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# COST – EFFECTIVENESS OF DOTS PROGRAMME IN TUBERCULOSIS TREATMENT

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**ABSTRACT**

The failure of old T.B. programme to achieve control, leads WHO to introduce DOTs as a new strategy for T.B. control. Health system research (HSR) aimed at the evaluation of effectiveness of the two strategies, is done by following two cohorts of patients; 112 patients on DOTs and 124 patients on old treatment regimen. Sputum smear conversion rate, cure rate and success rate were studied in a period of six months. The results showed that the age groups (15-44) years were mostly affected in both cohorts. Female to male ratio is 1:2.3 with mean age for males (33) years and (29) years for females. Sputum smear positive form (50) of the sample for those on DOTs and (57) for those on old regimen, with predominance of male to female (70%) and (30%) respectively. Higher rate of smear conversion was achieved after two months of treatment with DOTs (94%), than old regimen (70%). Success rate of treatment with DOTs was (94%) and old regimen (65%), defaulter rates were (6%) and (35%) respectively for the stratehies. Cost per case detection and follow-up in DOTs was (14) units. Cost per case detection and follow-up in old regimen was (23.5) units. Cost per case cured in DOTs ranged from (35.8) to (88.3) thousands ID according to category of patients. Cost per case cured in old regimen was (56.6) thousands ID. Compliance of patients with DOTs is much easier than those with the old regimen as many problems facing patients in old regiman were solved. A progressive adoption of DOTs all over Iraq in recommended.



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## INTRODUCTION

Tuberculosis problem which is still a global puplic health concern has been exacerbated in recent year specially in the developing countries (Zumla *et al*., 1999) Tuberculosis (T.B) programmes have failed to achieve control because they have not cured enough patients particularly the infection smear positive cases (WHO, 1997)**.** In the future, it is expected that T.B. will remain one of the ten leading causes of mortaliy and mortidiy in the world. Al though the rates of T.B. will decrease in many countries, the total number of patients will increase to about ten million cases in 2020. The reasons for increasing global T.B. buedon are mainly poverty changing demographic situation and inadequate health coverage. Moreover, under funding of T.B. control programmes which lead to inadequate cases and poor cure rates (Pierre, 1997).

**DOTS Definition:** Recently in the 1990's directly observed therapy short course treatment (DOTs) has become the WHO strategy for effective T.B. control, this strategy has been adopted by many countries to combat T.B. worldwide (kochi, 1997). DOTS stated by the WHO as the name for a comprehensive strategy by which health worker counsel and observe their patients swallowing each does of powerful combination of medicine and health services monitor the patient progress until each is cured. for successful outcome of the DOTs strategy, five essential elements are needed (Crange and Ganagaham,1998).

- Prompt diagnosis.
- Direct observation of the ingestion of drugs.
- Proper record keeping.
- Adequate and constant suppty of the drugs.
- The necessary funding to implement this programs.

Two or three months of intensive initial phase of therapy with antituberculosis drugs followed by four or six months of continuation therapy with follow up by sputum smear for acid fast bacilli as an indicator of response to treatment (Mohan, 1998). The most important determinant of the outcome of treatment of patient is the access that they have to erliable diagnosis and treatment services organized within the (NTP) as part of DOTs. of you succeed in reorienting well responding to new T.B. problem, we will be able to achieve the goal of T.B.

elimination by 2060,but may be never earlier than that (Maher,1998). WHO has documented DOTs strategy as a break through in T.B. control activities. It is considered as the most effective way to ensure drug compliance, it can significantly reduce the rates of relapse and drug resistance, it can significantly reduce the rates of relapse and drug resistance in the community (Harries and Maher, 1995).

**DOTs combines five elements (Who, 1998a)**

- Political commitment
- Microscopy services
- Drug supply
- Monitoring system
- Direct observation of treatment

DOTs strategy of T.B. control, counseling of the commitment of government to give high prioeity to T.B. control passive case finding with sputum smear examination by microscopy, directly observed treatment by standardized short course regimen of chemotherapy, well organized logistic for T.B. drugs and provision for reporting and monitoring system of T.B. including the evaluation of treatment outcomes by cohort analysis. marked achievements have been obtained in several countries which introduced DOTs strategy (shimao,1999). The success of DOTs has been proven in diversr area of the world with cuer rate of up to 95 even in the poorest countries such as china (94.5), Vietnam (89.1) (WHO, 1998b). The global targets of DOTs is to cure 85 of all new smear positive patients and to detect (70) of such cases by year 2000 (kochi, 1997).

