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＜Original＞

Community-involved strategy to improve tuberculosis (TB) treatment outcomes in Eastern Region of Ghana

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Abstract

Objective: To evaluate decentralization and community supervision of tuberculosis treatment as an effective intervention to improve treatment outcomes in Eastern Region of Ghana.

Methods: A historical comparison of treatment outcomes of cohorts registered in 2003-2005 with centralized Directly Observed Treatment short course (DOTs) at health facility level and cohorts registered in 2007-2009 with decentralized DOTs at the community level. Effectiveness was measured by comparing TB case finding and treatment outcomes before and after the introduction of the decentralization with participation of local communities providing the option of treatment supervision.

Results: In total 5128 cases were registered during the centralized period with 60% being men and 40% women. In the decentralized period 5309 cases were recorded with 62.7% men and 37.3% women. Among new smear-positive cases there was a significant difference between treatment success rates in the decentralized period as compared to the centralized period (82.7% vs 69.6%, respectively: *p-value < 0.0001*). Cured rate improved during the decentralized period as against the centralized period (75.8% vs 63.2%, respectively; *p-value < 0.0001*). Defaulter rate significantly reduced in the decentralized period as compared to the centralized period (3.6% vs 12.1%, respectively; *p-value < 0.0001*). Among new smear negative-and extra pulmonary TB patients, treatment completion rate was significantly higher in the decentralized period than in the centralized period (80.2% vs 56.3%, respectively; *p-value < 0.0001*) and defaulter rate was significantly reduced in the decentralized period than in the centralized period (3.3% vs 17.7%, respectively; *p-value < 0.0001*)

Conclusion: Decentralization of TB treatment to the community level, empowering TB patients to choose treatment supporters from the community and communities providing treatment supervision till cure, improved treatment outcomes in Eastern Region of Ghana.

keywords: tuberculosis (TB), decentralize, centralize, treatment outcome, Eastern Region and Ghana.

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Ⅰ. Introduction

One of the challenges facing the health systems is to bring the provision of health services as close as possible to those who need them. The need to promote community contribution to tuberculosis (TB) care as part of National Tuberculosis Programme (NTP) activities is particularly urgent in Sub-Sahara Africa, where the human immunodeficiency virus (HIV) is fuelling the TB epidemic [1-3].

Eastern Region of Ghana had a projected population of 2,420,927 with a growth rate of 1.4% (2000 National census). It is the sixth largest region in Ghana with a land area of

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19,323 sq. km., thus representing about 8% of the total land area of the country and 11.5% in terms of population.

The region with its capital Koforidua (New Juaben) is bounded on the East by the Volta Region, South by Greater Accra region, West by Central Region and on the North by Ashanti Region as shown in figure 1. The Eastern Region has 21 districts and a total of 136 sub-districts as shown in figure 2. There are 23 hospitals, 53 health centres, 126 Reproductive and Child Health (RCH) centres, 502 demarcated Community-based Health Planning Services (CHPS) compounds, 135 functional CHPS and 26 TB diagnostic centres. A rapid assessment of National Tuberculosis Control programme conducted in Koforidua (New Juaben) revealed that defaulter rate in the district was over 40% [4]. A cross-sectional study carried out in 2006 to elicit factors contributing to high tuberculosis treatment default rate in New Juaben came out that long distance from home to treatment centre (Odds Ratio; OR 6.14), poor family/community support (OR 3.43), lack of financial support (OR 4.14, poor attitude of staff (OR 2.72), lack of knowledge and long treatment duration (OR 2.83) were most influential contributing factors to default [5]. With Such challenges several studies have shown that decentralization of tuberculosis treatment, offering patients the option of treatment supervision in the community and with the necessary support, communities have the potential to contribute to TB care and improve treatment outcomes [6-15]. This necessitated the need to decentralized tuberculosis treatment, which is moving tuberculosis

Figure 1 Map of Ghana Showing the ten Regions.

Figure 2 Map of Eastern Region Showing the 21 Districts.

treatment care from health facility level to the community level to enable community members' offer their support and care to TB patients in order for their treatment outcomes to be improved.

