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**Assessment of Tuberculosis Treatment Completion in an Ethnically Diverse Population
Using Two Data Sources: Implications for Treatment Interventions**

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Abstract

Many adolescents who are prescribed therapy for tuberculosis (TB) infection fail to complete it. This paper presents the results of a demographic and epidemiological assessment of TB treatment completion in adolescent populations using 1) surveillance data from the Los Angeles Health County Department, and 2) a prospective/retrospective medical chart review from targeted clinics. Patients who did not complete the six-month recommended medical treatment for latent tuberculosis therapy (LTBI) averaged 13 weeks in care. Younger age (OR=1.15; 95% CI 1.03-1.29), birth in US (OR=1.92; 95% CI 1.14-3.22 compared to Mexico), and Asian ethnicity were associated with completion of care. In multiple logistic regression analysis, age (OR=.88; 95% CI .78-.98) and Latino ethnicity (OR=.53; 95% CI .29-.95) remained significant predictors of completion of treatment. These findings indicated the need for age-specific educational reinforcement and cultural differentials in completing care for LTBI.

139 words

Introduction

While the majority of persons with TB live in the developing world, TB is also a major health concern in developed countries. In the United States, although the TB case rate has decreased since its height in 1992, the current rate (4.4 cases per 100, 000 people in 1999) is still above the national goal for the year 2000 of 3.5 per 100,000 (MMWR, 1999; McKenna *et al.*, 1995; Zuber *et al.*, 1997). Nationwide, the state of California ranked number one with the highest annual number of reported TB cases. Locally, in Los Angeles County, TB rates were more than double the national rate from 1989 through 1995 and in 1996 new TB cases (1,498 cases) comprised almost 35% of California TB incidence (4,313 cases) and 7% of the total number of new cases in the United States (1,498/21,337).

Failure of patients to complete their medical therapy has been noted as the most important barrier to TB elimination internationally (WHO, 1998) and as one of the most serious remaining problems in the control of tuberculosis in the United States (Ziv, *et al.*, 2001). Patients with TB disease who fail to complete a standard course of therapy are at increased risk for treatment failure and may play a role in the emergence of drug-resistant strains of TB and further spread of TB (Telenti and Iseman, 2000). Patients with latent tuberculosis infection (LTBI) are not infectious; however, 1 in 10 persons will develop active TB if they fail to complete therapy (MMWR, 1990).

Preventive therapy is given to individuals with positive tuberculin tests in an attempt to prevent the disease. At the time of this study, treatment for LTBI entailed a 6 to 12-month drug regimen with monthly clinical monitoring (American Thoracic Society and CDC, 1994). The standard regimen was isoniazid (INH) as a single drug. While a 12-month course of INH provided optimal protection, a 6-month course was recognized to give significant protection

against TB activation. Therefore, some programs may have chosen the 6-month regimen due to operational considerations such as adherence issues, resources, etc... They may have determined that a 9-month regimen was too expensive or that their population or individual patients were unlikely to complete it and may have chosen to continue to recommend 6 months of isoniazid. In the present study, participants were under a 6-month daily regimen of INH.

Literature addressing completion of care for adolescent patients treated for LTBI is scarce. However, it has been noted that adolescence is a time when activation of latent infection is more likely to occur (Comstock and Cauthen, 1993). TB may be more aggressive within the adolescent patient due to hormonal changes and altered protein and calcium metabolism associated with adolescent growth (Starke, 1996; Wilcox and Laufer, 1994).

The present study was designed to gain an insight on the profile of adolescents who fail to complete LTBI therapy. Unlike TB disease, LTBI is not reportable at the national level and, therefore, trends cannot be determined. Since lack of completion of LTBI treatment constitutes a major obstacle to the control of TB, it is important to assess its magnitude in vulnerable populations, including adolescents from ethnic and racial minorities, so that appropriate strategies can be developed.

A review of the literature between 1981 and 2001 on the topic of completion of care rates among adolescents being treated for LTBI identified only a few studies with scientifically-validated outcome results. For example, Starr and colleagues reported adolescent LTBI adherence rates as low as 66% (Starr, 1999). In a similar study conducted in Boston, only 59% of a sample of 157 tenth graders and 74% of 73 seventh graders completed LTBI therapy (Barry , 1990).