## LITERATURE REVIEW

Recent projections showed that that T.B. control programme reaches the WHOs targets world reduce the incidence rate (11%) and death rate by (12%)yearly (dye *et al*., 1998) Sputum smear conversion of (85%)has been achieved in Bangladesh after two months of treatment by DOTs strategy and final treatment outcome resulte in (75%)cure rate (Kumeresan, 1998). In the russian Federation, with the assistance form the WHO, DOTs has been implemented in Ivanovo ablast show a profound impact in decreasing deaths and disabilities among the most productive age groups and make more effective use scarce resources by reducing hospitalization and other costly intervention. The rapid reduction in the pool of previously treated smear positive cases and more rapid treatment and cure of the new smear positive cases, the new strategy is significantly more cost-effective than the old strategy at all levels of cure rate (Migliori, 1998). In Nepal, DOTs strategy was adopted in 1997, the outcome of treatment is improved (Masuyama, 1990). DOTs programme in Colombia implemented in 1994, (89%) of tuberculosis casess were cured or completed treatment, (5%) defaulted, (3%) died and (1%) failure (Norval, 1998). Directly observed treatment was (2.8) times cheaper overall than conventional treatment, DOTs worked out 2.4-4.2 more cost effective. The 1996 case load of tuberculosis required (47) beds to dedicated to tuberculosis to implement directly observed treatment where as conventionally delivered treatment world have required (160) beds. Because of the reduced stay in hospital, DOTs treatment is cheaper, more cost effective and more feasible than conventional treatment in managing tuberculosis in Hlabisa (Floyd, 1997). A study in new york city, tuberculosis cases rate declined in the period 1991 to 1994 following more than a decade of increases decreasing T.B. was associated with a higher rate of application of DOTs (Davidaw, 1997). Another study shows both DOTs and fixed _dose combination therapy were less costly and more effective than conventional therapy, although DOTs was most cost_effective, in total cost per patient treated was $13.925 for DOTs $13.959 for fixed _dose combination therapy and $15.003 for conventional therapy. Relapses and deaths, when using DOTs, fixed _dose and conventional therapies were 31& 3,96 & 8 and 133 & 13 per 1000 patients treated (Moore,1996). There is a consistent evidence that fully ambulatory short course of chemotherapy programmes are currently the most cost- effective based service. Direct supervision may be more cost -effective than self -administration because of reduced need monitoring and follow up (Fryatt, 1997).

***HIV Associated tuberculosis:*** Tuberculosis is an important opportunistic disease among HIV infected persons world wide. In developing countries of africa, south east asia and latin america, where an 8.5 million persons co infected as of the middle of 1996. In the united states, co infection with HIV and mycobacterium tuberculosis are common in certain segments of the population, including drug user and some minorities the association between tuberculosis and HIV seopositivity is several time higher among patients with tuberculosis than among the ganeral population. In new york city, the rate is nearly (59%), and in african countries, it reaches (60-70%). second, marked increases in number of T.B. cases have been reported at location hard hit by the HIV epidemics. Globally, the proportion of tuberculosis cases associated with HIV infection is growing rapidly and many reach (14%) by the year 2000 (Harrison, 1998). HIV infection, by impairing cell-mediated immunity, appears to be the highest known risk factor for the reactivation of tuberculosis, and more susceptibility to new tuberculosis infection and many rapidly the overt disease (Harries *et al*., 1998).

***Data about Iraq:*** Incidence of T.B. in iraq has increased from 9/10000 in 1992 to 13/10000 in 1996 and for all ages (0-65years). Incidence of T.B. in nineveh Governorate has increased form 6.9/10000 in 1994 to 8.5/10000 in 1998 (khalaf, 1999). Then the number of T.B. cases are multiplied during last ten year in iraq. It jumped form 4755 cases in 1987 to 29897 in 1999. The active T.B. cases increased mainly from 2304 cases in 1992 to 1311 cases in 1998 ( MOH, 1999). The number of cases of pulmonary T.B. alone in nineveh Governorate is 1121 cases in 1999 (Al-Sadria, 1999-2000).

***Measuring Cost:*** It convers the following (Migliori, 1998)

***Diagnostic Procedure:*** It includes medical examination, tuberculine test (Which is independable now), sputum smear examination for AFB, Culture and chest x-ray.

