INT J TUBERC LUNG DIS 10(4):415–421

Undetected burden of tuberculosis in a low-prevalence area

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SUMMARY

SETTING: Under-ascertainment and under-reporting of tuberculosis (TB) hampers surveillance and control. Case detection is improved by record linkage of case registers and under-reporting can be estimated by capture-recapture (CR) analysis.

OBJECTIVES: To assess the completeness of the TB registration systems and estimation of TB incidence and under-reporting in the Piedmont Region of Italy in 2001.

METHODS: Record linkage of the 'physician notification system', the TB laboratory register and the hospital records register, and subsequent three-sample CR analysis.

RESULTS: Record linkage identified 657 TB cases; CR analysis estimated 47 (95%CI 31–71) unrecorded cases. Under-reporting of the 'physician notification system' was estimated at 21% (95%CI 20–23). The overall estimated TB incidence rate was 16.7 cases per 100 000 population (95%CI 16.3–17.3), varying according to the subset investigated: 12.7 for individuals from low TB prevalence countries and 214.1 for immigrants from high TB prevalence countries; 13.1 and 25.8 for persons aged $<$ and $\geq$60 years, respectively; and 32.1 in Turin, the regional capital and 10.8 in the rest of the region.

CONCLUSIONS: When multiple recording systems are available, record linkage and CR analysis can be used to assess TB incidence and the completeness of different registers, contributing to a more accurate surveillance of local TB epidemiology.

KEY WORDS: tuberculosis; epidemiology; capture-recapture; low-prevalence country

MEANINGFUL QUANTIFICATION and description of the distribution of tuberculosis (TB) within a community is an essential part of any TB control programme.[1,2] Under-reporting by local surveillance systems in countries with high and low endemicity for TB leads to underestimation of the TB burden and makes descriptions and interpretation of spatial and temporal variations unreliable.[3,4] In 2003, the World Health Organization (WHO) estimated that under-reporting of TB in Italy was 12%,[5] but according to other reports, it reached 37–54% in some areas of the country.[6,7]

Case detection can be improved by record linkage, i.e., comparing patient data in multiple registers,[6] and under-reporting can be estimated by capture-recapture (CR) analysis. The latter uses information after record linkage of various data sets, evidenced by the observed overlap in the registers, to estimate the number of cases unknown to all sources.[8] CR analysis was first used in studies of animal population biology and, more recently, in epidemiology.[8–10] It is now increasingly used to estimate the burden of both noncommunicable[11,12] and communicable diseases,[13,14] including TB.[4,15,16] We undertook record linkage of multiple information systems and subsequently conducted a CR analysis to estimate the TB incidence in the Piedmont Region of Italy in 2001, and to assess the performance of the surveillance system.

STUDY POPULATION AND METHODS

Study population and case definition

We focused the study on residents of the Piedmont Region, Italy, during 2001. According to the fourteenth national census in 2001, the total resident population of the Piedmont Region was 4 214 677, of whom 2 034 161 (48%) were men, 3 027 034 (72%) were aged <60 years, 865 263 (20%) lived in Turin, the capital, and 84 070 (2%) were immigrants from high TB prevalence countries (HTBCs), i.e., countries with an annual incidence of >80 cases per 100 000 population. About one third of the immigrants were from North Africa, one third from Eastern Europe or the former Soviet Union, and the remainder came from Asia, sub-Saharan Africa and Latin America.[17]

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Article submitted 12 May 2005. Final version accepted 31 October 2005.

We included in the study all new cases of pulmonary TB (PTB) and non-PTB diagnosed in the Piedmont Region in 2001 and known to at least one of three TB registers. TB cases were defined according to the guidelines of the WHO and the European Region of the International Union Against Tuberculosis and Lung Disease Working Group for Uniform Reporting on Tuberculosis Cases.[1,18] Cases were classified as follows: confirmed (culture-confirmed or smear-positive) or probable cases (clinically, radiologically or empirically diagnosed); PTB or non-PTB; patients aged $<$ or $\geqslant$60 years; resident in the Turin metropolitan area or in the remaining parts of Piedmont; and born in HTBCs or in low TB prevalence countries (LTBCs), i.e., countries with an annual incidence $<$80 cases/100 000 population. Cases caused by environmental mycobacteria (21 records) were excluded to improve the specificity and the positive predictive value (PPV) of each register.