Ⅱ. Methods

Study Design: Historical comparisons of the treatment outcomes: a) Cohorts registered in 2003-2005 with centralized DOTs at health facility level; b) Cohort registered in 2007-2009 with decentralized DOTs at the community level

Preparation for decentralization: Stakeholders meetings were held for the Regional Health Directorate (RHA) members, District Directors of Health Services (DDHS) and National Tuberculosis Programme (NTP) to solicit for their support.

Meetings were held for community opinion leaders, community members, Chiefs and elders, organized groups like Ghana Private Road Transport Unions (GPRTU), Chemical sellers groups and other key community members. Several community durbars were also held to discuss the essence of the study and the roles of community members.

Trainings were conducted for health staff, District TB Coordinators (DTC), laboratory staff and community volunteers and final year nursing training school students since they will soon complete and join the health service.

Ethical Consideration: Permission was sought from the Regional Director of Health services and NTP to conduct the study in Eastern Region. Patients' oral or written consent form was agreed or signed before a patient is rolled into the study.

Sputum collection and microscopy: Laboratory staffs from the 26 diagnostic centres were given training in sputum smear microscopy. All TB suspects reporting to any health facility at the Sub-district level were referred to these diagnostic centres for sputum smear microscopy with laboratory request form fully filled.

A patient with persistent cough for two weeks or more with fever, weight loss, and night sweat, sputum with blood stain, chest pain and difficulty in breathing or in case of HIV positive coughing for 24 hours or more was said to be a TB suspect

Patients were educated on how to produce sputum by clearing the back of the throat and cough but not spit. Three sputum samples (spot-early morning-spot) were collected for sputum smear microscopy from each patient in plastic containers with specimen identification numbers. Slides were prepared from each sputum, fixed and stained with Zeil-Neelsen solution, decolorized with 25% H_2SO_4 and counter- stained with 0.3% methylene blue. Degree of Mycobacterium infection was assessed by counting the number of bacilli at magnification 750X. Precautions were taken to avoid contamination as this could lead to false results [16].

Patients on treatment also had their sputum conversion follow ups done on months 2, 5 and 6 for all new TB patients and for re-treatment patients on months 3, 5 and 8.

Treatment Regimen: A new treatment regimen was introduced as a result of new drug formulation called Fixed Dose Combination formulation [17], where two or four drugs have been combined to form a single tablet for a dose (HRZE= I Tablet, HR=1 Tablet). Additionally there was no streptomycin injection for new cases. All patients who had never taken TB treatment or had taken TB treatment for less than one month were considered as new patient. A new patient may have positive or negative bacteriology and may have the disease at any anatomical site (new smear-positive Pulmonary TB; new smear negative pulmonary TB, new extra pulmonary TB). Patients who had previously received TB treatment for one month or more were considered as previously treated TB patients. A previously treated TB patient may also have positive or negative bacteriology and may have the disease at any anatomical site. They were further classified by the outcome of their most recent course of treatment as Relapse, Treatment failure and Treatment after interruption.

Treatment duration was six months for all new patients with initial phase of 2 months and continuation phase for four months. Treatment duration for all previously treated patients was eight months with initial phase of 3 months and continuation phase of 5 months.

The drugs were put into categories according to the patients' classifications. Category I drugs for all new patients, Category II drugs for previously treated patients and Category III drugs for children less than 12 year. The prescribed dosage was based on four weight bands for adults and children but not according to age groups.

Drug distribution: All anti-tuberculosis drugs were kept at the Regional Medical Stores (RMS). Drugs supplies to the districts were based on the district TB case-load reported in the previous quarter and the District TB coordinator supplied the drugs to all the sub-districts health facilities. The TB treatment supporters collected their drugs from their respective areas every two weeks in the initial phase and monthly in the continuation phase. The treatment supporter tallied all doses of drugs given to the patient under Directly Observed Treatment (DOT) in a treatment supporter's card. The chain of distribution of drugs was usually reliable to TB treatment supporter as the drugs come as patient Kit and blister form meant for full

treatment of the patient.

Home verification: All patients diagnosed as having TB were referred to their nearest health facility with a referral note and the community health officer in the area conduct home verification by visiting the home of the patient to verify:

- The home address of the patients
- Number of rooms in the house
- Number of people living in the same room with the patient
- If there is cross ventilation in the room
- If the compound is hygienic
- Type of meal often eaten by the people and the contacts
- Contacts in the house having sign and symptoms of TB
- Contacts in the house having signs and symptoms of HIV
- All children less than six years living in the same house with the TB patient.