***Finance:*** Thus represents the gross salaries of health personal.

***Chemotherapy:*** Ambulatory treatment (Antituberculous and non tuberculous drugs).

***Cost benefit analysis:*** Ill health results in loss of work productivity and of lives so effective programmes should lead to a decrease in mortality. Cost benefit analysis (CBA) measures costs benefits to society in monetary terms. But using monetary terms is limiting because of the difference in value of lives, level of education, gender and wealth. Also some health programmes as treating infective pulmonary T.B., the benefit is not limited to the patient himself but to

immediate contact. Society at large. for this reason, CBA remains an unpopular measure of health outcomes (zaidi,1999).

***Cost-effectivenness analysis:*** Cost -effectiveness analysis (CEA) is commonly used as a major criterion for the allocation of resources within health programme and related research activities (Varley, 1998). In CEA, the outcome is measured in terms of health, so there will be either lives saved reduction in infant mortality or intermediate measures like the number of cases cured or the number of children immunize and results are given as ratios like cost per child immunized or cost per life saved. CE allows one to determine the least costly technique or system to meet well defined quantified targets (Zaidi, 1999). CEA compare programme costs to programms performance measured by some non-monetary indicator of impact. CE measuring cost per unit of effect which is quality of every intervention and may be compared either to that of alternative intervention that produce similar effects or to specific programme cut -off value (Varley, 1998).

***Compliance of T.B. Patients:*** In developing countries, compliance with antituberculosis Chemotherapy poses specific problems because of epidemiological and socio- economic context in which it occure. (ashry, 1997). Non compliance patient in developing countries is quite frequently not because of his innate nature of irresponsible conduct or non cooperation, but as an unfortunate consequence of the drug delivery and treatment system, such person is forced to ignore or at the most, give a lower priority to his tuberculosis treatment than to his other demanding responsibilities job, wages, and even food and shelter (Grange and Gangadharam, 1998). Non-adherence to treatment is the main risk factor for the emergence of drug resistance and the most obvious indicator for an inadequate tuberculosis programme (Cock, 1995). While, DOTs is probably the most. Effective may to ensure drug compliance .adherence to treatment require the active participation of patients in self management of treatment and cooperation between the patient and health core provider the reasons for poor adherence are mutifaceted and complex, but include characteristic of the individual patient and socio-economic factors (Sumartory, 1993) such as:

- The availability of drugs.
- Communication between the patient and health care providers.
- Duration and number medication needed.
- Side effects and cost of treatment.
- Conpeting demands on time.
- Contradictory norms or expectations of families and cultural groups.
- The poor quality of the T.B. control infrastructure.

***Aims of the study:*** The aim of this study is the evaluation of effectiveness of the old and new DOTs prgramme for T.B. control and help policy maker in decision making.

**Specific objectives**

- To identify the epidemiological features of sputum smear positive patient in relation to age and sex.
- To determine treatment outcome of smear positive patient including the new and recurrent one.
- To identify the treatment success rate of smear positive case
- To analyze factor affecting compliance rate of the patient.
- To calculate the cost of each strategy.

## MATERIAL AND METHODS

T.B. control Programme is operating all over country since 1950's.the new project for T.B. control base On WHO strategy(DOTs) was implemented in nineveh Governorate on the 1st of october 1999 and gradually extended to all health centres in the governorate. All patient have free access to all care facilities for diagnosis and treatment of tuberculosis. There is one apecialized T.B. centre on the lest side to which all records of patient and data are regularly presented form other primary health care centres on the left and the right sides of primary health care sections. This study is a health system research (HSR) in which two cohorts of patients were studies for the evaluation of effectiveness of the old and the new DOTs strategies of T.B. control.

***First cohort:*** It included new patients who were following the old regimen in T.B. treatment and attended the left side sections, they were chosen by systemic sampling technique where every other case was included, form 1st of october 1999 till 31st december 1999.

***Socond cohort:*** It was all the T.B. patients on DOTs regimen who were recorded in the T.B. health centre in the right side section since the 1st of october 1999 to 31st of december 1999. The two cohorts were studied from diagnosis process, treatment and follow up in the initial and continuation phases looking for smear conversion rate, cure rates, defaulter and continuation of treatment and compliance rates.

**Source of data**

**Data were obtained form**

- Literatures of researches done during the tast ten years in world.
- Form official record at the health facility.
- Form structural interviews with patient.
- Assumptions were made when no data were available.

