

Estimating tuberculosis burden and case detection in Pakistan

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SUMMARY

BACKGROUND: The National Tuberculosis Control Programme (NTP) in Pakistan has officially achieved a tuberculosis (TB) case detection rate of 64% in 2011, with an estimated incidence rate of 230 per 100 000 population, but is likely to be missing an unknown number of patients, particularly in the private sector.

SETTING: All public and private sector providers in 12 randomly selected districts of Pakistan were included.

OBJECTIVE: To estimate TB incidence and TB notification rates in Pakistan in 2012.

DESIGN: A surveillance system was established among all eligible non-NTP providers in selected districts from January to March 2012. Record linkage and capture-recapture analysis was conducted.

RESULTS: Of 8346 TB cases identified after record

linkage, 6061 were registered with the NTP. The estimated number of unobserved TB cases was 10 030 (95%CI 7800–12 910), which meant that the proportion of notified cases was 32% (95%CI 17–49). The calculated annual incidence was 878 000 cases (95%CI 573 000–1 675 000), corresponding to a rate of 497/100 000 (95%CI 324–948) annually in the population.

CONCLUSION: The study estimated that the proportion of cases notified to the NTP was low, with actual incidence rates being higher than official estimates. TB surveillance should be strengthened to reduce under-reporting.

KEY WORDS: tuberculosis; surveillance; record-linkage; capture-recapture analysis

PAKISTAN has adopted World Health Organization targets for tuberculosis (TB) control, including that of detecting 70% of new sputum smear-positive cases occurring each year and of successfully treating 85% of detected cases.¹ In 2011, the estimated incidence of all types of TB in Pakistan was 231 per 100 000 population. Based on these estimates, the country reported a case detection rate of 64% for all types of TB.² It is possible that the case detection rate varies across the country; however, the estimates of disease burden upon which this is based was undertaken at the national level, and we have no reliable estimates for the sub-national level.

While the relatively high case detection rate is encouraging, it is based on estimates rather than direct measures of the disease burden, and it is not certain how correct these estimates are. This is particularly important as comprehensive case detection is essential for the prevention of disease transmission and reduction of the disease burden.

Outside the National Tuberculosis Programme (NTP), private and public health care providers at-

tend to an unknown but probably substantial number of TB patients. These health care providers are instructed to refer patients to the NTP but, as in other developing countries, this happens with varying comprehensiveness of notification.³ While public-private mix approaches can improve case notification,⁴ the NTP faces multiple challenges in expanding this approach. This is particularly important, as non-NTP providers do not always follow NTP guidelines for TB management,⁵ which could contribute to the emergence of clinically significant drug resistance.

Although the TB burden can be measured by prevalence studies, these are costly and time-consuming and may not be feasible.⁶ A simpler method of estimating TB burden and case notification is through assessing the completeness of TB registration by record linkage and capture-recapture techniques.^{7,8} The latter technique has been applied in Egypt and Iraq.^{9,10}

TB surveillance in Pakistan has improved since the introduction of the DOTS strategy in 1990; however, to date the programme has not achieved full coverage of all health care providers. We conducted a

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capture-recapture study involving all TB care providers in the non-NTP sector to estimate the TB burden. As TB is not notifiable by law in Pakistan, it is important to obtain evidence regarding the extent of missing cases from national notifications. The main objective of the present study was to assess the completeness of TB notification from all providers.

METHODS

Study setting

Administratively, Pakistan (population: 177 million in 2011²) is divided into four provinces, which are subdivided into 131 districts. TB services are provided by various institutions and groups. Public providers include the NTP and non-NTP public health services (public hospitals, university hospitals, occupational services such as petroleum companies, prisons, the army, etc). Private health services include private sector hospitals, teaching hospitals and universities, clinics of general practitioners (GPs), polyclinics, health facilities run by various charitable groups, and informal health providers. Some TB cases are also identified by private laboratories. The study data were collected from all care providers in the non-NTP sector, both private and public; routine NTP data were used for record linkage.

