Effectiveness of the Tuberculosis Control Programme in Portugal.

Epidemiological evidence from a recent, independent three-year period observation, evidence quality and improvements needed.

Tuberculosis » surveillance » methods

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INTRODUCTION

PRESENTATION

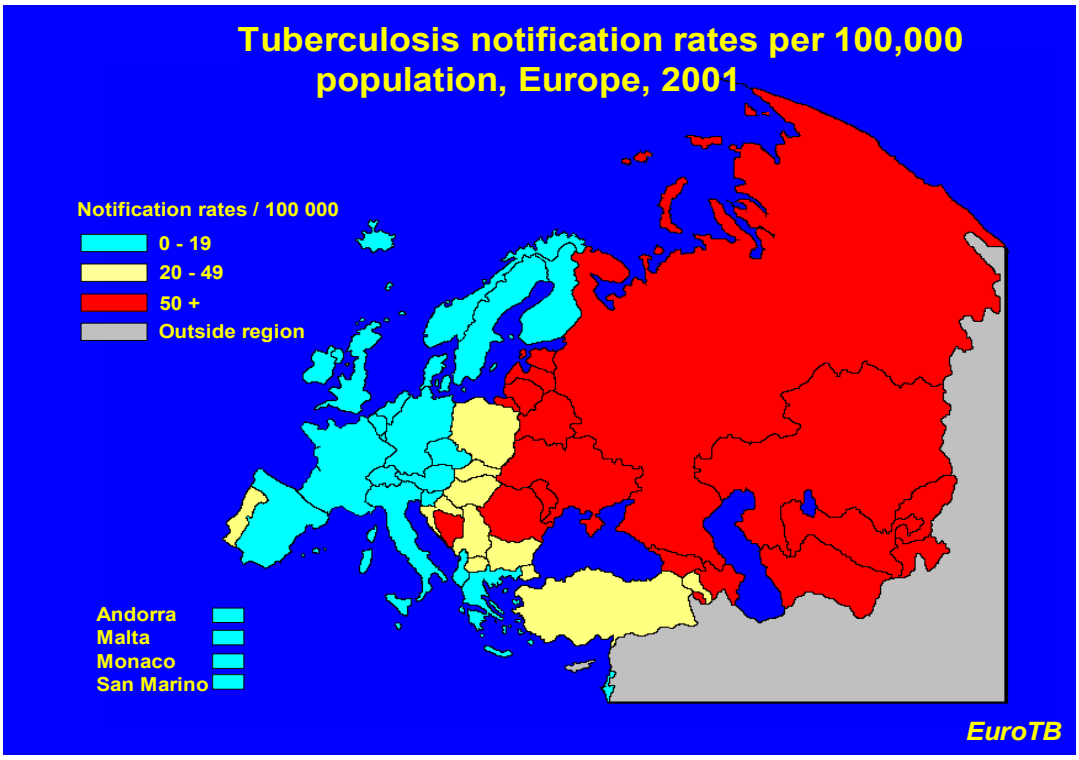
These are the **main preliminary results, after reviewing three recent, consecutive, independent observation exercises, regarding the impact and performance** of the *National Programme for Tuberculosis Control in Portugal* (*PNT*).

Such global epidemiological appraisal exercises, running since 2001 yearly, are an experience that is **framed by the objectives and methods of the *Portuguese Observatory for Health Systems*** (*OPSS*).

This revision also envisages approaching the **quality of the evidence used to monitor population impact of *PNT*, as well as the usefulness of independent appraisal exercises** themselves.

TUBERCULOSIS IN PORTUGAL, BRIEFLY

Portugal has the **highest notified incidence of Tuberculosis in Western Europe**, though its magnitude is medium-low in a world scale **(Fig. 1)**. W.H.O., 2004

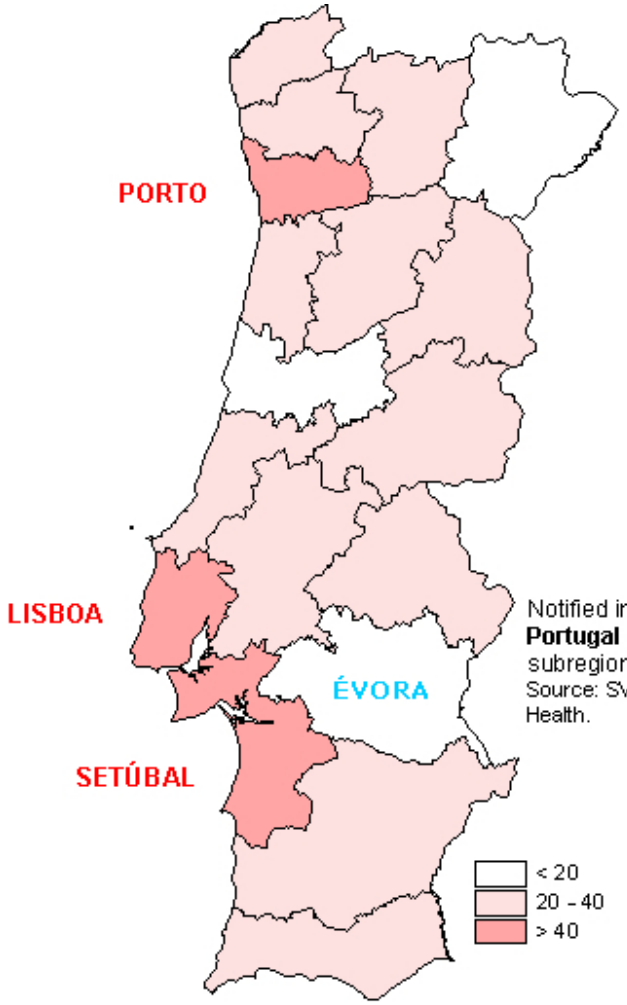


Eurotb, 2004 - http://www.eurotb.org/ (kind expressed allowance for presentations)

Fig. 1

At the same time, the estimated **case detection rate is one of the best in Europe**, which may artificially contribute to a less favourable relative image. Portugal, DGS, 2004

Geographic heterogeneity in incidence at the subnational level is striking as well, if an homogeneous detection rate is assumed **(Fig. 2)**. Portugal, DGS, 2004



Notified incidence rates /10^5, in **Portugal** (continent), 2002, per subregion.
Source: SVIG-TB, General Directorate of Health.