The research was conducted on mandatory regional registries set up following regional and national law; therefore, according to national legislation, no informed consent is required to obtain and store the information for public health and research purposes. The authors of the paper were authorised by the regional public health authorities to keep and analyse the data and to produce reports.

Sources of cases and record linkage

Three sources were used to identify TB cases between 2000 and the first half of 2002. The first was the 'physician notification system', including both notification and treatment outcome monitoring registers. The second source was the laboratory TB register, which collects reports of microscopic and culture identification of mycobacteria from the regional reference microbiology laboratories. The local public health service periodically checks these records for false-positive reports due to environmental mycobacteria and laboratory cross-contamination. Data from the 'physician notification system' and laboratory sources are not routinely merged and, according to national legislation, only the notification register contributes to the official national TB statistics. The third source of cases was the hospital discharge records register. Hospital discharge records including any form of TB (International Classification of Diseases-IX codes 010-018 and 647.3) were selected.

After correction for duplicate entries in each of the three registers, the records of TB cases were matched by a deterministic linkage procedure using the identifier's full name, date of birth and sex. Apparent matches were reviewed to avoid homonymous and synonymous errors. Prevalent cases diagnosed in 2000 were identified and were excluded from the study, whereas cases incident in 2001 were corrected for late reporting in the first half of 2002. A case-verification procedure was performed by inspecting the hospital charts of patients identified uniquely in this source to improve the PPV of this register. A similar procedure was not performed for cases identified in the other sources, as case verification is regularly performed by the public health care services. We defined observed source-specific sensitivities as the number of TB patients in each register divided by the total number of TB patients observed after record linkage. As local TB surveillance and control guidelines advise to investigate the human immunodeficiency virus (HIV) status of adults with TB after obtaining consent, information on HIV status was also collected.

Capture-recapture analysis

To use log-linear models for CR analysis, data from at least three different, partially overlapping and preferably independent sources are necessary.[8,19] The annual incidence and the source-specific sensitivity (i.e., the number of observed TB patients in each of the investigated sources divided by the estimated total number of TB patients by CR analysis) of the regional TB surveillance system were estimated by a three-sample CR analysis.[19] Pair-wise dependency between sources was incorporated into the log-linear models, and possible capture heterogeneity was tested. CR analysis was conducted on the full set of data and repeated for subsets defined according to geographical origin, site of TB, age group, bacteriological status and site of residence, as previously specified. For bacteriological status, due to the availability of only two sources for culture-negative TB patients, a separate calculation was made for microbiologically confirmed and unconfirmed TB cases.

Statistical analyses were conducted using the STATA version 8 software package (Stata Corp, College Station, TX, USA) and the S-PLUS 2000 software package (Mathsoft Inc, Seattle, WA, USA) with the CARE library.[20] Model selection was based on three statistical criteria: deviance, the Akaike information criterion and the Bayes information criterion, to limit the risk of selecting unstable or over-complex models. Point estimates and relative 95% confidence intervals (CIs) for the number of unrecorded cases were obtained using the method of Chao et al.[20]

RESULTS

Record linkage

Overall, we identified 657 incident cases of TB in the Piedmont Region in 2001, with 557 cases from the surveillance system, 406 from hospital discharge records and 285 from laboratory records (69 microscopically identified and 216 confirmed by culture). Figure 1 shows the distribution of all identified cases by source and their overlap, whereas Figure 2 shows the distribution of microbiologically confirmed cases. A verification procedure carried out for 322 cases identified uniquely from hospital discharge records con-

