. Greatest number (90.8%) of tobacco users were male and nearly two - third (59.0%) were married. Approximately 34.2% of tobacco users were having no children at the time of data collection or assessment completion. Nearly all (83.6%) of the tobacco users were employed either self, government or private.

Follow up characteristics among tobacco users

Follow up characteristics (table 01) were descriptively analyzed. The current study displayed more than half (52.4%, n=285) of the tobacco users had never done any follow up after initial assessment and less than half (47.6%, n=259) had done follow up after initial assessment. Out of which, 30% did phone follow up and 17.6% (n=96) did physical follow up at the tobacco cessation clinic. In addition, more than one - third (34%, n=185) had at least one follow up, 8.5% (n=46) did 2 follow up visits, 1.8% (n=10) did 3 follow up visits and 3.3% (n=18) did 4 or more follow up visits after initial assessment. Approximately, 30% (n=163) of follow ups were done by community health officers and 17.7% of follow up were done by the doctors who work at the clinic. As the used data was related to the last documented follow up status, the number or frequency of follow up done or attended by each team member may vary if identified separately.

The current study also revealed that more than half of the (52.4%) tobacco users had never done any follow up after initial assessment and less than half (47.6%) had done follow up after initial assessment. Based on the last documented follow up status and self - report history, it was revealed that only 12.5% (n=68) had reported that they had relapsed when the last follow up was done and 17.3% (n=94) had quitted when the last follow up occurred. As this is the last documented findings and retrospective data was used, at present many people who had relapsed could have quitted or who had quitted could have relapsed.

Nicotine Replaced Therapy (NRT) was prescribed to majority (99.1%) of the tobacco users who visited tobacco cessation clinic. Furthermore, behavioral counselling or tobacco cessation counselling was provided to every tobacco user who visited the clinic to quit tobacco use during given period of time. The present study reported 68% used willpower as a method of quitting followed by NRT (14%) during their previous quit attempts.

5. Discussion

The present study is aimed to identify tobacco users who attended tobacco cessation clinic at one of the Urban Primary Healthcare Center (Dhamanaveshi) from 2017 to the end of 2023, which is located in Greater Male' Area. The specific objectives were identifying characteristics of follow up among tobacco users who attended tobacco cessation clinic at one of the Urban Primary Healthcare Center.

The current study displayed more than half (52.4%) of the tobacco users had never done any follow up after initial assessment, and less than half (47.6%) had done follow up after initial assessment. This is in line with the findings by

Esen et al (2020) [29] who reported approximately half of the smokers had never attended the follow up visits.

The present study expressed that more than one - third (34%, n=185) had at least one follow up, 8.5% (n=46) did 2 follow up visits, 1.8% (n=10) did 3 follow up visits and 3.3% (n=18) did 4 or more follow up visits after initial assessment. In line with this, a study conducted in Hunan Province China showed that smokers had 1 - 4 times follow up visit and 93.0% of patients received 3–4 follow - up visits, while only 7% had less than 2 follow up visits by 6 months (Xie et al., 2021) [30]. Furthermore, Mishra et al (2009) [31] also reported multiple follow up visits by tobacco users.

Based on the last documented follow up status, it was revealed that only 12.5% had relapsed. This low relapse rate may not be accurate as follow up statuses of 53% of tobacco user are not documented in the clinic's documents and also the existing study expressed that 52.4% had never attended any follow up sessions after initial assessment. However, 2 previous studies have reported much higher relapse rate such as a study conducted in Qatar, which showed 23.3% relapse rate among smokers after completion of their smoking cessation clinic visits (Zainel et al., 2024) [32] and a study conducted in Turkey by Esen et al (2020) [29] which reported even slightly higher relapse rate (26.8%) among smokers. In contrast, a UK study revealed 5% relapse rate at the end of the 12 months (Cruse et al., 2001) [33].

Also based on the last documented status, which was self - reported by the tobacco user, it was revealed that 17.3% had reported quitting when the follow up was done. Two previous studies have shown similar findings with this study. A Turkish study by Altunsoy et al (2024) [34] reported 20.5% quit rate at 2nd year of follow up, while a UK study by (Cruse et al., 2001) [33] confirmed 20% quite rate at the end of 12 months. Furthermore, A more recent study conducted in Qatar demonstrated 63% quit rate among smokers after receiving smoking cessation services (Zainel et al., 2024) [32] and a Turkish study by Esen et al (2020) [29] who discovered that 62% of smokers had stopped (quitted) smoking after treatment. These findings show much higher quit rates among tobacco users as compared to the existing study. In addition, another recent analysis from Catalonia, Spain, also discovered 28% quit rate among smokers (Laroussy et al., 2024) [35]. Nevertheless, both quit and relapse rate showed in this study may not be comparable to any former studies as the findings of this study pertaining to quit and relapse status is based on last documentation, which was self - reported by the tobacco users during their follow up visits and may not be correct now. Furthermore, this study revealed 52.4% had never attended any follow up session after initial assessment, thus their quit status was not identified. In addition, those who have reported quitting may have relapsed by now and those who had relapsed may have quitted tobacco use later in life.