Fig. 2

Notified **incidence is declining too slowly** and an **endemic stabilization is recognized**, while there is evidence that, in industrialized countries, effective treatment can decrease the rate of infection by 10% to 15% or more each year. (Frieden, T, 2002)

THE NATIONAL TUBERCULOSIS CONTROL PROGRAMME AND INDEPENDENT OBSERVATION EXERCISES

Portugal is 100% covered by the *National Tuberculosis Control Programme*, which strictly follows W.H.O. *DOTS* strategy and regularly issues a progress report. Performance and population impact of *PNT* are being followed through external, independent observation exercises, in the context of the *Portuguese Observatory for Health Systems* activities, since 2001. *OPSS* is located at the Escola Nacional de Saúde Pública, Lisboa, and hosted by the Portuguese Association for Public Health Promotion. Portugal, DGS, 2004; Portugal, Observatório Português Sistemas de Saúde (OPSS), 2004; W.H.O., 2004

These exercises focused years 2000, 2001 and 2002. They consisted of **global epidemiological appraisals** of relevant, easily available information, which is interpreted considering its own quality.

Information used, regarding cases, is routinely provided by *SVIG-TB*, the specific *PNT* information system. Data are all related to notifications and the system is managed by the *PNT* coordination team, at the General Directorate of Health. This team kindly facilitates required information to the Observatory, for independent observation exercises. Population **denominators** are drown from official statistics, issued by the National Statistics Institute (*INE*).

***PNT* is a vertical intervention programme**, that involves state health services in a network, supported by *SVIG-TB*. Regional and subregional authorities and pneumological centres play a key, dynamic role in this programme network. Therefore, both programme functioning and end-results reflect performance and interactions of individual services involved, in a tracer-like fashion. Portugal, DGS, 1995; Portugal, DGS, 2004; Brown et al., w.d.

***PNT* capability to lower pulmonary cases incidence** (a *proxy* to its population impact), by detecting new infectious cases, by curing them and thus preventing new infections and by avoiding antimicrobial resistance, **is crucial in order to face emerging threats to current disease control** status in Portugal successfully. Such control is not yet acceptable, according to western European standards: transmission facilitators and mechanisms are keeping the disease endemic, while HIV infections, infected immigrants from high-prevalence countries and socially stressed groups increase pressure for further new infections and offer particular difficulties in controlling individual cases. Portugal, DGS, 2004; W.H.O., 2004

Standard indicators express *PNT* impact and performance; they are interpreted considering both Tuberculosis Natural History dynamics and applied intervention resources.

A **sounder understanding** of indicators evolution, of their quality and of the persisting knowledge limitations was found necessary, as well as of the role of independent appraisals, in order to improve the image of control being achieved and, therefore, the degree of disease control itself.

STUDY OBJECTIVES

To reappraise:

1. **Evidence of control evolution in 2000-2002**
   - ***PNT* population Impact**
   - ***PNT* internal Performance**
2. **Knowledge quality and limitations, regarding the control image**
3. **The interest and usefulness of independent observation exercises, as they have been undertaken so far**

METHODS

TYPE OF STUDY, POPULATION, DIMENTIONS AND INFORMATION SOURCES

This consists of a simple, exploratory, global evaluation approach, judging on easily available information, as it is, under an epidemiological viewpoint. Armenian, H, 1998; Petitti, D., 1998; Rossi & Freeman, 1993; Rutman, 1977; Wholey, 1977

It concerns the Portuguese population, in the period 2000-2002.

Dimensions of PNT quality considered, frequently regarding pulmonary cases only, were: Portugal, DGS, 2004; W.H.O., 2004

APPARENT POPULATION IMPACT – through:

evolving notified incidence during the observed period, attributable to the programme (*proxy* to case incidence)
----- » liable to under-reporting

PNT PERFORMANCE - through:

treatment success rate (*proxy* to cure rate), mainly, and other indicators ---------- » presumably reliable

new cases detection rate (capability to detect new cases, estimated at national level by WHO, on the basis of the number of notified sputum positive cases) ------ » a useful estimate, qualifying the impact image

some other complementary indicators, indicated later

The information sources used were: *SVIG-TB* (the same as *PNT* own reports), concerning either all cases, or pulmonary cases only when appropriate, and INE official statistics, from which rate denominators were taken.

Process

Both the three previous observation exercises and information used in them were reviewed, and an even closer focus was introduced to the Portuguese continent, at the subregion level. 8 out of the 18 districts were subject to a more detailed assessment, including complementary performance and impact parameters. Selected subregions were the 3 ones showing the lowest notified incidence (Coimbra, Évora and Santarém), the 3 ones having the highest incidence (Lisboa, Porto and Setúbal) and the 2 closest to the Continent's average (Beja and Faro), in 2002. The number of cases in Évora subregion were sometimes too small to enable safe calculations (18 total cases in 2002).

In this more detailed appraisal, "noise" introduced by cases admitted for retreatment or under long, unusual treatment schemes was taken into account, by removing them from calculations. Restricting to pulmonary cases brought easiness of interpretation; besides, they are the most important group to control, for interrupting transmission. W.H.O., 2004; Rieder, H, 1999

The following aspects and parameters were studied for each geographic unit, whenever possible, frequently looking at rates an percentages as merely "indicative", because of small numbers:

> Notified incidence rate, age/sex incidence distribution profile, median age at diagnosis, percentage of cases with laboratory confirmation (both bacilloscopic and by culture), median days from first consultation until starting treatment, treatment success rate (percentage, includes confirmed cures plus completed therapy, excluding cases with too long, unusual treatment courses), median duration of standard therapy, percentage of cases subject to directly observed treatment (*DOT*), percentage of cases recidivating, percentage of cases with multirresistant bacteria or resisting to isoniazid, percentage of cases associated to HIV infection, drug-dependence or immigration. Evolutions in this period were also approached.

Regarding quality of impact evidence, incidence indicators were reviewed as to their operational appropriateness for the purpose and as to their consistency with other complementary impact evidence.

Pertinence of independent observation exercises was assessed by reviewing their added value, after comparing their content with corresponding *PNT* official reports and by assessing these ones as to the evolution of their quality.

RESULTS (commented summary)

GLOBAL EVIDENCE OF CONTROL STATUS AND EVOLUTION AND *PNT* PERFORMANCE IN 2000-2002

Nature and operational definition of parameters approaching *PNT* impact and performance are very closely related, so it is more useful to exhibit and interpret their results together.