Some variables erlated to the diagnosed smear positive patients have to identified such as age, sex residence, category of oatient, sputum test result and treatment outcome. Each patient is given a treatment card to record treatment in the initial phase (2 months) daily attendance for direct observation, in the continuation phase (4 months), weekly supply of drug for self administration at home.

***Data collection:*** Using the questionnaire form recording number of patient, age sex, sputum smear result, chest x-ray, other investigations, follow up investigation, treatment outcomes (Cure rete, completing treatment defaulter deaths, treatment failure, transfer out) and lastly patient compliance (Annex 1).

**Approach to case detection and management**

**Case detection**

- Tightly defined sysptomatic diagnostic criteria (cough>3 weeks, loss of weight, haemoptesis).

- Three sputum examination for suspected tuberculosis patients
- Limited use of X-ray particularly in DOTs patients.

**Patients categonization for treatment (Mohan, 1998)**

**1ST Category**

- Positive smear sputum as new detected cases.
- Negative smear sputum
- T.B. outside lung
- Severely ill patient

Treated by two month of isoniazid +rifampicin+ pyrazinamid + ethambutol or streptomcin (IHRZE orS in the intial phase followed by for months of isoniazid with rifampicin (4HR) in continuation phase

**2nd category**

- Relapsed cases.
- Failure treatment.

Treated by two months the initial phase by isoniazid + rifampicin + pyrazinamide + ethambutol + streptomycin (2HRZES) followed by one month of isoniazid + rifampicin +pyrazinamide + ethambutol ( IHRZE) and continuation phase of five month of isoniazid +rifampicin + ethambutol (5HRE).

**3rd category**

1negative sputum smear (limite) Materials and Methols Two 2. T.B. outside lung Treated with two months Isoniazid Rifampicin Pyrazinamide (2HRZ) and follow up with four months of Isoniazid + Rifampicin (4HR) 2.4.3 Follow up of Patients By sputum smear examination two months after starting treatment, another smear examination one month later if it was positive and repeated at the end of the fifth month of treatment course. Smear conversion when smear converted to negative at end of initial phase 2.5 Definitions of Particular Variables The followings are WHO standard definition of some terms used (WHO, 1994, MOH, Iraq, 1999) I. Smear Positive Patient with at least two sputum specimens positive for acid fast bacilli by microscopy, or one with positive smear and radiographic abnormalities consistent with active pulmonary TB, sub classified on the bases of the history taking anti tuberculosis drug and for purposes into two categories a. New Patient: who never had treatment for T.B. or taken treatment for less than one month. b. Retreatment Patient: who had taken anti T.B. drugs for one month or more at any time in the past. 2. Sex of Patient 3. Age of Patient: classified into (5-25), (25-34), (35-44), (45-54), (55-664) and 2 65 years old. 4. Treatment Outcome Sub classified into six groups which are Cured: Who has completed treatment and has had negative sputum smear at least twice, one of which at completion of treatment.

***Treatment Completed:*** Who completed treatment with no or with only one negative sputum examination in the continuation phase. 3. Defaulted: Who did not collect anti T B drugs for two months or more. 4. Treatment Failure: Who remianed or became again smear positive five months or later after starting of the treatment. 5. Died: Who died during treatment, regardless of cause. 6. Transfer Out: Who transferred out to another treatment unit and the treatment results are unknow. 5. Treatment Success Rate the proportion of the cured and those completing their treatment. 2.6 Calculation of the Cost 2.6.1. Diagnostic Cost It includes cost per case detected plus cost of case follow-up. Cost Per Case Detected Active screening of population groups is not carried any more any suspected case (cough for 2 weeks, weight loss, haemoptesis) should have sputum smear for AFB in three successful examinations; one is the first day sample, second on next day morning and the third on the same day (Mohan, 1998) Diagnosis as T.B. (Harrison, 1998) 1. Two positive results are considered pulmonary TB 2. One positive smear with chest x-ray shows evidence of lung involvement or lymph node enlargement. 3. Three negative smears with chest x-ray shows cavitations consolidation, lymph node enlargement. 14 1. ESR examination was carried out with old regime only Cost of Follow-up 1. Sputum smear examination was carried out after two months from the start of treatment, delayed at end of the fifth month of treatment in both treatment strategies. 2. Chest x-ray: repeated frequently in the oldregimenonly 3. ESR: used in oldregimenonly Cost Per Case Detected in DOTs It computes: 1. Cost of three sputum smear examination. 2. Cost of 0.5 chest x-ray Cost of Case Follow-up in DOTs Cost of two sputum smear examinations. Cost of diagnosis per case -cost of case detection + cost of case follow-up Total diagnostic cost- cost per case dingnosis X numher of tuberculosis cases Diagnostic Cost in the Old Regimen Cost per case detected 1. Cost of three sputum smear examination. 2. Cost of one CXR. 3. Cost of one ESR examination. Cost per case follow-up 1. Cost of two sputum smear examination 2. Cost of two CXR. 3. Cost of one ESR examination. Cost of diagnosis per case - cost per case detection + cost per case follow-up Total diagnosis cost - cost per case diagnosis X number of tuberculosis cases. 15th