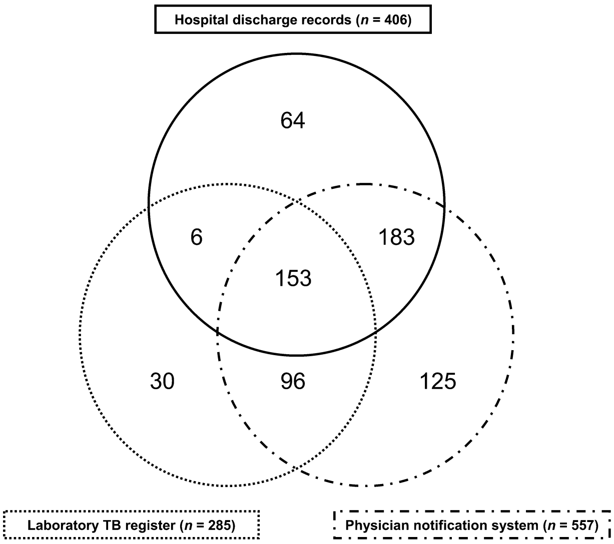

Figure 1 Distribution of all cases of TB found in the investigated sources. TB = tuberculosis.

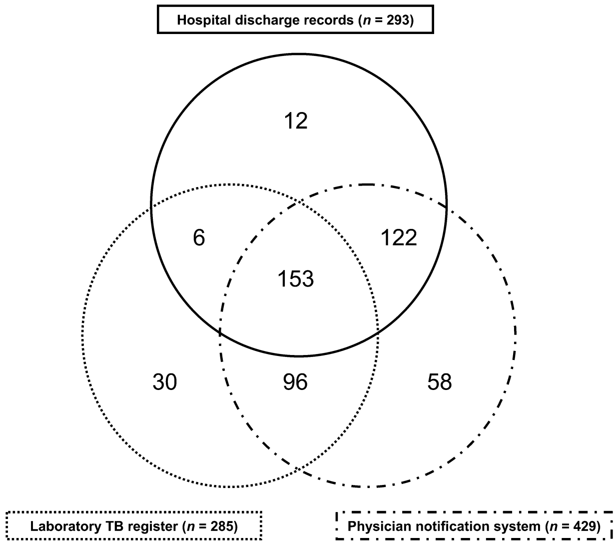

Figure 2 Distribution of microbiologically confirmed cases of TB found in the investigated sources. TB = tuberculosis.

firmed 64 cases, resulting in an overall PPV of 63%. Table 1 shows the total and subset distribution of the TB cases identified. The sexes were equally represented in the different geographic areas: 286 males were from LTBCs (59% of all individuals from LTBCs) and 91 from HTBCs (54% of all individuals from HTBCs). The age distribution was bimodal, with a difference of >30 years in average age at diagnosis between immigrants from HTBCs (median age 32 years; range 1–78) and those born in LTBCs (median age 63 years; range 1–101). There was no difference in age distribution between males (median 54 years; range 1–101) and females (median 53 years; range 2–96). HIV status was known to be positive in 32 TB patients (5%), 23 (72%) of whom were from industrialised countries (data not shown).

Observed source-specific sensitivity

The overall proportion of cases detected in the 'physician notification system', was 84.1% (71.1% for

Table 1 Total and subset numbers of cases of tuberculosis (TB) identified by investigated sources and source-specific observed sensitivities