In recent years, the decline of **notified incidence** **(Fig. 3)** is very slow and not compliant with funded expectations, if control programme were performing well enough. Frieden, T, 2002

New cases notifications / 10^5 , per year, whole **Country**, all types of cases, 1972-2002. Source: *SVIG-TB*, General Directorate of Health.

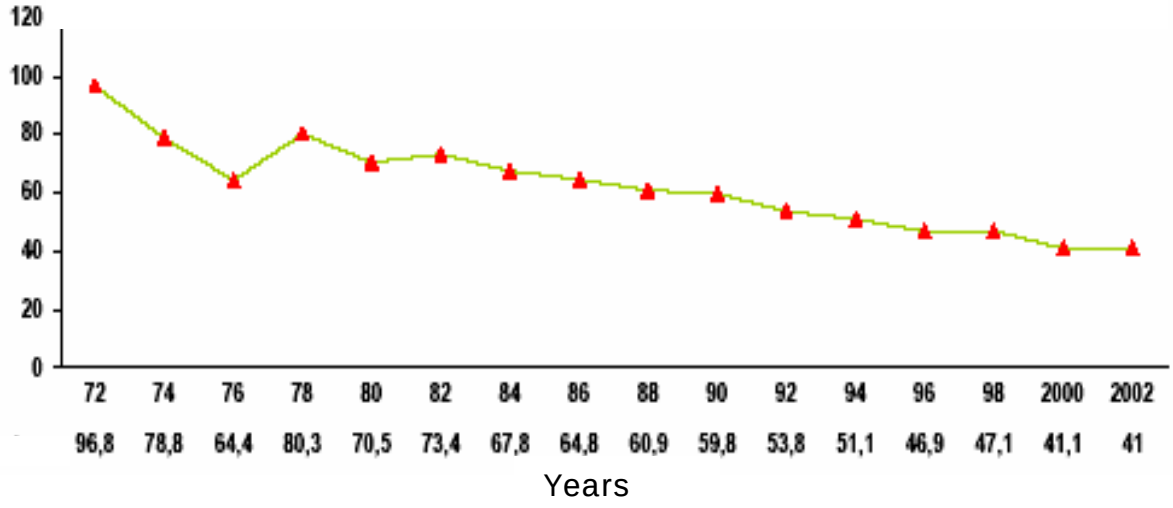
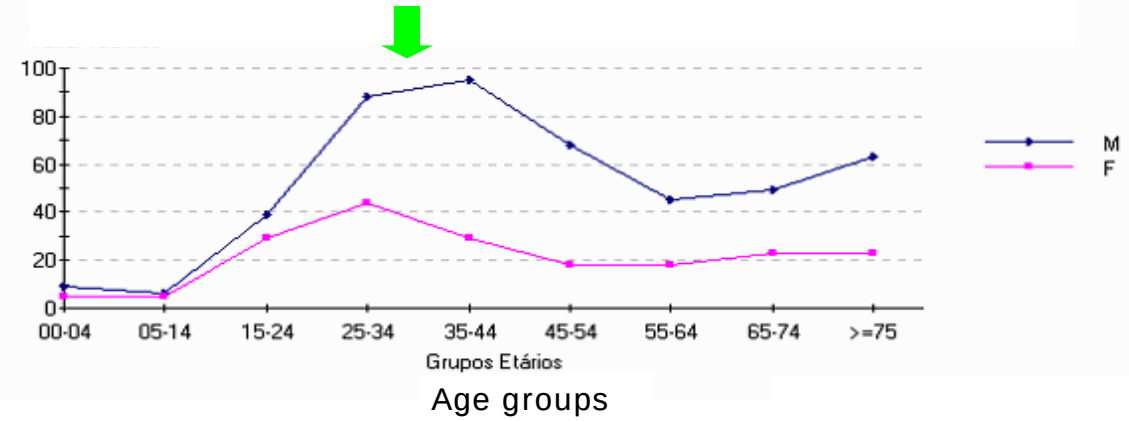


Fig. 3

Age/sex distribution of the notified incidence **(Fig. 4)** clearly evinces an endemic pattern. In fact, the highest rates in young adults, predominantly in males, suggest their increased risk to be infected, as usual in endemic statuses. This interpretation holds, even if under-reporting is not homogeneous along all ages, as values in that group are high (under-reporting may affect more both young children and older persons, resulting in an artificially lower number of notifications in these ages). In the latter, new cases will probably correspond to reactivation of old infections, differently from children, thus being less relevant to assess current community control. EuroTB, 2003; Johns Hopkins University, 2003; Rieder, H, 1999

Notifications rate / 10^5, per age group and sex, whole **Country**, all types of cases, 2002. Source: *SVIG-TB*, General Directorate of Health.



Age groups

Fig. 4

Incidence **heterogeneity in geographical distribution (Fig. 2)** is outstanding, as mentioned: Porto, Lisboa and Setúbal (litoral, mostly urban subregions) show the highest values, Évora (inner, mostly countryside) shows the lowest incidence**.**

As an example and confirmation of **endemicity**, the age/sex pattern in four subregions in the Continent, having very different notified incidence rates /10^5 in 2002, pulmonary cases only, are shown in **Figs. 5 to 8** (as already stated, rates are only indicative, because of small numbers, particularly regarding Évora): highest (Porto, 49.9), closest to the continent average (Beja, 34.1; Faro, 29.1) and lowest (Évora, 10.6). Lisboa, with an endemic pattern as well, had a rate of 41.1 . This graphic panorama corresponds quantitatively to low median ages at diagnosis found, which are known to increase with the degree of control reached, as referred later **(Fig. 12).** EuroTB, 2003

Notifications rate / 10^5, per age group and sex, **Porto**, pulmonary cases, 2002. Source: SVIG-TB, General Directorate of Health.