It appears that adolescents who are prescribed LTBI therapy often fail to complete

treatment. Adolescents' ability to follow medical recommendations regarding the management and cure of long-term infectious diseases such as LTBI parallels treatment concerns for other conditions such as asthma. Individual characteristics, developmental issues, and family dynamics all impact adolescent's ability to complete the prescribed therapy (Liefoghe, 1997; Jaramillo, 1998). For example, older adolescents, nonwhites, and those from poorer functioning families were found to be less likely to complete therapy (Bender et al., 2000). Barry and colleagues further reported completion rates among seventh graders 1.25 times greater than that of tenth graders (Barry et. al., 1990). Older adolescents may be a particularly challenging group to encourage completing medical therapy. Additional factors unique to treating adolescent populations include feeling different, treatment limitations based on body image, self-esteem, ability to appreciate future consequences, perceived threat of the disease, denial of the need for medication, and the need to focus on short-term goals (Cromer and Tarnowski, 1989). The adolescent's perception of family supportiveness also affects specific behaviors, such as keeping medical appointments and following medical advice (Friedman and Litt, 1987). Issues of personal responsibility versus parental/familial control are especially relevant with the adolescent patient (Blair and Bowes, 1995; Fotheringham and Sawyer, 1995).

In this study, two different data sources, County surveillance and medical chart reviews, were used to quantify the magnitude of LTBI completion of care in the local health department. The characteristics of adolescents who fail to complete LTBI therapy in two Los Angeles County Health clinics were also described. Each method provides unique information. County surveillance data allow the identification of clinics having low completion of care rates. However, although readily available, surveillance data may provide accurate or detailed information about the patients. Medical chart review data, on the other hand, provide more specific information on the patients, such as socio-demographic characteristics and immigration

status.

We present the results of these two independent assessments procedures and provide specific information to identify the components of potential behavioral intervention strategies for future program implementation among adolescents entering and receiving LTBI care. The results of this study will be used to develop health education and promotion as well as provider reinforcement strategies that will be directed and tailored to those individuals exhibiting characteristics associated with lack of completion of care.

Methods

Two independent assessment approaches were implemented in order to provide baseline data for future program implementation and assessment. These included: 1) quantitative assessments of surveillance data from the County Health Department, and 2) a retrospective/prospective medical chart review from the targeted clinics.

Surveillance data

The Los Angeles County Health Department provided statistics on the total number of patients started on LTBI treatment as well as the proportion who complete care. Surveillance data were obtained for 1995 and 1996.

Medical Chart Reviews

Two clinic sites in Los Angeles County were selected to participate in the medical record review. These sites were the largest providers of adolescent LTBI care in the County, and reflected the socio-demographic characteristics of adolescents receiving care for LTBI from Health Department statistical reports. The medical record review assessment of an adolescent cohort diagnosed as needing LTBI treatment and attending the clinic sites was conducted over a 15-month period.

All adolescents entering care for LTBI during a three-month window period (October to December 1995) were included in the baseline assessment. Essentially, we reviewed the charts of the patients who had completed care during this window period back to when the patients first began treatment which was as early as April 1995 (retrospective chart review). We also reviewed the charts of those who had started treatment during this window period and followed them until they completed their treatment program which was as late as July 1996 (prospective chart review). These records provided information concerning treatment regimen, appointment history, length of treatment and completion of care, defined as having completed at least 5 months of treatment and having a notation from the clinician that care was completed. Socio-demographic variables collected included gender, race/ethnicity, primary language, age at start of treatment, site of care, birthplace, whether or not the individual was born in the United States and how long they have resided in the United States.

All charts were reviewed and abstracted by trained researchers. A sample of the abstracted results was independently validated by the program manager who identified an inter-rater reliability of greater than 95 percent for all items.

Statistical Analysis

All analyses were performed with SPSS. Frequencies and percentages were calculated for categorical variables and descriptive statistics including means and standard deviation were obtained for continuous variables. Age was used as both a continuous and categorical variable. The outcome variable, completion of care was cross-tabulated with socio-demographic characteristics (independent variables). To ascertain the most important demographic predictors of completion of care in this population and to examine the impact of confounding variables evaluated in the univariate analysis ($p < .05$), multiple logistic regression model analyses were performed.