	Observed cases *n* (%)	Physician notification system		Laboratory		Hospital discharge records	
		Frequency	Sensitivity %	Frequency	Sensitivity %	Frequency	Sensitivity %
Total	657	557	84.8	285	43.4	406	61.8
Sex							
Male*	377 (58)	322	85.4	168	44.6	226	59.9
Female*	278 (42)	235	84.5	115	41.4	180	64.7
Area of origin							
Low TB prevalence countries	486 (74)	401	82.5	198	40.7	319	65.6
High TB prevalence countries	171 (26)	156	91.2	87	50.9	87	50.9
Site of TB							
Pulmonary TB†	434 (66)	387	89.2	250	57.6	268	61.7
Extra-pulmonary TB†	211 (32)	158	74.9	52	24.6	193	91.5
Age, years							
<60	374 (57)	328	87.7	155	41.4	232	62.0
⩾60	283 (43)	229	80.9	130	45.9	174	61.5
Status							
Confirmed cases	477 (73)	429	89.9	285	59.7	293	61.4
Probable cases	180 (27)	128	71.1	0	0.0	113	62.8
Area of residence							
Turin‡	271 (41)	256	94.5	108	39.9	177	65.3
Piedmont, excluding Turin‡	331 (50)	276	83.4	147	44.4	229	69.2

* No information available for two cases.
† No information available for 70 cases.
‡ No information available for 55 cases.

probable cases; 89.9% for confirmed cases) (Table 1). This system was more sensitive for identifying persons from HTBCs than for those from LTBCs (91.2% vs. 82.5%), for PTB than for non-PTB (89.2% vs. 74.9%), for TB patients aged <60 than for older patients (87.7% vs. 80.9%), and for persons from the Turin metropolitan area than from the rest of the Piedmont Region (94.5% vs. 83.4%). The sensitivity of hospital discharge records was 61.8%, ranging from 50.9% for persons from HTBCs to more than 90% for extra-pulmonary (EPTB) cases. The laboratory source had the lowest overall sensitivity (43.3%), and the highest sensitivity levels for this source were for confirmed (59.7%) and PTB cases (57.6%).

Capture-recapture models

The estimates for each log-linear model are shown in Table 2. The selected model allowed for capture dependency between the surveillance and laboratory sources, and did not take into account heterogeneity (deviance 27.6; standard error [SE] 10). Three models with appealing goodness-of-fit criteria were rejected because their estimates were unstable, as reflected by the high SE. The selected model estimated 47 (95%CI 31–71) TB patients unknown to all three sources, resulting in an estimated total of 704 (95%CI 688–728) incident cases of TB in the Piedmont Region in 2001. We then estimated the number of TB cases in various subsets (Table 3), using the same log-linear model for all grouping variables. Figure 2 shows the distribution of microbiologically confirmed cases by source. The total number of microbiologically confirmed cases was then estimated, using the three sources, at 500 (95%CI 490–517). The number of probable TB cases, which by case definition cannot be captured by the laboratory source, was estimated, using two sources, at 237 (95%CI 214–273). The 95%CI of the total number of TB cases estimated by geographic origin, site of TB, age group and bacteriological status overlapped with the 95%CI of the non-stratified estimate.

Estimated source-specific sensitivity and incidence

The overall estimated ascertainment of TB cases (i.e., cases recorded in at least one of the registers examined) was 93.3%. Although notification of diagnosis and treatment of TB is mandatory, the estimated sensitivity of the 'physician notification system' system

Table 2 Capture-recapture estimation models (deviance, df, SE, cases estimated, upper and lower 95%CIs for three sources), obtained with the CARE library[20]