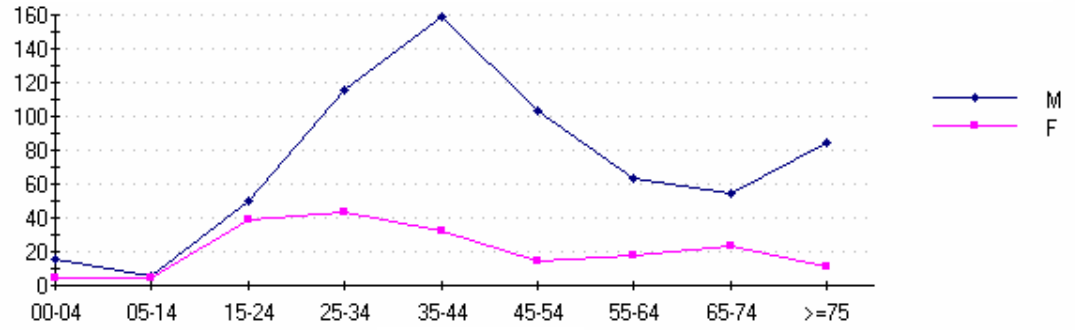


Fig. 5

Notifications rate / 10^5, per age group and sex, **Beja**, pulmonary cases, 2002. Source: SVIG-TB, General Directorate of Health.

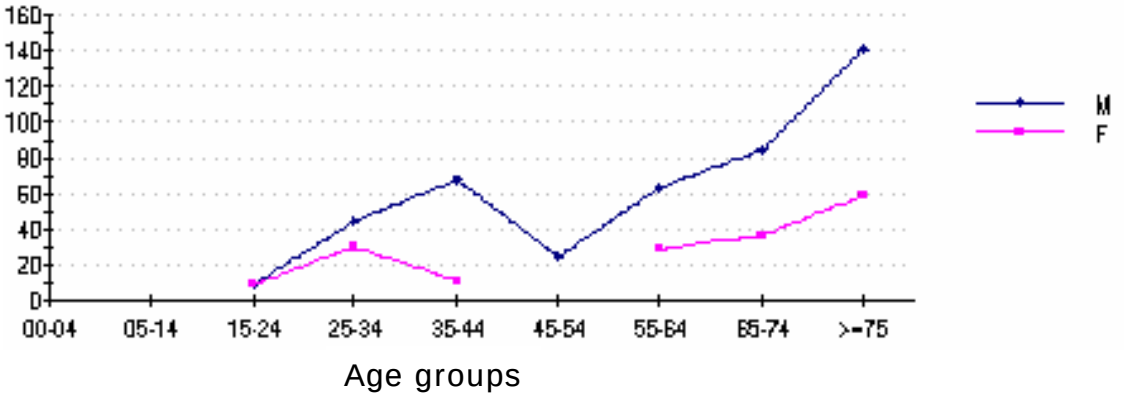
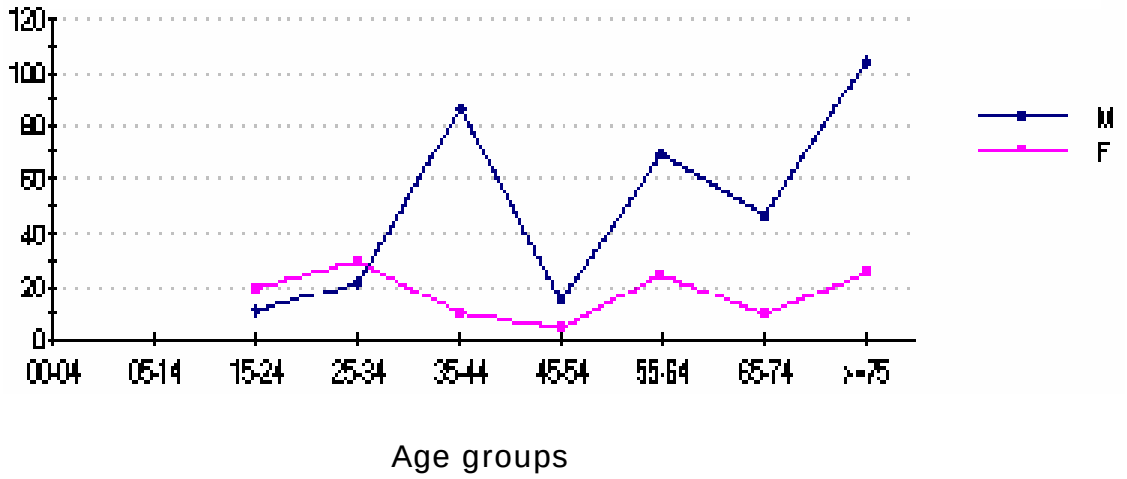


Fig. 6

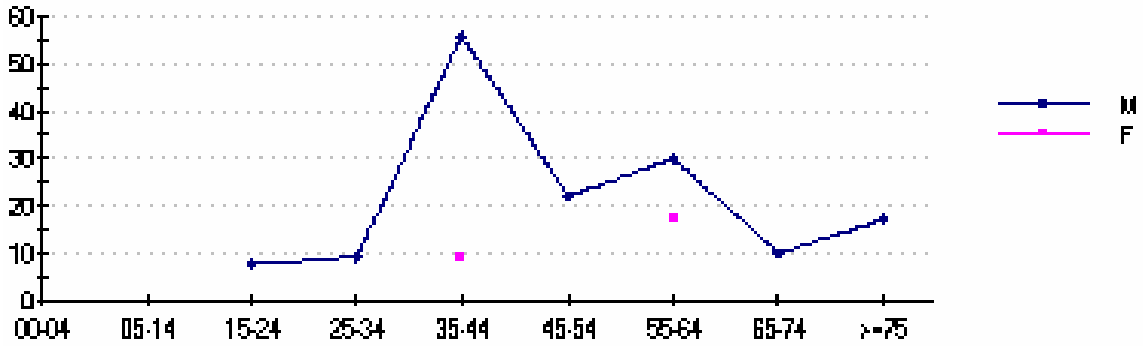
Notifications rate / 10^5, per age group and sex, **Faro**, pulmonary cases, 2002. Source: SVIG-TB, General Directorate of Health.



Age groups

Fig. 7

Notifications rate / 10^5, per age group and sex, **Évora**, pulmonary cases, 2002. Source: SVIG-TB, General Directorate of Health.



Age groups

Fig. 8

National incidence evolution in time **(Fig. 3)** doesn't seem to be artificially explained by any relevant change in the detection rate. **Detection rate levels** have been quite acceptable, by the W.H.O. standard. **Treatment success** looks somewhat unstable and below the recommended standard **(Fig. 9)**.