Nicotine Replacement Therapy (NRT) was prescribed to majority (99.1%) of the tobacco users who visited tobacco cessation clinic. A previous study conducted in Lebanon has showed a lower percentage of NRT usage with 64% and 33% for nicotine gum and nicotine patches respectively (Bacha et al., 2018) [36]. Likewise, a study conducted in Turkey also reported 46.6% of NRT usage during tobacco cessation program (Altunsoy et al., 2024) [34]. In addition, Manis et al (2017) [37] reported 21% for those who utilized NRT for tobacco cessation.

Numerous literatures support the current study findings. Hollands et al (2022) [38] conducted a study using participants who attended smoking cessation clinic in primary healthcare which revealed that participants consumed average 23.4mg combination NRT daily consisting of 16.5mg NRT patches and 6.9mg oral NRT. A study conducted by Broozary et al (2022) [39] reported that one - fourth (25%) of the study subjects used NRT for quitting smoking.

The methods used in selected tobacco cessation clinic (in urban primary healthcare center) were nicotine replacement therapy and behavioral counselling or tobacco cessation counselling. The clinic applied 5As & 5Rs intervention to assist tobacco users to quit and to motivate tobacco users to quit. The aforementioned two specific methods (NRT+ behavioral support or counseling) were provided to all tobacco users as all the tobacco users who attended the clinic were at preparatory stage when considering their stage of change. In addition, all of them were ready to quit; hence, motivational interviewing was not applied to any client.

Previous studies reported different options for quit smoking. which includes for nicotine replacement therapy (25%) money or gift cards (17%), prescription medication (17%) and 16% for switching to e - cigarettes (Boozary et al., 2022) [39]. Moreover, Ransing et al. (2016) [40] reported approximately 36% of tobacco users used counseling, while 32% used counseling and NRT as an intervention for quitting tobacco use. Mishra et al (2009) [23] reported tobacco users quitted tobacco after counselling by tobacco control team. A study by Agaku et al (2021) [14] reported that 7.1 % used cessation counseling, 28% used any medication for cessation, and 31% used any cessation aid to quit tobacco use. Contrary to this, a few studies reported willpower as method for quitting tobacco (Kim et al., 2021, Manis et al., 2017) [11, 37]. However, it is disclosed that in this study 68% reported willpower as method of quitting in their previous quit attempts and only 14% reported that they had used NRT in their previous quit attempts. Similarly, Manis et al. (2017) [37] demonstrated that the majority (70.2%) of smokers quit without any cessation aid.

6. Limitation

This research was conducted utilizing secondary data from one the tobacco cessation clinic (urban primary healthcare setup called "Dhamanaveshi") which has been collected in the past 7 years; henceforth, this data cannot be generalized neither to cessation clinics in Greater Male' Area, nor nationwide. With this it also suggests that future researches can be conducted to discover the given objectives using data of other cessation clinics and to conduct a comparative study.

This piece of research work was developed by utilizing data from its original research project and has only assessed the data pertaining to given objectives (follow up characteristics

among tobacco users), thus unrelated data to the given objectives were not employed in this study. Similarly, biases such as information bias, recall bias is highly likely to occur while reporting the items included in Fagerstrom's test for nicotine dependence and practices of tobacco use.

In addition, quit rate was assessed based on self – reporting and this may not be accurate, thus introduction of cotinine test is recommended as literature shows that assessing cotinine level is best markers to distinguish between tobacco users and non - tobacco users (Balhara & Jain, 2013) [18]. Similarly, a huge number of tobacco users did not attend follow up visits, thus if proper follow mechanism was maintained throughout the period, there could be an increase in both relapse and quit rate among tobacco users. Therefore, it is recommended to establish a better follow up mechanism at the selected clinic.

7. Conclusion

The study concluded that the majority of tobacco users did not attend follow up visits after the initial assessment, indicating a need for better follow up mechanisms. Both NRT and behavioral counseling were the primary methods used. Introducing cotinine testing and establishing regular follow up, including phone follow ups, could improve quit rates and reduce relapse rates among tobacco users

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Disclaimer: This is an article produced by selecting certain objectives from original research. Nevertheless, no article has been published yet with this tile in a peer reviewed journal. Future articles may be created using different objectives from original research and may be published in a near future in a peer reviewed journal.

This is an article produced by selecting certain objectives from original research. Nevertheless, no article has been published yet with this title in a peer reviewed journal. Two articles were produced previously from actual research project. One was titled as "Characteristics of tobacco users who visited the tobacco cessation clinic in an urban primary healthcare center in Male' Maldives from 2017 - 2023: A retrospective, descriptive cross - sectional study" (A. A. Hameed, 2024) [27] produced and published by same author in a peer reviewed journal. Another article was also published by same author in a peer reviewed journal which was targeted on objective 4th and 7th of actual research projected titled as "Nicotine dependence and its variation among tobacco users who visited the tobacco cessation clinic in an Urban Primary Healthcare Center in Male' Maldives" A. A. Hameed (2024) [28].

Conflict of interest
The author is the primary researcher who works as a team member at tobacco cessation clinic established in one of the urban primary health care centers (Dhamanaveshi) in Greater Male' Area, Maldives. The author gets no financial benefits or incentives.

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