Estimation model		Cases estimated (95%CI)	Estimated number of unknown cases	Deviance (SE)	df	AIC*	BIC†
Independence between sources	Independent	689 (678–706)	32	44.32 (7)	3	52.32	70.27
One dependency between two sources, no catchment heterogeneity	Physician notification and laboratory	704 (688–728)	47	27.60 (10)	2	37.60	60.04
	Hospital and laboratory	686 (675–703)	29	42.15 (7)	2	52.15	74.59
	Physician notification and hospital	701 (684–728)	44	40.63 (11)	2	50.63	73.07
Two dependencies between two sources, no catchment heterogeneity	Physician notification and hospital; hospital and laboratory	696 (680–724)	39	39.55 (11)	1	51.55	78.48
	Physician notification and hospital; physician notification and laboratory	977 (790–1424)	320	0.24 (150)	1	12.24	39.17
	Laboratory and hospital; physician notification and laboratory	701 (685–725)	44	26.80 (10)	1	38.80	65.73
Heterogeneity (heterogeneous probability of capture among individuals)	Symmetric heterogeneity between sources	726 (695–782)	69	273.08 (21)	4	279.08	292.54
	Quasi-symmetric heterogeneity between sources	721 (692–775)	64	36.70 (20)	2	46.70	69.14
	Partial-quasi-symmetric heterogeneity between physician notification–hospital and hospital–laboratory sources	726 (695–781)	69	25.09 (21)	1	37.09	64.02
	Partial-quasi-symmetric heterogeneity between surveillance–hospital and physician notification–laboratory sources	1019 (802–1559)	362	0.20 (178)	1	12.20	39.13
	Partial-quasi-symmetric heterogeneity between physician notification–laboratory and hospital–laboratory sources	743 (702–823)	86	33.49 (30)	1	45.49	72.42
Full dependency between sources	Saturated	1005	138	0.00 (174)	0	14.00	45.41

CI = confidence interval; CARE = capture-recapture; SE = standard error; df = degrees of freedom; AIC = Akaike information criterion; BIC = Bayes information criterion.

Table 3 Capture-recapture estimates: cases estimated (95%CI); estimated sensitivities of physician notification system and estimated crude annual TB incidence

	Estimated unknown cases *n* (95%CI)	Estimated total cases *n* (95%CI)	Estimated sensitivity of physician notification system % (95%CI)	Estimated TB incidence in 2001 (cases/100 000 population) Incidence (95%CI)
Total	47 (31–71)	704 (688–728)	79.1 (76.5–80.1)	16.7 (16.3–17.3)
Area of origin				
Low TB prevalence countries	36 (22–57)	522 (508–543)	76.8 (73.8–78.9)	12.6 (12.3–13.1)
High TB prevalence countries	9 (3–22)	180 (174–193)	86.1 (80.8–89.6)	214.1 (207.0–229.6)
Site of TB				
Pulmonary TB	19 (10–35)	453 (444–469)	85.4 (82.5–85.4)	10.7 (10.5–11.1)
Extra-pulmonary TB	2 (1–9)	213 (212–220)	74.2 (71.6–74.5)	5.0 (5.0–5.2)
Age, years				
<60 years	24 (14–34)	398 (388–417)	82.4 (78.6–84.5)	13.1 (12.8–13.8)
⩾60 years	23 (13–41)	306 (296–324)	74.8 (70.7–77.4)	25.8 (24.9–27.3)
Area of residence				
Turin	7 (3–18)	278 (274–289)	92.1 (88.5–93.4)	32.1 (31.7–33.4)
Piedmont, excluding Turin	29 (17–49)	360 (348–380)	76.7 (72.6–79.3)	10.8 (10.4–11.3)

was 79.1% (95%CI 76.5–80.1) (Table 3). The system performed better in the Turin metropolitan area (sensitivity 92.1%). The analysis showed that persons aged ⩾60 years (sensitivity 74.8%) and EPTB cases (sensitivity 74.2%) are relatively under-reported or under-detected. The system was more likely to capture cases in persons from HTBCs (sensitivity 86.1%) than in those from LTBCs (sensitivity 76.8%).

The estimated overall annual TB incidence rate was 16.7/100 000, with 11.9/100 000 microbiologically confirmed. The incidence estimates varied widely according to the population subset being investigated. The estimated annual incidence rate was 12.6/100 000 among persons from LTBCs and 214.1/100 000 among immigrants from HTBCs. The estimated annual TB rate in the Turin metropolitan area (32.1/100 000) was nearly three times higher than in the rest of the Piedmont Region (11/100 000). The estimated annual incidence of PTB (10.8/100 000) was twice that of EPTB (5.0/100 000), as was that of cases in persons aged ⩾60 years (25.8/100 000) when compared with younger persons (13.1/100 000).