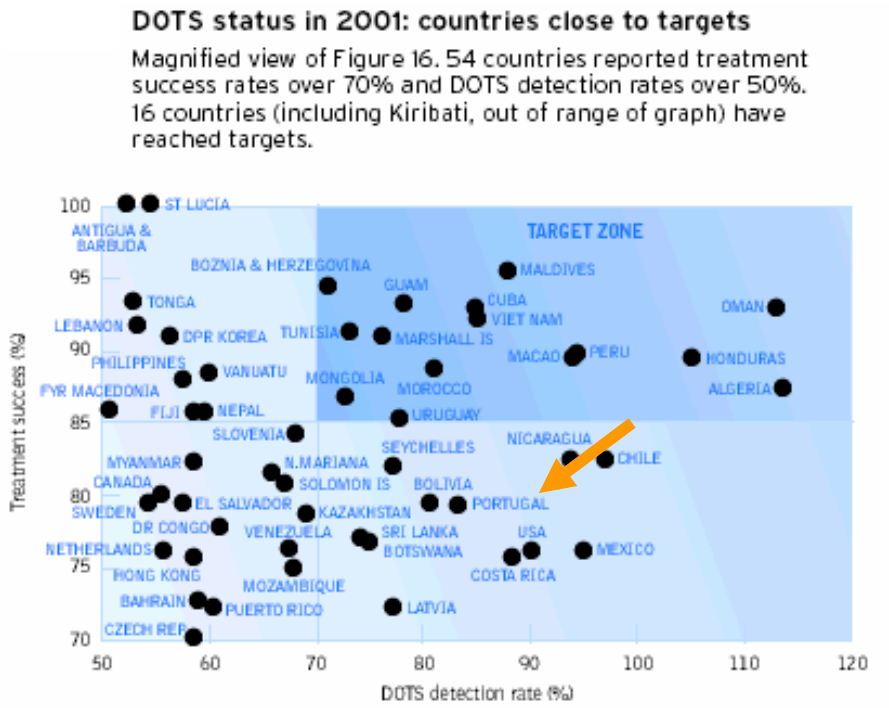
Treatment success rate in smear positive pulmonary cases, evolution 1997-2002. (WHO target »= 85%)

78,4%	73,8%	85,4%	82,0%	77,0%
1997	**1998**	**1999**	**2000**	**2001/02**
67%	83%	77%	83%	83%

Detection rate of pulmonary cases. Evolution in the analyzed cohorts, from 1997 to 2001. (WHO target »= 70%) Sources: DGS, SVIG-TB 2003; WHO, 2004

Fig. 9

The **relative position of Portugal**, regarding standard performance parameters in a "*DOTS* world" context, suggests that improvement in "treatment success" of *PNT* towards the target zone may be rather accessible **(Fig. 10)**.



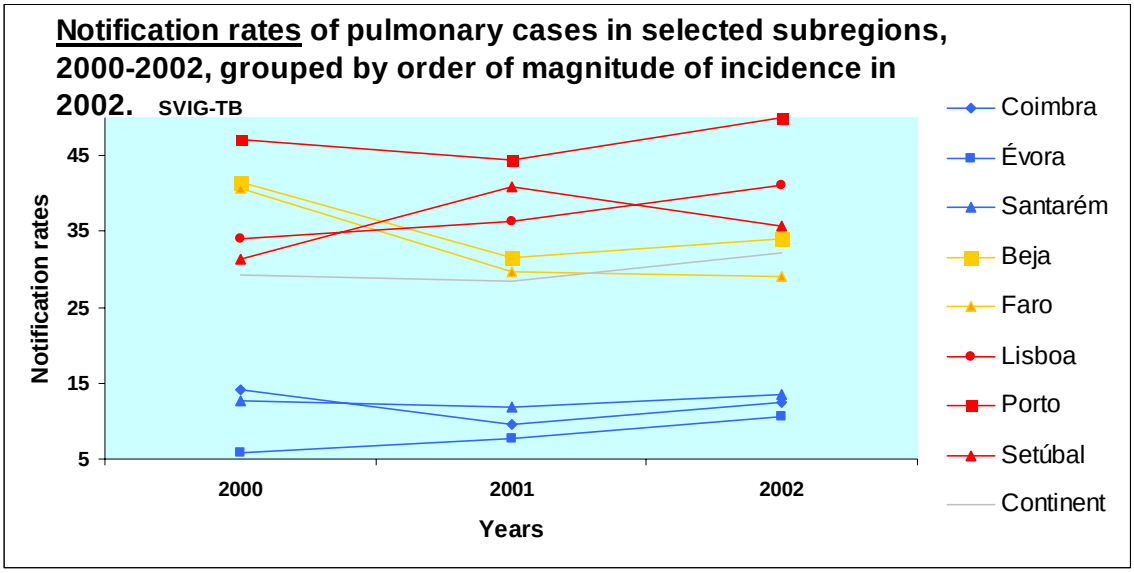
Source:WHO,2003 http://www.who.int/gtb/publications/globrep03/index.html
(kind expressed allowance for non-commercial purposes)

Fig. 10

Next, some additional parameters on *PNT* impact and performance and their recent time evolution are **broken down geographically**, whenever possible, helping to zoom in the understanding of control image, given the spatial heterogeneity in incidence. This exercise raises specific difficulties and demands prudence in data interpretation, as nothing is known about possible differences in detection rates among subregions and over time, as enough *SVIG-TB* internal information performance is only presumed and because of small numbers.

NOTIFICATIONS RATE and MEDIAN AGE AT DIAGNOSIS: an approximation to impact

The order of **magnitude of incidence rate** (pulmonary cases only) seems quite stable in recent time, in subregions having the lowest incidences. It may be decreasing in subregions closest to the Continent's average. In highest incidence subregions, either incidence or detection rate may be increasing, except in Setúbal, where it may happen that a decrease in the detection rate could hide a real increase in incidence **(Fig. 11)**.



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Medium magn.