**Category ITI**

- Two months of (H + R + 2)
- Four months of (H + R). Cost of eure per case cost of (1) + cest of (2) + cost of non-tuberculises drugs Cost per Case Cured in Old Standard T.B. Regimen (Davidson's, 1981)

***Initial phase:*** Two months of Rifampicin + isoniazid + Ethambutol or Streptomycin injection (2HRE or S). 2. Continuation phase of seven months of Rifampicin + isoniazid (7HR) Cost per case cured - cost of (1) + cost of (2) + cost of non-tuberculosis drugs.

***Data Processing:*** This is to be done according to the objectives of the study, the description of the gender of samples was done by tables to show age and sex distribution, mean age and standard deviation for both sexes in both program samples. Tables for sputum smear poitive variants according to sex and category of patients, smear coaversion, treatment outcome and factors affecting compliance of patients with treatment Test of significance (z-test) as a statistical analysis of data will be used.

## RESULTS

The results of this study shows that (124) T.B. patients on old strategy treatment and (112) patients on DOTs strategy are collected during the period from the 1st of September 1999 till 31t of December 1999 and followed for six months from the

start of the treatment. 3.1 Patient's Age and Gender The study sample of the two groups are distributed according to age and sex in Tables (1 & 2). Males (70%) are affected more than females (30%) in both sample, the mainly affected age group are (15-24), (24-34) and (35-44) years with the percentage of cases (25.9%), (29.4%) and (62.3%) respectively. 3.2 Smear Positive Patients:-The sputum smear positive cases sentence (50) in sample of DOTs and (57) in old strategy treatment out of the total samples which is (112) and (124) cases in DOTs and old strategies respectively. More than two third of the cases were male in both samples (70% & 74%) respectively
3.3 Smear Conversion Rate The percentage of smear positive conversion to negative was higher in patients on DOTS program (94%) than that of patients on old TB. program me (70%) after two months of treatment.

**Table 1. Age and sex distributions of T.B. patients in DOTs strategy in Nineveh Governorate in 1999: Sex Age Female Total**

| Age Group | sex | | | | Total |
|---|---|---|---|---|---|
| | Male | | Female | | |
| | No | % | no | % | |
| 0-14 | 1 | 0.9 | 0 | 0 | 1` |
| 15-24 | 29 | 25.9 | 10 | 9.5 | 39 |
| 25-34 | 33 | 29.4 | 7 | 6.2 | 40 |
| 35-44 | 7 | 6.0 | 4 | 3.6 | 11 |
| 45-54 | 6 | 5.0 | 8 | 7.1 | 14 |
| 55-64 | 2 | 1.9 | 3 | 2.7 | 5 |
| ≥ 65 | 1 | 0.9 | 1 | 0.9 | 2 |
| total | 79 | 70% | 33 | 30 | 112 |

**Table 2. Age and sex distribtions of T.B patients in old standard strategy in Nineveh governorate in 1999**

| Age Group | sex | | | | Total |
|---|---|---|---|---|---|
| | Male | | Female | | |
| | No | % | no | % | |
| 0-14 | 1 | 0.9 | 1 | 0.9 | 2 |
| 15-24 | 27 | 21.8 | 9 | 7.3 | 36 |
| 25-34 | 24 | 19.3 | 10 | 8 | 34 |
| 35-44 | 14 | 11.3 | 12 | 9.7 | 26 |
| 45-54 | 7 | 5.7 | 7 | 5.7 | 14 |
| 55-64 | 6 | 4.9 | 3 | 2.4 | 9 |
| ≥ 65 | 2 | 1.7 | 1 | 0.9 | 3 |
| total | 81 | 65.3 | 43 | 34.6 | 124 |

## Treatment outcomes

The difference in success rates (cure rate + completing treatment rate) of the two programs z-test-4.18 and P 40.001, The cure rate was about (20%) in both strategies, while complete treatment was (74%) in those following DOTS strategy and (43.9%) in patients on old treatment regimen, these results give a significantly higher success rate in patients on DOTs than in patients on old treatment regimen. Defaulter constituents (6%) only in patients on DOTs regimen, while they were increasing up to (35%) in patients on old regimen. Cases of treatment failure, patients are referred to Baghdad where sputum culture can be dong.but there is no treatment failure or death occurrences in the samples of both groups in this study.