DISCUSSION

The main findings of this study are that in Piedmont the reported TB incidence rates are largely underestimated. Although Piedmont remains a low-prevalence area, the burden of TB is higher than was previously thought. Record linkage considerably improved the estimated case-ascertainment to 93.3%. The CR estimate of under-reporting of 21% is almost twice that of the WHO for Italy as a whole.[5] The estimated crude annual incidence of TB (16.7/100 000) was about twice that of all Italy (8/100 000) and was also higher than reported for the Piedmont region (12/100 000).[5,7,21] Record linkage with additional CR analysis is a valuable means for quantifying under-reporting, and can provide relatively accurate estimates of the annual incidence of TB in areas where multiple recording systems are available.[22]

The incidence estimates found are representative of low TB prevalence areas. The overall crude annual incidence rate is similar to those of neighbouring countries such as Austria, France and Switzerland, which range from 11 to 16/100 000.[7]

Inaccurate estimates of the annual incidence of TB, particularly among high-risk subsets of the population such as immigrants from HTBCs and urban dwellers, vitiate the implementation of appropriate prevention and control measures. Our analyses for different subsets of the population in this study confirmed that persons from HTBCs have a much higher risk of developing TB than the local population. A similar phenomenon has been reported among immigrants and asylum seekers elsewhere.[23] The estimated annual TB rate in the Turin urban area is 32.1/100 000, which is three times higher than the rate in the rest of the Piedmont Region. A comparable trend has been reported in other metropolitan areas of Europe, such as Amsterdam, London and Rotterdam.[23,24] These rates reflect larger risk groups for TB in the populations of large cities, such as certain ethnic groups, illegal immigrants, homeless persons and drug addicts.[25] The high rate among the elderly (97% of whom originated from LTBCs) is typical of TB epidemiology in low-incidence countries. Few young people are infected and develop active disease, while older persons can experience endogenous reactivation of latent TB infection or of a previous episode of TB in the era before effective chemotherapy. Although HIV infection is a well-known predisposing factor for active TB,[26] it makes a minor contribution to the burden of TB in Piedmont, as 5% of all cases were found to be HIV-seropositive. This proportion is consistent with the estimates of TB-HIV in the WHO European Region.[27]

Our finding of a sensitivity of around 85% for the 'physician notification system' currently implemented in the Piedmont Region for detecting TB in immigrants from HTBCs, PTB and confirmed cases (the most important groups in terms of TB transmission control) is encouraging. This might reflect heightened awareness among both clinicians and public health authorities about the notification and surveillance of potentially infectious TB. Our observation confirms that TB patients aged ⩾60 years are at risk of under-detection[28,29] (25% for 'physician notification system'). The sensitivity of hospital discharge records, ranging from 50.9% for persons from HTBCs to more than 90% for EPTB cases, is presumably affected by a different need for hospitalisation of the two groups, the former preferably being managed as out-patients and the latter usually being admitted to hospital for diagnostic workup.

We have described how assessment of TB incidence and case detection of TB in areas where multiple recording systems are available, such as the Piedmont Region in Italy, can be improved considerably by record linkage of different data sources, such as the 'physician notification system' and laboratories. Implementation of routine independent reporting from laboratories should be enforced to reduce under-ascertainment and improve the quality of information on diagnostic practices and criteria. Subsequent CR analysis, despite its inherent methodological limitations,[30] can be used to estimate total TB incidence and the completeness of registration, thus contributing to more accurate surveillance of local TB epidemiology. A detailed subset analysis can further identify gaps in the surveillance system and indicate adequate corrective interventions, such as improving the education of health care providers about reporting requirements or modifying reporting procedures.

Acknowledgements

The authors would like to thank Prof B Terracini, Prof A Biggeri, Prof N Pearce and Dr C Sacerdote for helpful comments and support in the research. The study was supported by 'Ricerca Finalizzata' Regione Piemonte/CIPE. The capture-recapture methods were developed within the framework of the Special Project 'Oncology', Compagnia San Paolo FIRMS, and of a grant from the Italian Association for Cancer Research.