The study population consisted of all patients with symptoms suggestive of TB in 12 randomly selected districts in Pakistan. All individuals with a cough of >2 weeks' duration who consulted public or private providers for their symptoms were included. Following a pilot study to assess feasibility,¹¹ data for record linkage were collected from July 2011 to June 2012 and the data from modified diagnostic and laboratory registers was collected on the registers from January to March 2012.

Study design and sampling methods

Prospective surveillance was set up to identify cases presenting to all known providers in the sampled dis-

tricts. Suspects were consecutively enrolled and followed up until confirmation of diagnosis. Stratified cluster random sampling was used to obtain a representative sample from 12 of 131 districts of Pakistan in 2010, with strata defined by four equal-sized groups (quartiles) according to levels of smear-positive notification rates, i.e., quartile 1 (low) <10 smear-positive notification rate; quartile 2 (intermediate) 10–15; quartile 3 (high) 15–21; and quartile 4 (very high) >21. The number of selected districts (Table 1) from each stratum was allocated proportionately weighted on its population size. One district was obtained from stratum 1, 6 from stratum 2, 2 from stratum 3 and 3 from stratum 4. All non-NTP facilities in the selected districts were mapped, and consenting providers were enrolled.

Definitions

Incident TB cases were defined as 1) all TB patients registered with the NTP between 1 January and 31 March 2012, or 2) all TB cases confirmed according to NTP criteria during the same time period for cases known to non-NTP providers.

Registers and record linkage

Four sources of information were used: the NTP TB Register, non-NTP public health facilities, private health facilities and private laboratory facilities. The NTP TB Register was reviewed and data on all patients recorded. Modified TB and laboratory registers were created and reviewed; these data collection tools were used to record the management of patients by non-NTP health care providers without changing their routine practice.^{9,10} These facilities were visited weekly by field officers and district tuberculosis coordinators (DTCs) to check records, with instructions to collect missing names for proper record linkage and evaluate the accuracy and notification status of TB cases. Non-registered non-NTP cases were contacted to verify diagnoses per NTP criteria.

Every eligible patient was recorded in the study

Table 1 Characteristics of the selected districts: sampling category and smear-positive notification rates per 100 000 population

District	Population	Smear-positive notification rate	Category of stratification	All facilities	NTP facilities	Non-NTP facilities
Labella	388256	4	Low	92	4	88
Mirpurkhas	1303938	10	Intermediate	199	13	186
Rawalpindi	4152499	12	Intermediate	1986	25	1961
Khushab	1118820	13	Intermediate	139	13	126
Lodhran	1446195	14	Intermediate	513	9	504
Zhob	342308	15	Intermediate	51	6	45
Washuk	131871	11	Intermediate	14	2	12
Rajanpur	1362341	18	High	259	13	246
Larkana	1196782	19	High	203	9	194
Buner	628331	56	Very high	114	7	107
Battagram	381364	56	Very high	52	5	47
Swat	1561064	71	Very high	172	14	158
Total	14013769			3794	120	3674

NTP = National Tuberculosis Control Programme.

database with four names as a unique identifier: first given name, father's name, grandfather's name and family name. If all four names could not be recalled by the patient, the national ID number was recorded. The NTP register entered in the Excel database (Microsoft, Redmond, WA, USA) was examined two quarters before and one quarter after the study period (i.e., between July 2011 and June 2012) to check and correct any misclassification of patients not diagnosed during the study period or referred late for notification. Confirmed non-registered cases were added after the study period into the NTP register. Forms collected by field officers were forwarded to the DTCs and then to the NTP.

Record linkage was performed using the combination of first, father's and family names as unique identifiers⁹ for each case. If at least three names were found as an absolute match between non-NTP and NTP data, the case was considered as notified. All non-notified cases were entered into a separate TB register in each district maintained by the DTCs. The completeness of the NTP registers was assessed by comparing the list of all patients identified by the study with those recorded in the NTP registers.