Results

Surveillance Assessment

Table 1 presents the number of adolescents initiating and completing treatment for LTBI therapy for years 1995 to 1996, as reported by the Los Angeles County Tuberculosis Control Program. The number of adolescents being treated for LTBI increased from 1995 to 1996. Overall, only 52.6% of adolescents initiating treatment completed care. The ethnic distribution of patients receiving treatment was 69.6% Hispanic, 20.1% Asian, 5.7% white/others, 4.6% African American. Ethnic differences with respect to treatment outcomes were also noted, with Asian adolescents having the highest completion rates (62.3%) and African/American adolescents the lowest, 41.0%. Hispanics and white/others adolescents were found to have an intermediate completion rate of 50.5% and 52.5% respectively.

Medical Chart Review

A combined clinic site total of 478 patient medical charts were reviewed for baseline assessment of LTBI regimen compliance (Table 2). The adolescents were primarily Hispanic (62.7 %) and predominantly foreign born; 60.6% of the sample was born outside of the United States. Most of the adolescents were born in Spanish-speaking countries; the largest percentage of adolescents was from Mexico (28.2% of the total sample). The majority of adolescents began treatment within two years of immigration (24.5% began within the first year of immigration and 20.6% began treatment during the second year of residency in the United States). Most adolescents were referred to the TB clinics through school referral mechanisms (74.0%) while a smaller percentage (10.8%) required LTBI treatment due to actual contact with a TB case. Males comprised 55.4% of the sample. The study populations from the two sites differed in terms of gender, ethnicity, age at start of treatment, birthplace and duration of immigration.

Of the 478 individuals included in this analysis, 331 (71.3%) completed their LTBI treatment. Significant differences between the adolescents who completed care and those who did not are noted in Table 3. Individuals who did not complete treatment were older, 15.4 versus 15.0 years of age ($F= 6.257, P < .05$). US-born adolescents were significantly more likely to complete care than Mexican-born adolescents ($OR=1.92, p=.014$) and adolescents born in other countries ($OR=1.75, p=.027$). Ethnic differences were evident when comparing completion rates. Asian adolescents were the most likely to complete treatment (81.3%, $X^2_{(3)} = 13.89, p < .05$ versus 60% for whites and others). Gender did not affect completion rates.

The average number of weeks in treatment for those who completed therapy was 27 weeks; 147 individuals dropped out of care, or 28.7 percent of the total group started on LTBI therapy. The average number of weeks of treatment received by patients who did not complete treatment amounted to 13 weeks. And 46.9% of participants who discontinued treatment did so within 3 months of the start of treatment.

The results of the multiple logistic regression model predicting completion of care are presented in Table 4. The logistic model included gender, age at start of treatment, site of care, and ethnicity. Age and Hispanic/Latino ethnicity were found to be predictors of completion of care. Older adolescents were less likely to complete care than younger adolescents ($OR=.88, 95\% CI .78-.98$) and Hispanic/Latino adolescents were half as likely to complete care as Asian adolescents ($OR=.53; 95\% CI .29-.95$).

Discussion

Overall completion of treatment among adolescents entering care at one of the Los Angeles County Clinics during 1995 to 1996 was 52.6 percent, compared to the 71.3 percent rate identified in the medical chart review conducted during the same time period. The average length of treatment for patients who do not complete care amounts to 13 weeks and 46.9% of the

individuals who dropped out did so within 3 months of treatment. Completion of care was significantly associated with age at start of treatment, site of care, birthplace, and ethnicity. After adjusting for potential confounding, age at start of treatment and Latino/Hispanic ethnicity remained significant predictors of completion of care.