All contacts who were found to be having signs and symptoms of TB or HIV or both were referred to the district hospital for assessment by a clinician.

Options for DOTs: Very ill patients or those with social problems were admitted at the main hospital. The health facility staff gave the patients the opportunity to choose a treatment supporter from the community where he/she lives. The treatment supporter can be a community volunteer, family member or a health staff if the patient lives close to the health facility. The TB patient had the final word in choosing their DOT option. Both the TB patient and the treatment supporter were then educated on TB and HIV with regards to causes, mode of transmission, treatment, follow up for sputum, side effects of drugs and preventive measures. They were also made to understand that treatment is free.

The role of TB treatment supporter: The role and the responsibilities of a treatment supporter were to collect the tablets on monthly or weekly basis, and store them safely. Directly observing the intake of tablets (in the right number of drugs and dosage), recording the daily intake of drugs in the treatment supporter card, encouraging the patient to attend the health centre and hospital/clinic for follow up as required. Identifying possible side effect and refer to the health facility if necessary. They help the patient to overcome difficulties to continue the treatment and identifying the patient who does not arrive for support and help trace and retrieve them.

Supervision of community TB treatment supporter: The community health officer (CHO) in the community supervises the TB treatment supporter in facilitating treatment completion by the patient and is responsible for ensuring an effective relationship between patient and treatment supporter. The treatment supporter reports to the Sub-district health facility for advice and renewal of the drugs.

Registering TB patients: All diagnosed TB patients were classified and assigned to the correct patient treatment groups. All details of the patients were entered into the Institutional and District TB registers. In addition patients who were being treated at the community level were registered in the community health officers' register.

TB/HIV collaborative activities including referral mechanism: All TB suspects were screened and counseled for HIV. They were offered testing and those who were reactive were referred to the Anti-retroviral Therapy (ART) clinic and put on ART and co-trimoxazole prophylaxis (CPT) if needed. All HIV clients were screened for TB using a TB screening tool at the Anti-retroviral Therapy clinic and those found to be TB suspects referred to DOTs centre for further investigations.

Quality Assurance (sputum microscopy): Quality control (internal quality assurance), external assessment and blinded re-checking were done in all the 26 diagnostic centres. Feedback of assessment of smear preparation, grading and bio-safety were given to all facilities concerned. Thirty five laboratory officers were trained in QA sputum microscopy.

Outcome measures: Assessment outcomes of patients either being successfully treated or not were grouped into cured, treatment failure, treatment completed, defaulted, transfer out or died and properly documented in the patient's treatment card.

- Cure: Sputum smear positive (+) patient who is sputum smear negative (-) in the last month of treatment and at least once before.
- Treatment completed: Patient who has completed treatment but does not meet the criteria to be classified as cured or a failure.
- Default: Patient whose treatment was interrupted for 2 consecutive months or more.
- Died: Patient who dies from any cause during the course of treatment.
- Treatment failure: New patient who is sputum smear positive (+) at months 5 or later during the treatment or a previously treated patient who is sputum smear positive (+) at the end of his retreatment.
- Transfer out: Patient who has been transferred to another recording and reporting unit for whom treatment outcome is not known.

Data collection and analysis: The district TB coordinators visited all the sub-district health facilities twice

every month and collected all the TB data for analysis. A data clerk at the regional level assisted in the collection of the data and entered them into MS Excel and analyzed. Statistical significance of treatment outcomes were tested by using Chi-square at 5% significance level.

Ⅲ. Results

Case-finding:

Table 1 shows all TB cases detected by categories. The number of TB cases (all forms) recorded for the centralized period (2003-2005) and the decentralized period (2007-2009) were 5128 and 5309, respectively. There was no significant difference in the proportion of smear positive TB cases detected in the centralized period as against the decentralized period. The majority of TB patients in both the centralized and the decentralized periods were new smear-positive pulmonary (2927 and 3044 patients, respectively). The proportion of males was larger than females in both the centralized (60%) period and the decentralized (62.7%) period. It was observed that the proportion of TB infection was large in the age groups of 25-34 (23.3% vs 21.5% in the centralized period and the decentralized period, respectively) and 35-44 years (30% vs 23.8% in the centralized period and the decentralized period, respectively) among new smear-positive pulmonary TB cases.