TB data were entered in an Access database (Microsoft, Redmond, WA, USA) and NTP data in an Excel spreadsheet. After data cleaning and validation by double data entry of all records, completeness of registration was explored by adding records from all three sources, and duplicates were removed (inventory method). Data quality was improved by cross-validation between data sources.¹²

Capture–recapture analysis

Data from partially overlapping registers of TB in the community were analysed using capture–recapture,¹³ which examines the extent of overlap between sources to estimate the total number of unobserved cases. In particular, log-linear models are typically applied to three or more data registers so that dependencies between sources can be accounted for via interaction terms. Denoting capture by each source as *A*, *B* and *C* and indexing these sources by *i*, *j* and *k*, respectively, the expected counts $E(n_{ijk})$ are expressed as follows:

$$\log E(n_{ijk}) = \mu_0 + \mu_A x_A + \mu_B x_B + \mu_C x_C + \mu_{AB} x_{AB} + \mu_{AC} x_{AC} + \mu_{BC} x_{BC} + \mu_{ABC} x_{ABC}$$

where the *x* terms are indicator variables and the μ terms are log risk ratios, e.g., x_{AB} corresponds to capture by both source *A* and *B*, and μ_{AB} is an interaction term for these sources. Typically, the 3-way interaction term, μ_{ABC} , is omitted so that estimation can proceed. The μ_0 term corresponds to capture by none of the sources and therefore its exponential $\exp(\mu_0)$ provides an estimate of the number of unobserved cases. The total number of cases is then given by $N_{\text{obs}} + \exp(\mu_0)$, where N_{obs} is the total of observed

TB cases. Further details and limitations of the method and assumptions are described elsewhere.^{8,14}

This approach has been used in studies to estimate TB in other resource-limited settings.^{9,10,15} As non-NTP public provider data did not overlap with non-NTP private providers, this could not be used as a third source; non-NTP laboratories were therefore used as a third source, and data from the NTP, non-NTP private providers and the non-NTP laboratories were used for the final log linear analysis. This was preferred, as it was less likely to be compromised by violation of the assumption of independence, as opposed to two linked registers, which do not allow for between-source dependence.^{8,14,16,17}

Eight standard models (including three possible 2-way interactions) and three non-standard models (including 3-way interaction at the expense of one of the 2-way interactions) were applied, and the model with the lowest Akaike Information Criteria (AIC) value was chosen, with lower values indicating better models. This is a standard method for model selection in capture–recapture studies.⁸ These models also incorporate the 2-source overlap between NTP and non-NTP public providers, which must be assumed to be independent. Estimates were therefore an average of the 3-source model and this 2-source model, with the AIC based to some extent on how well the model fits the 2-source data.

The selected model was then used to predict the total number of TB cases in Pakistan by adjusting for the sampling design. This allows for the proportion of observed cases to be estimated (observed/estimated total), denoted the case ascertainment rate; the estimated proportion of notified cases is the number of TB cases after record linkage (NTP) divided by the estimated total.¹⁵ By applying the estimated proportion of NTP notifications to the annual number of notified TB patients in all districts in 2011–2012, we obtained an estimate of the total number of TB patients in Pakistan in 2012. All analyses were performed using Stata version 12 (Stata Corp, College Station, TX, USA).

Ethics approval

Ethics approval for this study was obtained from the National Bioethics Committee of the Pakistan Medical and Research Council. Informed consent was obtained from non-NTP providers, but not from patients, as the registers introduced follow the national guidelines of the nominal public health surveillance system for TB.

RESULTS

Record linkage

Table 2 indicates that a total of 8346 TB cases was identified in the 12 study districts between 1 January 2012 to 31 March 2012. Of these, 6061 (73%) were

Table 2 Contingency table of the three sources: NTP, non-NTP private health facilities and private laboratories, and the overlap between NTP and public sources. The final row in the table corresponds to unobserved cases

NTP	Non-NTP private health facilities	Private laboratory	Non-NTP public health facilities	<i>n</i>
Yes	Yes	Yes		5
Yes	Yes			308
Yes		Yes		17
Yes				5713
	Yes	Yes		61
	Yes			1889
		Yes		288
Yes			Yes	18
			Yes	47
				Unobserved