Comparison of completion of care data from the two independent assessment techniques yielded two different estimates and substantiated our initial impression regarding the underreporting of LTBI cases by surveillance data. The discrepancy in overall completion of care rates might have stemmed from underreporting in the surveillance data as County TB Control Programs often fail to receive approximately 20-30% of the LTBI yearly closure records, due to misplaced or lost medical charts from the numerous reporting clinics (MMWR, 1993). In this instance, it seems like the underreporting particularly affected cases that completed therapy. This might be due to the fact that patients who completed therapy were in care for a longer period of time, thus the probability of their charts being lost or misplaced increased with time. In addition, the differences between the two methods might have been due to reporting errors. Such errors were more likely to happen when clinic staff, in addition to their already demanding daily job requirements, had to report such data to the state collecting agency. On the other hand, when charts were reviewed and abstracted by trained researchers with a sample of the abstracted results independently validated by the program manager, reporting errors or omissions were less likely to occur. We believe that the chart review technique provided a more accurate estimate of completion of care rates and that independent assessment techniques such as chart reviews should be used as a baseline indicator for planned educational programs in the study clinics. Chart reviews provided additional information concerning adherence behavior not often provided in statistical reports such as specific socio-demographic characteristics and immigration status and are more accurate than surveillance data because underreporting and errors are likely to

occur.

The data presented in this study have implications for the development of strategies to improve completion of care rates among adolescents being treated for LTBI. An important finding that should be addressed by health professionals in the development of intervention strategies is the significant drop out of care during the early stages of treatment. The cost of preventive therapy is highest during the initial treatment period in which laboratory workup costs, diagnosis, counseling and scheduling of future appointments are made. This high upfront cost makes it all the more important to assure that adequate time is invested into patient education and understanding of the long-term commitment of medication-taking and appointment-keeping behaviors. The need for reinforcement of completion of care behaviors early in the treatment phase is critical for ensuring completion of care.

The finding that Latino adolescents were significantly less likely to complete therapy than their Asian counterparts confirms previous reports on ethnic disparities with regard to adherence to tuberculosis preventive therapy. More specifically, Ailinger and Dear (1998) found that “adherence to treatment is a problem of great magnitude among Latino immigrants.” This is particularly relevant as TB disproportionately affects those foreign-born individuals and the majority of Latino adolescents in our study were born outside the United States. Because of the importance of the family in Latino culture, health professionals might include the family’s health in teaching programs have been suggested as efficient ways to improve adherence among Latino adolescents.

The age differences in completion of care corroborate the results of a previous study conducted in Boston (Barry et al, 1990). Our results indicate that older adolescents may be a particularly challenging group to encourage completing therapy. One possible explanation for the age differences might be that parental involvement is less present for older adolescents than for

younger ones. In light of this finding, future research should focus on developing age-sensitive educational reinforcement. Intervention programs aimed to promote adherence should be tailored to this age group.

Treatment of LTBI may be the first time adolescents need to take medication over an extended period of time. The literature has identified several programs that facilitate adolescent adherence to long-term medical regimens (Evans *et al.*, 1997; Schlenk and Boehm, 1998). However, unlike LTBI therapy, these medical regimens address diseases in which severe and immediate physical symptoms of non-adherence will occur. For example, non-adherence to asthma or diabetes medical regimens may result in severe wheezing or hypoglycemic shock, both requiring emergency room visits (Wasilewski *et al.*, 1996; Schlundt *et al.*, 1994; O'Hara *et al.*, 1966). This is not true for LTBI non-adherence, although an incomplete treatment regimen increases the likelihood of developing an active case of TB in the future. Methods to improve adolescent treatment adherence include the delivery of cues, or reminders, to take medication, increasing emotional support from friends, and improving the social acceptance of the need to use medication (Blair and Bowes, 1995; Slack and Brooks, 1995).

Those methods that proved to be successful in improving medication compliance in the asthmatic or diabetic adolescent patient may be applicable with the adolescent needing LTBI treatment. Peer counseling and contingency contracting are two such intervention techniques that have been used with adolescent populations (Morisky and Ebin, 2000). An adolescent peer is an ideal source of social support and encouragement for a newly diagnosed adolescent patient requiring medical treatment. Contingency contracting is a means of reinforcing the desired behavior of medication compliance by providing incentives or rewards (Self *et al.*, 1996). Contingency contracting has proven to be quite successful in enhancing compliance with TB