Table 2 shows the annual treatment outcomes for the centralized period and the decentralized period among new smear-positive pulmonary, smear-negative and extra-pulmonary TB patients.

Treatment outcomes:

Table 3 shows a comparison of treatment outcomes between the centralized period and the decentralized period. There was a significant difference between treatment success rates for new smear-positive pulmonary TB cases in the decentralized period as compared to the centralized period (82.7% vs 69.6%, respectively; *p-value* < *0.0001*) and the proportion of patients who were cured improved during the decentralized period as against the centralized period (75.8% vs 63.2%, respectively; *p-value* < *0.0001*). Regarding smear-negative and extra-pulmonary TB patients, the proportion of patients who completed treatment was significantly higher in the decentralized period than in the centralized period (80.2% vs 56.3%, respectively; *p-value* < *0.0001*), and the proportion of patients who defaulted was significantly lower (3.3% vs 17.7%, respectively; *p-value* < *0.0001*) in the decentralized period than in the centralized period. The proportion of new smear-positive pulmonary TB patients who defaulted was significantly reduced in the decentralized period as compared to the centralized period (3.6% vs 12.1%, respectively; *p-value* < *0.0001*). Few proportion of patients were transferred from one reporting unit to another in the decentralized period as against those in the centralized period (3.1% vs 7.3%, respectively; *p-value* < *0.0001*) among smear pulmonary positive patients. There was no significant difference in other treatment outcomes (failed and died) among new smear sputum positive pulmonary TB patients.

There was much lower proportion of smear-negative and extra-pulmonary TB patients who were transferred from one reporting unit to another in the decentralized period than in the centralized period (2.7% vs 12.9%, respectively; *p-value* < *0.0001*) and there was no significant difference between patients who died during the decentralized period

Table 1 TB case finding for centralized period (2003-2005) and decentralized period (2007-2009)

	year	Total n (%)	New smear positive n (%)	New smear-negative n (%)	New EPTB n (%)	Re-treatment smear-positive n (%)	HIV Counseled	HIV Tested	HIV Positive	at HIV Clinic	on ART	on CPT
Centralized period	2003	1719 (100)	1002 (58.3)	550 (32.0)	97 (5.6)	70 (4.1)						
	2004	1665 (100)	923 (55.4)	522 (31.4)	129 (7.7)	91 (5.5)						
	2005	1744 (100)	1002 (57.5)	557 (31.9)	87 (5.0)	98 (5.6)						
	Total	5128 (100)	2927 (57.1)	1629 (31.8)	313 (6.1)	259 (5.1)						
Decentralized period	2007	1669 (100)	978 (58.6)	536 (32.1)	70 (4.2)	85 (5.1)	0	244	82	0	25	77
	2008	1737 (100)	1019 (58.7)	516 (29.9)	98 (5.6)	104 (6.0)	1326	1076	364	221	113	328
	2009	1902 (100)	1047 (55.0)	661 (34.8)	116 (6.1)	78 (4.1)	1630	1498	381	279	109	372
	Total	5308 (100)	3044 (57.3)	1713 (32.3)	284 (5.4)	261 (5.0)	2956	2818	827	500	247	777

Table 2 Treatment outcomes for centralized period (2003-2005) and decentralized period (2007-2009)