NTP = National Tuberculosis Control Programme.

recorded in the NTP TB register. Among all cases detected during the study period, 2633 (32%) were diagnosed in the non-NTP sector: 1950 (23% of all cases) in the private health services, 288 (3%) in private laboratories and 47 (0.56%) in non-NTP public health facilities. A total of 348 (4%) patients were known to both the NTP and non-NTP sector, and 2285 (27%) were not notified to the NTP. The Figure displays the distribution of these cases in the four registers in a Venn diagram, identifying the overlap in data sources. In general, there was relatively little overlap between sources.

Capture-recapture analysis

In this study, the model with the lowest AIC score was the non-standard model S1, with two 2-way interactions (NTP×Private, NTP×Laboratory), and one the 3-way interaction between all sources (NTP×Private×Laboratory; Table 3). There was negative dependence for NTP×Private and NTP×Laboratory, although the 3-way interaction was positive. The estimated proportion of notified cases in this study was 33%

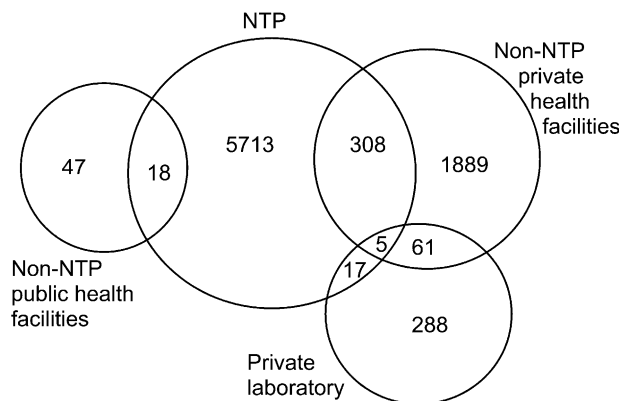


Figure Venn diagram showing study participants (*n* = 8346) by source of identification. NTP = National Tuberculosis Control Programme.

(95% confidence interval [CI] 17–49), and the estimated case ascertainment rate was 45%.

The proportion of cases notified to the NTP was estimated at 32% (95%CI 17–49) after adjusting for sampling design. When applied to NTP data for the whole of Pakistan in 2011, we obtained an estimated incidence of 878 000 cases (95%CI 573 000–1 675 000) annually and a rate of 497/100 000 (95%CI 324–948).

DISCUSSION

In this capture-recapture study, we found that a substantial proportion of TB cases were identified in the non-NTP public and private sectors. The proportion of notified cases for all TB cases after record linkage in Pakistan and the case ascertainment was quite low. The corresponding TB incidence rate was more than double the official rate. To obtain a high degree of precision, the recommended sampling fraction is 50%.¹⁸ Due to the huge number of facilities in Pakistan and resource constraints, 12 districts

Table 3 Estimated numbers of unobserved tuberculosis cases in the study area from the eight standard models (M1–M8) and three non-standard models (S1–S3) that include a 3-way interaction

Model	NTP× Laboratory	NTP× Private health facilities	Laboratory ×Private health facilities	NTP× Laboratory ×Private health facilities	<i>n</i>	95%CI	Detected %	Notified %	AIC*	Model weight %
S1	Yes	Yes		Yes	10 030	7 800–12 910	45.4	33.0	78.3	48.7
M8	Yes	Yes	Yes		18 500	10 890–31 420	31.1	22.6	78.9	36.4
M6	Yes		Yes		33 930	30 090–38 260	19.7	14.3	81.8	8.5
S2	Yes		Yes	Yes	33 930	30 090–38 260	19.7	14.3	83.4	3.8
M5	Yes	Yes			10 030	7 800–12 910	45.4	33.0	84.2	2.6
S3		Yes	Yes	Yes	54 680	38 570–77 530	13.2	9.6	99.2	0.0
M7		Yes	Yes		54 680	38 570–77 530	13.2	9.6	99.8	0.0
M4			Yes		37 510	33 410–42 110	18.2	13.2	103.5	0.0
M2	Yes				29 670	26 540–33 170	22.0	15.9	147.9	0.0
M3		Yes			25 060	20 040–31 350	25.0	18.1	172.8	0.0
M1					32 900	29 540–36 640	20.2	14.7	177.6	0.0