treatment in South Carolina (Snider et al., 1989; Pozsik et al., 1993). In this case, a nurse practitioner tailored different incentives to individuals based on specific needs. Incentives have been very successful in increasing return rates for TB skin-test readings, vaccination programs, and first TB follow-up appointment (Chaisson et al., 1996; Unti et al., 1997; Pilote et al., 1996). A recent study found that non-monetary and monetary incentives dramatically increased the return rate for TB skin test reading among drug users who are at high risk of TB infection (Malotte et al., 1999). It has been suggested that contingency contracting and the involvement of parents in adolescent treatment might promote long-term adherence to medical regimens (Miller, 1994). However, the relationship between the parent and adolescent, and need to avoid possible parent-adolescent conflict, must be considered prior to encouraging parental involvement in the adolescent's treatment regimen. Where appropriate, parental involvement could enhance and complement the adolescent's treatment outside the healthcare setting, providing continuity of care and familial social support. Differences in completion of rate with regards to race/ethnicity and country of birth suggest that cultural sensitivity must be an integral component to any program addressing compliance within this ethnically diverse population.

Some limitations of this study should be noted. The County Health Clinics collects only information on the demographic characteristics of the patient population. Additional information on predisposing, enabling, facilitating factors and existing barriers, found in the literature to be associated with staying in care (for example diabetes and asthma), were not available from the health county department or from the medical chart reviews. Therefore, we were unable to take these other factors into consideration in our analysis; the effects of age might be mitigated by these unmeasured factors.

Conclusions/Recommendations

This study's methodology represents an attempt to provide scientifically validated,

independent assessment techniques in quantifying completion of care rates among adolescents receiving LTBI treatment. The two sources of information used for the needs assessment, i.e., surveillance data from the County TB Control Program and medical chart reviews, provide important information for the design, implementation, and evaluation of educational strategies to improve adolescent's adherence to medical recommendations and completion of treatment for latent tuberculosis.

The fact that half of those individuals who discontinued care (dropped out) did so within 3 months of treatment indicates the need for early intervention and tailored educational messages. Preventing early drop out of care as a result of increased educational counseling and staff reinforcement may reduce the overall cost per completed case, resulting in a more efficient and cost effective TB control program. Not understanding the importance of compliance can be addressed by demonstrating the problems of resistance and activation of infectious tuberculosis. This may have a direct effect on the content of educational materials and tailored counseling approaches.

A disproportionate number of Latino and non-U.S. born adolescents receiving LTBI treatment at the two clinic sites indicates that cultural sensitivity to ethnic issues must be an integral component to any program addressing compliance within this ethnically diverse population. Furthermore, given the finding that older adolescents are more likely to discontinue therapy for LTBI treatment indicates the need for tailored educational approaches to this group as well.

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TABLE 1
Treatment Completion Rates for Adolescents 12-18 Years of Age Receiving LTBI
Therapy for Tuberculosis in Los Angeles County Health Care Centers by Racial Groups*:
1995 and 1996

Year	Ethnicity	Treatment Started N	Treatment Completed N (%)
1995	Asian	531	320 (60.3%)
	Black/African American	99	41 (41.4%)
	Hispanic/Latino	1743	824 (47.3%)
	White and Others	144	72 (50.0%)
	All ethnicities	2517	1257 (49.9%)
1996	Asian	587	377 (64.2%)
	Black/African American	157	64 (40.8%)
	Hispanic/Latino	2126	1130 (53.2%)
	White and Others	174	95 (54.6%)
	All ethnicities	3044	1666 (54.7%)
Total	Asian	1118	697 (62.3%)
	Black/African American	256	105 (41.0%)
	Hispanic/Latino	3869	1954 (50.5%)
	White and Others	318	167 (52.5%)
	All ethnicities	5561	2923 (52.6%)