## Cost Analysis

## Dlagnostic Cost

- Sputum smear for AFB (microscopically) cost 2.5 units
- For case detection needs to repeat three times7.5 units
- For follow-up repeated twice 5 units
- So in both regimens, it equally costst 2.5 units.

Chest x-ray cost 3 units

In DOTs, it is not necessarily done for smear positive patient, so as average, it is done 0.5 time in both case detection and follow-up 23.

ESK cost- 1 unit

ESK is only dependent in old regimen.

Once done in case detection and in follow-up once. Each case detection and follow up in DOTs cost 14 units. Each case detection and follow up in old regimen cost 23.3 units.

***Treatment Cost:*** In case when Streptomycin injection used cost of distilled water and disposal syring is calculated. The TB control program in Irag adopted the same treatment for each categorypry in the table above one SUS-1 2 thousand ID. Accordingly, the cost of treatment of tuberculosis case with antituberculous drug only will be as follows -initial phase cost + continuation phase cost.

DOTs Catepory 1-193 + 154-34.7X1.2-41.64 thousand ID
Categpry I1-464 272-73.6 X12-88.32 thousand ITD 24
Category II 14.5 + 15.4- 29.9 X 1.2 35.8 thousand ID
Of the (112) cases of DOTs (111) cases were from category I so their total cost will be 41.64 X 111 4622.04 thousand ID.

Only one case is of category II costing 88,32 X1 88.32 thousand ID For the total antituberculosis drug treatment of 112 cases DOT treatment was 4622.04+ 88.32 4710.36 thousand ID.The cost of old regimen antituberculous drug therapy cases 20.25 + 26.9 47.15 X 1.2 56.68 thousand ID. Cost for the 124 cases of old regimen was-56.68 X 124 7015 92 thousand ID. Cost of treatment for category I of DOTS per 100 case 4164 X 100 416 thousand ID. Cost of treatment for category II of DOTs per 100 case 88.32X 100 8832 thousands ID.

Cure rate in DOTS - 20%,
Success rate in DOTS - 94%

Cost of treatment for old regimen per 100 eases 56, 68 X 100 5668 thousand ID Cure rate in old regimen - 21%, Success rate in old regimen - 65%, the cost of non-tuberculous drug (Tonics, bronchodilation, analegesic antiematic) is about 7.5 thousand ID per case.

***Patient's compliance:*** Most of patients on old regimen complain of drug availability (84%), while those on DOTs regimen, their main complaints were drug delivery system which force them to come daily to the health center to receive the drug (52.7%). Physical fitness of the patients in both regimens as a factor of compliance was not so prominent except for few patients (14.6%) for those with old regimen. Economically, tuberculosis is a disease of poverty and the economic factor is more prominently with the old regimen patients (50%), while those of DOT 's only represent (20%). Patients following both regimens have the problem of socially acceptance, with old regimen was (17.8%), while with DOTs (31%). Educational status affect the compliance of the patients in both treatment strategies nearly equal (19.7%) and (16%)

respectively. Transportation more complained by the patients following old regimen forming (50%), while in DOTs (1 7%).