*AIC scores and model weights are explained in the Methods. Models are ordered in terms of AIC score, with lower values indicating better models. NTP = National Tuberculosis Control Programme; CI = confidence interval; AIC = Akaike Information Criteria.

were sampled. This is the reason for the low degree of precision. Future studies in Pakistan would need to be conducted at provincial rather than national level.

Assumptions and limitations of capture-recapture analysis are described elsewhere.^{8,19-24} The independence assumption is often violated in epidemiological studies, as service providers may collaborate, leading to a positive dependence and hence underestimation of the number of unobserved cases. Conversely, if service providers are largely distinct, a negative dependence between sources may occur, leading to overestimates.²⁵ Individual-level heterogeneity in patients' propensity to be recorded in different registers can produce similar effects.²⁶ Log-linear models may address dependencies via interaction terms, but standard models cannot account for potential 3-way interactions (or the n -way interaction in an n source study). Other assumptions are that record linkage is perfect, and that the population is closed, i.e., the effect of death and migration is small. Late referrals or notifications can lead to misclassification, which was reduced by examining NTP registers two quarters before and one quarter after the study period. This also reduced violation of accuracy of diagnosis, and cases captured outside the study period were excluded. The frequent visits by research assistants ensured good quality of the non-NTP records and should stimulate further collaboration with non-NTP providers.

The fact that three registers were linked allowed us to account for possible pair-wise dependencies between sources via interactions in log-linear models.²⁷ However, there is a strong possibility of a 3-way interaction, unmeasured heterogeneity, or both. We were led to this conclusion because the standard saturated model gave a good model fit but unreasonably high estimates of TB cases. We therefore selected a non-standard model that allowed for a 3-way interaction at the expense of the lower-order interaction between non-NTP private health facilities and private laboratories. We attempted to assess potential heterogeneity according to age and found that this did not affect our results; however, it is of course not possible to assess heterogeneity according to unmeasured covariates, such as care-seeking behaviour. As the 95% CIs were wide due to low overlap between registers, our conclusions are uncertain.

High-quality information on individual unique identifiers (four names in Urdu) minimised violations of perfect record linkage. Visits of field officers every week reduced failure to match incomplete registers. The study period lasted 3 months to reduce violations of the closed population assumption by reducing population mobility during this time. All participants were defined by the study period; we checked the registers before and after this period to ensure persons were not missed or mistakenly included in the study. The study did not include asymptomatic cases or those who

do not have access to health care providers. These factors may contribute to heterogeneity and violate the assumptions of capture-recapture analysis; the results should therefore be viewed with some caution.

Impact on future public health policy

The estimated proportion of notified cases of the NTP surveillance for all TB cases in Pakistan is higher than the latest WHO estimates.² The involvement of all health care providers with the NTP should improve the future completeness of routine TB surveillance notification. Although model uncertainty means that our results do not provide an accurate estimate of true TB incidence in Pakistan, we nevertheless conclude that the TB burden has been underestimated.

Non-NTP providers appear to use NTP laboratories fairly frequently. This may be because services are provided free of charge to individuals with presumed TB by these laboratories, and due to confidence in the services offered. However, the NTP registration process occurs after the drugs have been provided, and not automatically from the laboratory register, which should ideally be done to identify cases who are detected but never registered and started on treatment.

To estimate the completeness of TB notifications in resource-limited countries, use of record-linkage studies and capture-recapture techniques will increase communication between all those involved in TB diagnosis and care and improve TB surveillance systems. Capture-recapture modelling should be undertaken with care, as violation of assumptions can lead to biased estimates, and the results should be treated with caution. Nevertheless, our analyses indicate a high TB incidence rate in Pakistan. It has been noted that anti-tuberculosis drugs are available over the counter,²⁸ and when considered alongside the high quantity of drugs used by the NTP for TB patients, an estimated annual incidence of over 800 000 cases is not unreasonable. A high proportion of non-NTP cases are diagnosed at NTP laboratories but are under-notified. Cross-checking of the laboratory and TB registers is recommended to complete the registration of all cases.