		year	Total n (%)	Cure n (%)	Treatment completed n (%)	Failed n (%)	Died n (%)	Defaulted n (%)	Transfer n (%)
Centralized period	New smear sputum-positive pulmonary TB	2003	1041 (100)	600 (57.6)	74 (7.1)	19 (1.8)	111 (10.7)	151 (14.5)	86 (8.3)
		2004	923 (100)	616 (66.7)	58 (6.3)	9 (1.0)	76 (8.2)	105 (11.4)	59 (6.4)
		2005	1012 (100)	660 (65.2)	60 (5.9)	16 (1.6)	99 (9.8)	104 (10.3)	73 (7.2)
		Total	2976 (100)	1876 (63.2)	192 (6.4)	44 (1.5)	286 (9.6)	360 (12.1)	218 (7.3)
	new sputum smear-negative pulmonary and extra pulmonary TB	2003	647 (100)	–	346 (53.5)	–	87 (13.4)	123 (19.0)	91 (14.1)
		2004	403 (100)	–	231 (57.3)	–	44 (10.9)	76 (18.9)	52 (12.9)
		2005	607 (100)	–	354 (58.3)	–	89 (14.7)	92 (15.2)	72 (11.9)
		Total	1657 (100)	–	931 (56.3)	–	220 (13.0)	291 (17.7)	215 (13.0)
Decentralized period	New smear sputum-positive pulmonary TB	2007	999 (100)	742 (74.3)	58 (5.8)	15 (1.5)	83 (8.3)	43 (4.3)	58 (5.8)
		2008	1002 (100)	767 (76.5)	74 (7.4)	18 (1.8)	105 (10.5)	22 (2.2)	16 (1.6)
		2009	1025 (100)	784 (76.5)	76 (7.4)	13 (1.3)	88 (8.6)	43 (4.2)	21 (2.0)
		Total	3026 (100)	2293 (75.8)	208 (6.9)	46 (1.5)	276 (9.1)	108 (3.6)	95 (3.1)
	new sputum smear-negative pulmonary and extra pulmonary TB	2007	629 (100)	–	481 (76.5)	–	97 (15.4)	19 (3.0)	32 (5.1)
		2008	660 (100)	–	541 (82.0)	–	95 (14.4)	15 (2.3)	9 (1.4)
		2009	769 (100)	–	632 (82.2)	–	88 (11.4)	36 (4.7)	13 (1.7)
		Total	2058 (100)	–	1654 (80.2)	–	280 (13.7)	70 (3.3)	54 (2.7)

Table 3 Comparison of treatment outcomes for centralized (2003-2005) and decentralized (2007-2009) period

	Outcome of treatment	Centralized period (%)	Decentralized period (%)	p-value*
New smear sputum-positive pulmonary TB	Cure	63.2	75.8	< 0.0001
	Treatment completed	6.4	6.9	0.512
	Failed	1.5	1.5	0.894
	Died	9.6	9.1	0.515
	Defaulted	12.1	3.6	< 0.0001
	Transfer	7.3	3.1	< 0.0001
	Success (cure and completed)	69.6	82.7	< 0.0001
new sputum smear- negative pulmonary and extra pulmonary TB	Treatment completed	56.3	80.2	< 0.0001
	Died	13.0	13.7	0.771
	Defaulted	17.7	3.3	< 0.0001
	Transfer	12.9	2.7	< 0.0001

*Chi-square test

and the centralized period (13.7% vs 13.0%, respectively; *p-value = 0.771*) among new sputum smear pulmonary and extra pulmonary TB patients.

TB/HIV collaborative activities: There was no such activity during the centralized period and hence there was no data for such activity. Data collection started in quarter 4 of 2007 as shown in table 1.

Ⅳ. Discussion

The community involved strategy and decentralization of TB care in Eastern Region proved to be a highly effective and acceptable alternative to conventional TB care that relies completely on health facility provision of TB care. In the face of decreasing government resources for health and an increasing TB case-load fuelled by HIV, Eastern Region was able to successfully decentralized TB treatment to the community level and this reduced the workload on health staff as ample time gained was used to manage other equally important activities at the facilities.

The key findings of this study were that TB cases detected (all forms) increased during the decentralized period: 1670 (in 2007), 1737 (in 2008), 1902 (in 2009) making a total of 5309 as against the centralized period 1719 (in 2003), 1665 (in 2004), 1744 (in 2005) making a total of 5128, but case-finding among smear-positive pulmonary TB cases stagnated for both the decentralized period and the centralized period 978 (in 2007) , 1019 (in 2008), 1047 (in 2009) vs 1002 (in 2003), 923 (in 2004), 1002 (in 2005), respectively. The 26 diagnostic centres in the region are woefully inadequate to cater for a population of 2,420,927 (2000 census). It is therefore recommended that more diagnostic centres should be opened so that suspected TB cases can easily have access to diagnostic services and on time to avoid delays. It was also observed that diagnostic services and TB care can only be accessed from public health facilities and it is therefore long overdue to bring the private health care providers on board to improve TB case detection and management which will lead to improved treatment outcomes. Several studies showed that Public-Private Mix DOTs (PPM-DOT) has the potential to improve TB case detection and treatment outcomes [18-21].