*Reported data from the Los Angeles County TB Control Program

TABLE 2

**Socio-demographic Characteristics of the Adolescent Population at two study Sites
(N=478)**

	Site 1 (N=234)	Site 2 (N=244)	Total Population (N=478)
	n (%)	n (%)	n (%)
Gender*			
Male	112(47.9)	153(62.7)	265(55.4)
Female	122(52.1)	91(37.3)	213(44.6)
Ethnicity*			
Hispanic/Latino	148(63.5)	150(62.0)	298(62.7)
Black/African American	37(15.9)	9(3.7)	46(9.7)
White/other	32(13.7)	3(1.2)	35(7.4)
Asian	16(6.9)	80(33.1)	96(20.2)
Age at start of Treatment* (mean, sd)	15.37,1.88	14.91,1.57	15.14, 1.74
12-14	96(41.0)	147(60.5)	243(50.9)
15-16	84(35.9)	67(27.6)	151(31.7)
17-18	54(23.1)	29(11.9)	83(17.4)
Birthplace*			
US-born	37(16.7)	128(67.7)	165(39.4)
Mexico	83(36.1)	35(18.5)	118(28.2)
El Salvador	29(12.6)	2(1.1)	31(7.4)
Guatemala	21(9.1)	4(2.1)	25(6.0)
Philippines	6(2.6)	8(4.2)	14(3.3)
Other	54(23.5)	12(6.3)	66(15.8)
Began LTBI treatment within*			
First year of immigration	49(26.5)	20(20.6)	69(24.5)
Second year of immigration	50(27.0)	8(8.2)	58(20.6)
3-5 th year of immigration	33(17.8)	22(22.7)	55(19.5)
More than 5 years	53(28.7)	47(48.5)	100(35.4)
TOTAL	185(100)	97(100)	282(100)
School as referral source	163(74.1)	176(73.9)	339(74.0)

* p<0.05

TABLE 3
Comparison of Selected Demographic Variables: Completed versus Not Completed by

Assessment of Completion of Care

Study Site (N=478)

	Site 1 (N=234) Completed care		Site 2 (N=244) Completed care		Total (N=478) Completed care	
	Yes	No	Yes	No	Yes	No
Total	147(62.8)	87(37.2)	184(75.4)	60(24.6)	331(71.3)	147(28.7)
Gender						
Male	70(62.5)	42(37.5)	117(76.5)	36(23.5)	187(70.6)	78(29.4)
Female	77(63.1)	45(36.9)	67(73.6)	24(26.4)	144(67.6)	69(32.4)
Age						
Mean (sd)	15.22(1.90)	15.62(1.82)	14.83(1.46)	15.16(1.86)	15.00(1.68)	15.43(1.85)*
Center						
Site 1					147(62.8)	87(37.2)**
Site 2					184(75.4)	60(24.6)
Birthplace						
Mexico	51(61.4)	32(38.6)	23(65.7)	12(34.3)	74(62.7)	44(37.3)*
Other	66(60.0)	44(40.0)	22(84.6)	4(15.4)	88(64.7)	48(35.3)
US	27(73.0)	10(27.0)	99(77.3)	29(22.7)	126(76.4)	39(23.6)
Ethnicity						
Hispanic	93(62.8)	55(37.2)	106(70.7)	44(29.3)	199(66.8)	99(33.2)*
Black	25(67.6)	12(32.4)	6(66.7)	3(33.3)	31(67.4)	15(32.6)
White/other	20(62.5)	12(37.5)	1(33.3)	2(66.7)	21(60.0)	14(40.0)
Asian	9(56.2)	7(43.8)	69(86.2)	11(13.8)	78(81.2)	18(18.8)
Immigration						
1 st year	30(61.2)	19(38.8)	16(80.0)	4(20.0)	46(66.7)	23(33.3)
2 nd year	32(64.0)	18(36.0)	6(75.0)	2(25.0)	38(65.5)	20(34.5)
3 rd -5 th year	20(60.6)	13(39.4)	17(77.3)	5(22.7)	37(67.3)	18(32.7)
> 5 years	31(58.5)	22(41.5)	32(68.1)	15(31.9)	63(63.0)	37(37.0)
US-born	27(73.0)	10(27.0)	99(77.3)	29(22.7)	126(76.4)	39(23.6)

*p<.05

**p<.01

TABLE 4
Logistic regression predicting completion of care (N=475)

	Odds Ratio	95% CI	P value
Male	1.02	0.68-1.53	0.9158
Age	0.88	0.78-0.98	0.0238
Site 1	0.70	0.45-1.08	0.1094
Race/Ethnicity (Asian is reference group)			
Black	0.59	0.25-1.38	0.2193
Hispanic/Latino	0.53	0.29-0.95	0.0318
White/others	0.47	0.19-1.17	0.1063

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