CONCLUSIONS

In this study, we have used record linkage and capture-recapture techniques to show that the proportion of cases notified to Pakistan's NTP may be quite low, and that our estimates of Pakistan's annual incidence rate are much higher than 2011 WHO estimates. Improved notification by all providers and access to proper treatment to reduce TB transmission is recommended to reduce the TB burden in the community.

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R É S U M É

CONTEXTE : Le Programme National de Lutte contre la Tuberculose (PNT) au Pakistan a atteint officiellement un taux de détection des cas de tuberculose (TB) de 64% en 2011, avec un taux d'incidence estimé de 230 pour 100 000 habitants, mais il est probable qu'il a laissé échapper un nombre inconnu de patients, particulièrement dans le secteur privé.

CADRE : On a inclus tous les pourvoyeurs de soins des secteurs public et privé dans 12 districts sélectionnés au hasard au Pakistan.

OBJECTIF : Estimer l'incidence de la TB et la déclaration de la TB au Pakistan en 2012.

SCHÉMA : On a élaboré un système de surveillance chez tous les pourvoyeurs de soin éligibles hors PNT dans les districts sélectionnés entre janvier et mars 2012. On a analysé les liens des déclarations et une analyse capture-recapture.

RÉSULTATS : Après lien entre les dossiers, on a identifié au total 8346 cas de TB, dont 6061 étaient enregistrés au PNT. Le nombre estimé de cas de TB non observés a été de 10 030 (IC95% 7800–12 910), ce qui implique que la proportion de cas déclarés était de 32% (IC95% 17–49). L'incidence annuelle calculée a été de 878 000 cas (IC95% 573 000–1 675 000), ce qui correspond à un taux de 497 (IC95% 324–948) pour 100 000 habitants annuellement dans la population.

CONCLUSION : Cette étude estime qu'une faible proportion des cas a été déclarée au PNT, les taux d'incidence étant beaucoup plus élevés que les estimations officielles. Il est nécessaire de renforcer la surveillance de la TB pour réduire la sous-déclaration.

R E S U M E N

MARCO DE REFERENCIA: El Programa Nacional contra la Tuberculosis (PNT) de Pakistán alcanzó oficialmente una tasa de detección de casos de 64% en el 2011 y la tasa de incidencia se calculó en 230 por 100 000 habitantes, pero es posible que estas cifras excluyan un número desconocido de pacientes, sobre todo del sector privado. En el presente estudio se incluyeron los profesionales de salud del sector público y el sector privado de 12 distritos de Pakistán escogidos de manera aleatoria.

OBJETIVO: Calcular la incidencia de tuberculosis (TB) y evaluar la calidad de la notificación de casos en Pakistán en el 2012.

MÉTODOS: De enero a marzo del 2012 se estableció un sistema de vigilancia de todos los profesionales de salud externos al PNT que cumplían con los requisitos en los distritos escogidos. Se vincularon los registros y se practicó un análisis de captura y recaptura de datos.

RESULTADOS: Tras la vinculación de los registros se detectaron 8346 casos de TB y 6061 se encontraban registrados en el PNT. El número calculado de casos pasados por alto fue 10 030 (IC95% 7800–12 910), lo cual indica que la proporción de casos notificados fue 32% (IC95% 17–49). La incidencia anual calculada fue 878 000 casos (IC95% 573 000–1 675 000), lo cual corresponde a una tasa de incidencia de 497 por 100 000 habitantes por año (IC95% 324–948).

CONCLUSIÓN: En el estudio reveló una baja proporción de casos notificados al PNT de Pakistán, con tasas de incidencia superiores a los cálculos oficiales. Es necesario fortalecer la vigilancia de la TB con el fin de corregir la subnotificación.