Majority of TB patients in both periods were new smear-positive pulmonary TB patients. Treatment success which was significantly higher in the decentralized period than in the centralized period (82.7% vs 69.6%, respectively; *p-value* < *0.0001*) may be attributed to a lot of factors which include the fact that TB treatment was successfully decentralized to the door steps of the TB patients. The involvement of the community volunteers, treatment supporters, health staff, opinion leaders and other key stakeholders in the early stage of planning and implementation facilitated the decentralization process. The introduction of new drug formulation where many drugs have been fused into a single tablet (fixed dose combination) made it easy for TB patients to ensure proper compliance during the decentralized period. The removal of streptomycin injection which was replaced with Ethambutol in the new treatment for new cases during the decentralized period also facilitated the decentralization process that is, TB patients do not have to commute to the health facility every day for the injection. This also saved the patients the economic hardship of transport fares and the long distance to the health facility every day. As the drugs were packed in kits for the full treatment duration, drug stock out was thing of the past during the decentralized period. The treatment duration which was shortened as a result of the new drug formulation was also a contributing factor to the high treatment success during the decentralized period. {2(HRZS)+6HT centralized versus 2(HRZE)+4HR decentralized for new cases} and 12(HRZE) centralized versus 2(HRZES)1HRZE +5(HRE). Defaulter rate dropped significantly from 12.1% to 3.6% during the centralized and decentralized periods, respectively (*p-value* < *0.0001*) and this could be attributed to the above mentioned factors and the close monitoring of the patients by treatment supporters. Transfer out dropped from 7.3% to 3.1% during the centralized and decentralized periods and this was due to the fact that TB patients had access to TB treatment and care in the community where he or she lives. For smear-negative pulmonary and extra pulmonary TB cases treatment completed, defaulter rate and transfer out significantly improved during the decentralized period than in centralized period. One alarming observation was the proportion of TB patients who died before completing treatment. Such a high TB deaths makes it difficult or impossible to achieve the 85% WHO target for treatment success. It is therefore recommended that TB deaths should be audited to elicit the true cause of death.

Advantages of decentralizing TB care were that, the training of health staff, volunteers, treatment supporters and community members resulted in increase awareness, decreased stigma, improved documentation, monitoring, supervision and a more educated population. Many persons became more motivated seeing the initial success in community involvement in TB care and witnessing cures among TB patients. The communities' leaders acknowledged the immense contribution these people were putting in TB care and respected them as such. Choosing volunteers rather than the family was exceedingly beneficial because of the immediate, direct involvement of the community in such a key public health issues. As a result of high commitment of the treatment supporters to care for TB patients, most TB patients agreed to stay at their homes and received TB care and this reduced transfer outs which mostly were declared defaulters during the centralized period. TB patients also became motivated to complete their treatment as a result of the inspirational words and care they received from their treatment

supporters. Other advantage of the decentralized TB care was that it increased the human resource base for TB control as compared to the centralized TB care where only health staffs were involved.

The disadvantage of decentralizing TB care was that in communities where members could not keep confidential issues, community involved strategy does not work.

TB/HIV collaborative activities immensely improved management of co-morbidity patients and this can be a learning process for HIV programme to follow suit since this will prevent lost to follow up patients which are increasing in the HIV control.

Limitations:

The study could not separate the effect of decentralization and the new drug formulation and treatment regimen. Also the study could not elicit the causes of TB deaths and which phase of treatment these deaths occurred. There was no data on population of Eastern Region on age groups and to determine the prevalence of TB infection in the different age groups and sex.

Ⅴ. Conclusion

The community involved strategy and decentralization of TB care with empowering people with TB to choose treatment supporters from their communities, communities to provide effective TB care by supporting TB patients throughout treatment until cure, reducing treatment duration and the use of fixed dose combination drugs can immensely improve treatment outcomes. It is therefore recommended that community-involved strategy in TB control should be scaled up to other regions in the country.

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