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Fig. 11

Median ages at diagnosis (Fig. 12) were very low in higher incidence subregions, as expected. Beja, an inner district, is stable at the highest values; a tentative explanation points to a combination of influences: (1) early new, exogenous infections may be relatively less frequent there and a more valid notification rate may be occurring, suggesting better impact image and better local control of endemy; (2) reactivations in its old-aged population would be fostering its medium level global incidence; (3) much less probably, an age-specific under-detection could be increased in young adults. A relatively moderate age value in lower incidence subregions suggests that heavy underreporting may be explaining such incidence level. EuroTB, 2003; Rieder, H, 1999

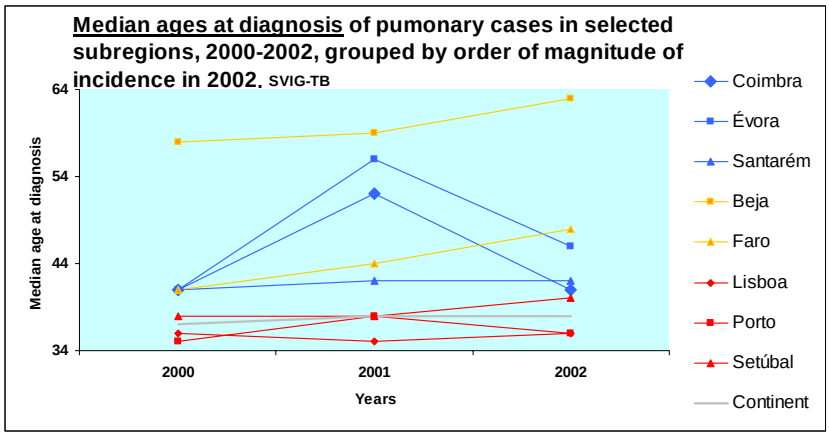

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Fig. 12

EXTERNAL PRESSURES ON INCIDENCE AND THREATS TO CONTROL

Figs. 13 to 15 refer to the available information about pressures on incidence that are external to *PNT*. Possibly, this geographic distribution is reflecting subregions where HIV infected people, drug addicted people and immigrants (regardless their origin) tend to concentrate. Some degree of differing "admition bias" into *PNT*, due to institutional or psychosocial selection mechanisms, may be acting as well.

Such pressures seem to be operating already in highest incidence subregions (except for Porto, concerning immigrants), but not only. Faro (medium magnitude) and Santarém (low magnitude) may be pressed as well, though less.

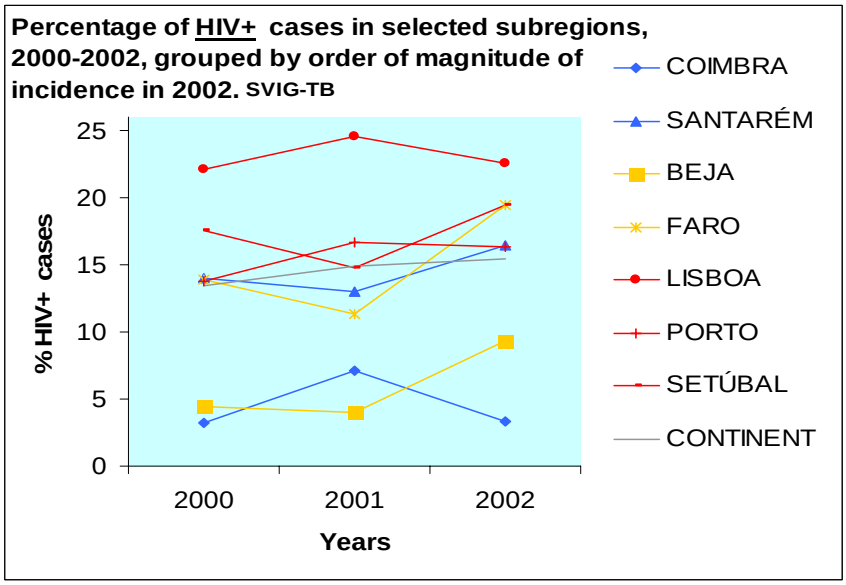

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Fig. 13

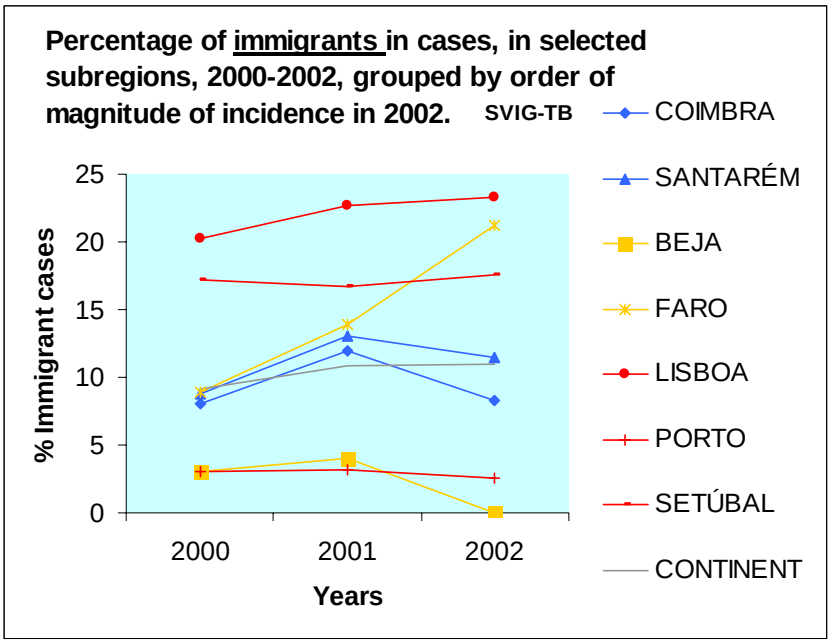

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Fig. 14

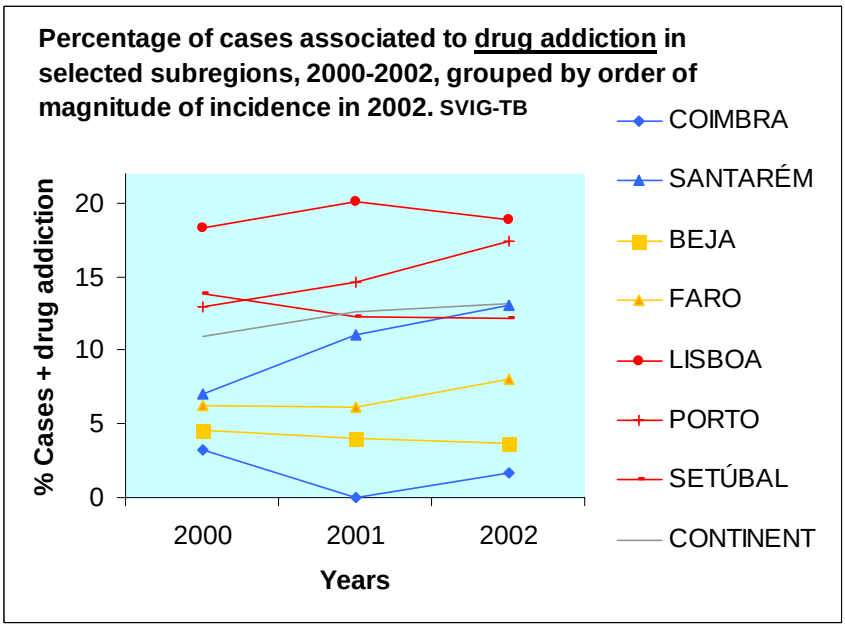

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Fig. 15

DETAILED OVERVIEW OF *PNT* PERFORMANCE

Further findings from detailed subregional information on performance parameters are as follows.