## DISCUSSION

The aim of the study was to compare the two treatment strategies of TB. control programs, the DOTs and old strategy by means of cost- effectiveness analysis with cost per case detected and cost per case cured for both ways of treatment. The data were collected for the two cohorts with the beginning of adoption of DOTs in Nineveh Governorate on the first of October 1999. Patient's Age and Gender Most of tuberculous cases occur in the age group of (20-49) years which represent men and women in their most productive years (Pierre, 1997) which resembles the findings in our study, where maximum number of patients fall in that same age group under both programs (Table 1 and 2). The study also reveals that mean age of females (29) years is significantly younger than the mean age of males (32) years (Table 3). This finding is in agreement with that of WHO report (WHO, 1997) which considers that females in their productive ages have a higher risk of developing active T.B. than males in the same age group, the hormonal and nutritional stresses of pregnaney may weaken the women's immune system. The same finding had been found in Nepal (Masuyama, 1998) where mean age for males is higher than that for females. Smear Positive Patients The preáominance of males among the diagsosed smear positive patients abie 34) is sinmillar conducted in Saudi Arabia (Khalifa 1998), in which (65%) of patients were males. These differences in rates reveal that T B males may harve a better chance to attend the health facilities to the findings of a hospital brashed stuby. The comibination of biogical and social factors including stigma is liable fox ese dfference in rates in both sexzes. Anyhow, the ratio of females to malies in this study was 12 3 for both programs samples which is apably simiar to giaball ratio notified by WHO (Diawan Thorson 1999) which was 1-2.1. Smear Conversion Rate Smear czerversion rate is a sensitive indicator of response to treatment Olian, 1998) The result in this study shows (94%) cceversion rate for DOTs patients (Table 5), while for old regimen paients, de ccovenaon rate was (70%).

**Table 3. Mean and standard deviation of male and female patients on DOTS and old standard strategies**

| Programme of treatment | Sex | Number | Age in years | | z-value p-value |
|---|---|---|---|---|---|
| | | | Mean | Standard deviation | |
| DOTs programme | Male | 79 | 32.6 | 6.8 | 3.03 |
| | Female | 33 | 28.9 | 5.3 | <0.001 |
| Old standard programme | Male | 81 | 34 | 6.5 | 4.2 |
| | Female | 43 | 29 | 5 | <.001 |

There are significant differences in the mean age for both male and female patients on DOTs and old standard strategies. Table (3.3) show significantly hight mean of male patients (32.6%) than female ones (28.9%) .p-va;ue is < 0.001 , the same difference was found in the old standard programme.

In Bangladesh, are ar conversion of (85%) has been achieved after two months of treatment by DOTs (Kumaresan, 1998). Treatment Outcome the mot important determinant of treatment outcomes of bercullosis patients is the access that they have to reliable diagnosis and treatment services organized within a national TB program (NTP) 2s part of DOTs. Accurate evalusation of treatment outputs require the inclusicon of all pets diagnosedcluding those sot registered, Part of routine NIP masagemest should exist involve regular cross check bewen laborators diagpostic registers and NTP treatment registrants OMaber, 1998.

The achieved cure rate in this study was (20%). This cure rate according WHO definition constituents patients being completing their treatment with two negative sputum smear. While those completing treatinent formed (74%), with only one negative sputurn smear in follow-up, Second smear can not be done mostly because patients have neo sputum as written in their cards or as the health supervisor claimed. So, success rate which is considered by other studies as a cure rate, has reached is (94%) in our research Compared to Cambodia study in which (89%) were cured or completed treatment (Norval, 1998) In Nepal study, the treatment outcome could have improved after the introduction of DOTs strategy (Masuyama, 1998) The higher success rate in patient following DOTs (94%) than that of patient following old strategy treatment (70%) was probably due to strict observation of patient taking drugs daily. The same result has been reported by studies in rural communities demonstrated that, the achieved cure rate of new smear positive patients treated with ambulatory DOTs exceeded the WHO target, in China (94.5%) (China TB. Control Collaboration, 1996) and in Bangladesh (85.3%) (Chowdhury *et al*., 1997).

The reason for this successful cure rate in the mentioned studies may be related to the use of some monitory benefits given to the village doctor (China) and to the community health worker (Bangladesh) for their strict supervision and follow-up of each patient at home. The direct observation of treatment is certainly the best method of avoiding treatment interruption. In this study direct observation only took place in the intensive phase, while treatment interruption might also occur during the continuation phase of treatment which is often self-administered. DOTs element has been criticized because it means that the patient has to visit the health center or worker or viee-versa (Diwan & Thorson, 1999, Six percent defualter rate of our DOTs sample is comparable with the expected defaulter rate with DOTs which was less than (10%) mentioned by Iseman *et al*. (1993) and less than the (10%) rate reported in Bangladesh for (10142) new smear positive patients treated with ambulatory DOTs (Kumareson, 1998), in which the supervision place is the health center similar to this study 4.5 Cost Analysis.