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RÉSUMÉ

CONTEXTE : Une insuffisance de confirmation et de déclaration de tuberculose (TB) est un obstacle à la surveillance et au contrôle de la maladie. La détection des cas est améliorée par les liens entre des déclarations dans les divers registres de cas, et la sous-déclaration peut être estimée par l'analyse capture-recapture (CR).

OBJECTIFS : Evaluer dans la Région du Piedmont en Italie en 2001 le caractère complet des systèmes d'enregistrement de la TB et de l'estimation de l'incidence de la TB, ainsi que les sous-déclarations.

MÉTHODES : Liens entre les déclarations du « système de déclaration du médecin », du registre de laboratoire de TB et du registre des déclarations hospitalières et analyse ultérieure CR de trois échantillons.

RÉSULTATS : Les liens entre les déclarations ont identifié 657 cas de TB et l'analyse CR a estimé les cas non-déclarés à 47 cas (IC95% 31–71). La sous-déclaration du « système de déclaration du médecin » a été estimée à 31% (IC95% 20–23). Le taux global estimé de l'incidence de la TB a été de 16,7 cas pour 100.000 habitants (IC95% 16,3–17,3), ce qui varie en fonction du sous-groupe investigué : 12,7% pour les individus provenant de pays à faible incidence de TB et 214,1% pour les immigrants provenant de pays à haute incidence de TB ; respectivement 13,1% et 25,8% chez les sujets âgés $<$ et $\geqslant$60 ans ; ainsi que 32,1% à Turin, la capitale régionale et 10,8% dans le reste de la région.

CONCLUSIONS : Lorsque des systèmes multiples d'enregistrement sont disponibles, les liens entre les déclarations et l'analyse CR peuvent être utilisés pour évaluer l'incidence de la TB et le caractère complet des différents enregistrements, ce qui contribue à une surveillance plus adéquate de l'épidémiologie locale de la TB.

RESUMEN

MARCO DE REFERENCIA : El subdiagnóstico y la subdeclaración de los casos de tuberculosis (TB) obstaculizan el control y la vigilancia epidemiológica. La detección de casos puede perfeccionarse estableciendo asociaciones entre los archivos clínicos de los registros de casos ; la subdeclaración puede calcularse mediante un análisis de captura y recaptura (CR).

OBJETIVOS : Evaluar la integridad de los sistemas de registro de la TB y estimar la incidencia de la TB y la subdeclaración de casos en la región Piemonte de Italia, en 2001.

MÉTODOS : Se establecieron asociaciones entre los archivos clínicos del sistema de declaración clínica, de los laboratorios de TB y de los expedientes hospitalarios y se aplicó luego un análisis CR de tres muestras.

RESULTADOS : Mediante la asociación de los archivos clínicos se reconocieron 657 casos de TB y con el análisis CR se estimó que 47 casos no habían sido registrados (IC95% 31–71). Se calculó que la subdeclaración al sistema de notificación clínica fue del 21% (IC95% 20–23). La incidencia global de TB fue de 16,7 casos por 100 000 individuos (IC95% 16,3–17,3), con variaciones que dependieron del subgrupo analizado, así : 12,7 para individuos provenientes de países con baja prevalencia de TB y 214,1 para inmigrantes de países con alta prevalencia ; 13,1 para $<$60 años y 25,8 para personas $\geqslant$60 años ; la incidencia fue 32,1 en Torino, la capital regional y 10,8 en el resto de la región.

CONCLUSIONES : Cuando se cuenta con diversos sistemas de registro, pueden utilizarse la asociación entre los diferentes archivos clínicos y el análisis CR con el fin de evaluar la incidencia de TB y verificar la integridad de los diferentes registros y con ello se contribuye a una mayor precisión de la vigilancia epidemiológica local de la TB.