Laboratory detection of mycobacteria by microscopy shows no obvious pattern either in time, or among selected subregions, and values are generally acceptable by the W.H.O. standard (65-80%), although they are relatively low (ranging from 45% to 75%). The same applies to sputum **positive cultures** (that varies between 50% and 77%).

As to **treatment success**, values tend to be lower in highest incidence subregions (and below the envisaged 85% W.H.O. standard) and they are either stable or decreasing slightly in time, in all of the three groups. Globally in the Continent, there is an obvious decline **(Fig. 16)**. WHO, 2003

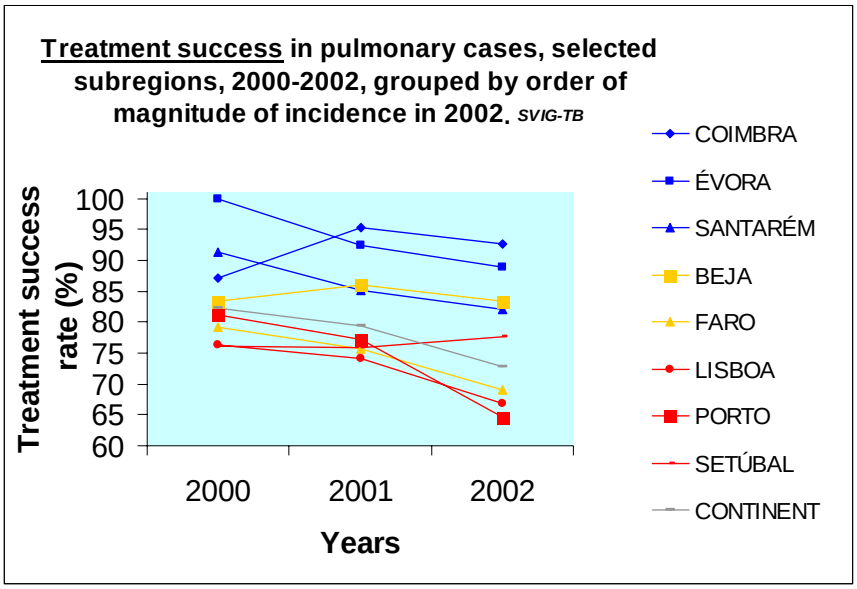

Fig. 16

Coverage by directly observed treatment (*DOT*) is also declining in the Continent, to which two of the three highest and one lowest incidence subregions do contribute. The lowest incidence subregions seem not to insist much in this technique **(Fig. 17)**.

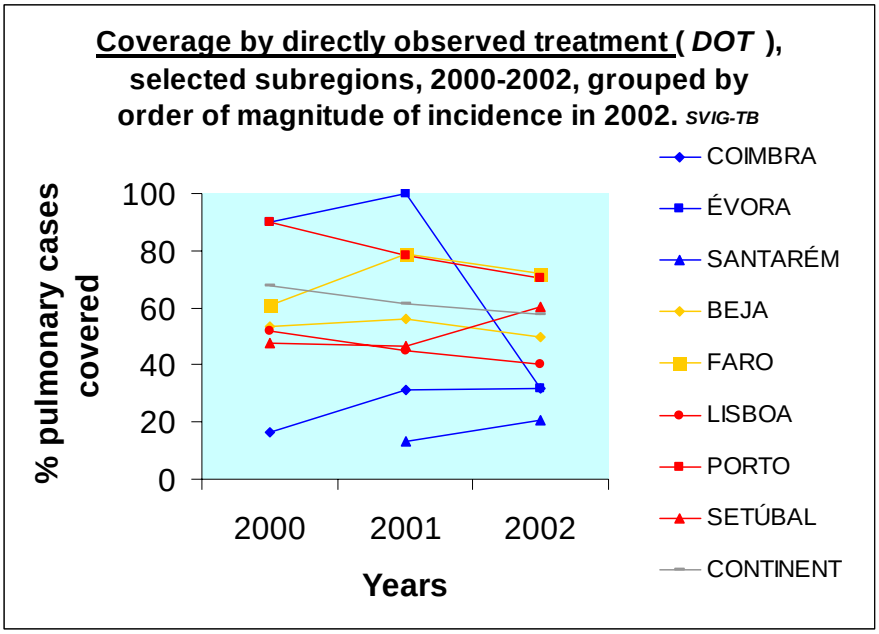

Fig. 17

Recidivation is stable over time in the Continent and the highest incidence subregions seem to provide the major contribution, although percentages are small. It fluctuates, ranging from 1.6 (Coimbra, 2000) to 9.1 (Porto, 2001) in the observed period.

Median number of days since first consultation through starting treatment is 11 in the continent, in 2002, ranging from 1 (Coimbra, 2002) to 41 (Beja, 2002) in selected subregions and period, with no obvious pattern among them. And the **median duration of standard treatment** in 2002 ranges from 6,5 months (Faro) to 9,3 (Évora), with slightly lower values in medium incidence subregions. The Continent's value is 9.1 .