Diagnostic Cost The most specifio test in TB diagnosis is sputum smear examination microscopically for acid fast bacilli, in both programs. independent in DOTs, but was considered in the old regimen, causing more costing. So, the cost per case detected and follow-up with old regimen is (23.5 units) (Table 7) much more than (14 units) in DOTs cas C. 4.5.2 Treatment Cost According to patients category, the highest cost is for category Il (which includes relapsing cases) (Table 8), the cost per case cured (88.3 thousand ID) and their treatment continue for eight months costing even more than old regimen (56.6 thousand ID), this figure sometimes was doubled specifically in the early years of blockade in Iraq as drugs were not always free in the health center forcing patient to get them from the black market. The cost of cured case on DOTs regimen in our study is even less than that found in Ivanovo's (1998), where the cost decreased from $ 6293 to 1197on shifting from old to new WHO DOTs strategy (Migliori, 1998). A study in Hlabsia health distric, South Africa in 1996 showed that directly observed treatment was (2.8) times cheaper overall than conventional treatment (S 740.90) compared with ($ 247.70) to deliver Directly observable technique worked out (2.4-4.2) times more cost effective, costing (S 890.50) per patient cured compared with

either the best case (2095.60) and the worst case ($ 3700.40) for conventional treatment (Floyd, 1997). Another study compared three alternative strategies for a six months course of treatment for tuberculosis: directly observed drug therapy (DOT), self-administered fixed dose combination drug therapy and self-administered conventional individual drug therapy (Moore, 1996), this found that both DOT and fixed dose combination therapy were less costing and more effective than conventional therapy DOTs is more cost effective strategy than self-administered therapy because it decrees the retreat cost associated with therapy failure and associated drug resistance (Yew, 1999).

A new approach to T.B, control in Iraq based on WHO strategy may indeed have a substantial impact from rapid reduction in the pool of previously treated smear positive care and more rapid treatment and cure of a new smear positive cases. Ultimately, there will be a permanent reduction in the incidence of T.B The result of this study showed that substantial saving could have been made by shifting towards DOTs strategy recommended by WHO. The saving in DOTs strategy is carried out through decreasing in the cost of case detection and increasing in the success rate achieved. Patient's Compliance Many factors had been found to be affecting adherence of a patient to treatment, and each patient has more than one factor in this study The most important factor that plays a role in patient's compliance following old regimen was drug availability (84) %), particularly with the blockade state in Iraq Antituberculous drugs like many others, were not available in the private charging health centers and their prices increased beyond the capacity of many patients. Drug delivery system and communication with health care provider factor in Dors is prominent (52.7%), due to the daily supply ofdrug by health center specifically in the initial phase which is part of the direct observation of DOTs program, Absence of health worker who help in communicating and providing the drugs to patients at home in this study sample necessitate the daily coming of the patients to health center, the presence of a responsible educated person in tuberculous patient family helps and reduces this complaint specifically for too young or too old patient or physically unfit.

A recently case control study in Madagascar showed that the quality of communication between ambulatory TB, patients and the health worker was associated with compliance in an urban areas Comolet ctal., 1998) very small proportion of DOTs patients (2.7%) were physically unfit and those on old regimen forming (14.6%) and sometimes can be helped by hospitalization or need help of educated member of patient's family Economic factor is prominent more in the old termime (50%) as most of them forced to buy their very expensive drugs. Soeally, being infectious disease, the patient is not well-accepted by the community and patient always tries to deny his disease and affects this compliance therapy Some drugs as pyrazinamide which is in excessive use now darken skin color make it a problem specifically for females, social factor in DOTs forming (31%) Educational state, approximately has the same effect in both programs (19.7% in DOTs and 16% in old term). Transport, in patients with old regime is more evidenced as a factor affecting patient compliance (50%) because ofdifficulty to reach the only one antituberculous center in Nineveh Governorate in the left side district for treatment and follow-up, while DOTs services are provided at level of PHC even in the farthest districts.

**Conclusions and Recommendation**

Most of tuberculous patients are in the active productive age group with the males showing higher infection rates, higher mean age and. Smear conversion rate is (94%) for DOTs which is higher than that. DOTs is most cost-effective, through decreasing in the cost of case higher percentage of sputum smear positive. obtained from old regimen (70%) with similar success rates in both. detection and increasing the success rate of treatment. According to the results of this study, a progressive adoption of the new WHO strategy all over IRAQ in the near future is recommended. Training of PHC staff for better case detection specifically laboratory technicians for accurate sputum smear examination for AFB. Tuberculosis is a treatable and curable disease and its infectivity can be controlled within a short time with the proper drug therapy, this should be realized by population for global T.B. treatment and prevention. Further studies are advised to be carried out after completing one year of using DOTs program for its further evaluation.

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