As to antimicrobial resistance, its is thought that, in practice, it is tested mainly in immigrants and in cases with co-morbidities, as they are more problematic in follow-up; thus, numbers may be biased in favor of these cases. Values must be representing a minimum, an "at least" proportion of cases offering resistance to antibiotics. **Resistance to isoniazid in new cases** doesn't seem to bear a clear relationship with notified incidence level and appears rather unstable in time, with an apparent decrease, except in Faro **(Fig. 18)**. **Multirresistance** in the whole Continent, though not as much severe as in eastern European countries, is in fact an issue of concern, even more if (suspected) under-identification is taken into account and challenges to control are confirmed **(Fig. 19)**. Coverage by tests is indicated here: in retreatment cases it would be decreasing (just a rough suggestion, given small numbers) and it is increasing in new cases, which means a progressively more valid picture. Stop Tb, 2004

Resistant new cases may not necessarily mean insufficient *PNT* performance, as they may either be imported from Africa, Asia, Brazil or East Europe, or infected from imported cases. W.H.O., 2004 a

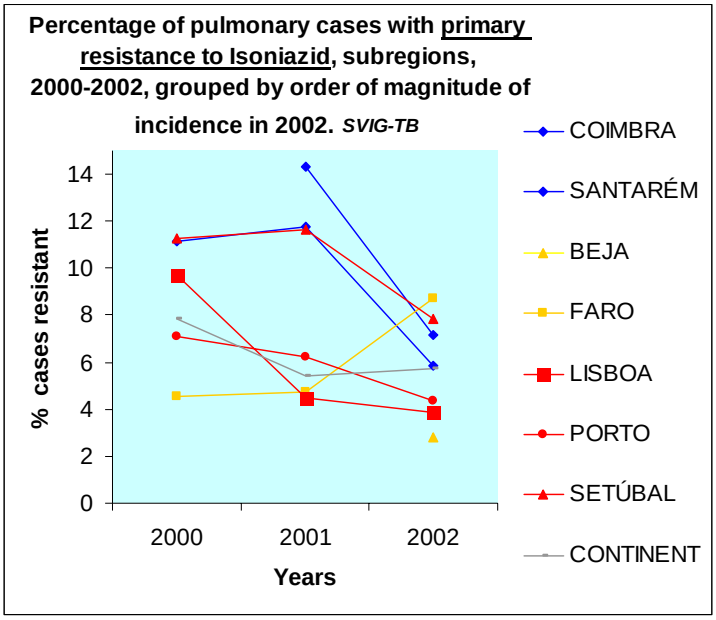

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Fig. 18

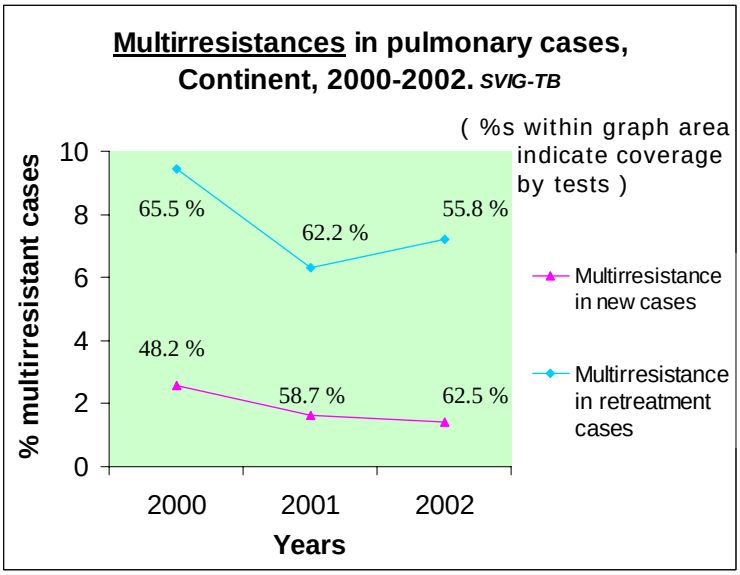

Fig. 19

Note: coverage in retreatment cases is just roughly indicative, given small numbers involved

KNOWLEDGE QUALITY AND LIMITATIONS, REGARDING THE CONTROL IMAGE

Impact image is drawn from evolving notified incidence rate, in accordance with *DOTS* guidelines. Its main source of distortion comes from underdetection of cases in the population, which may happen to vary in time, by subregion and by person-related variables, like age, sex and socioeconomic status. Ideally, each value should carry a "quality label", with some parameters supporting the degree of confidence for us to interpret it better.

At national level, the estimated underdetection may be biasing down incidence profile by about 17%, in a stable manner over time. Unfortunately, corresponding values for subregions are not yet available, and so it can't be shown how much of the geographical variability is explained by a varying undernotification at present. The same applies to incidence trends in time, preventing accurate enough judgements on local impact of *PNT* to be done.

Age-sex profiles both at national level and concerning high and average notified incidence subregions indicate an endemic stability, as expected **(Figs. 4, 5 to 8, 12)**. But the same endemic pattern found in the lowest incidence level subregions **(Figs. 8, 20 and 21)** either means an endemic equilibrium any way at a lower incidence level, or that a heavier undernotification is occurring in these subregions, or possibly both.

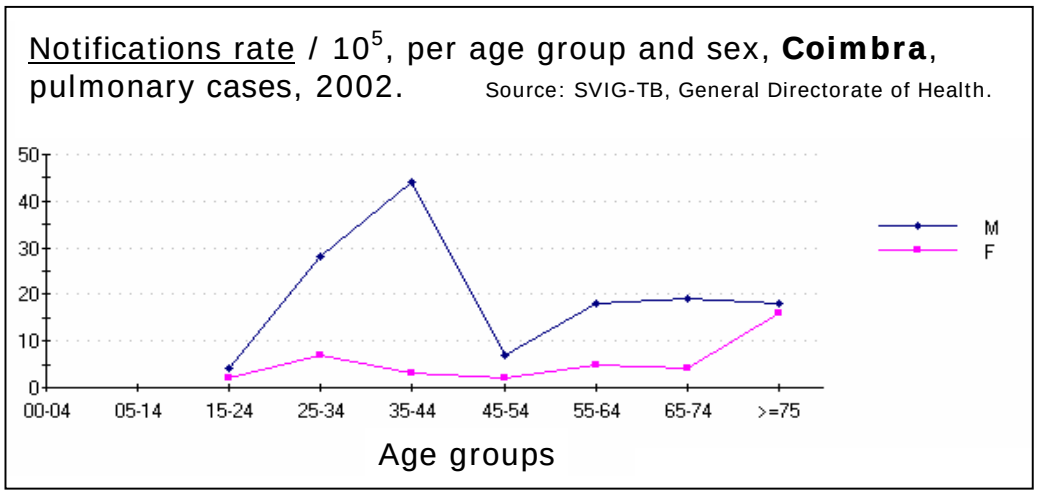

Fig. 20

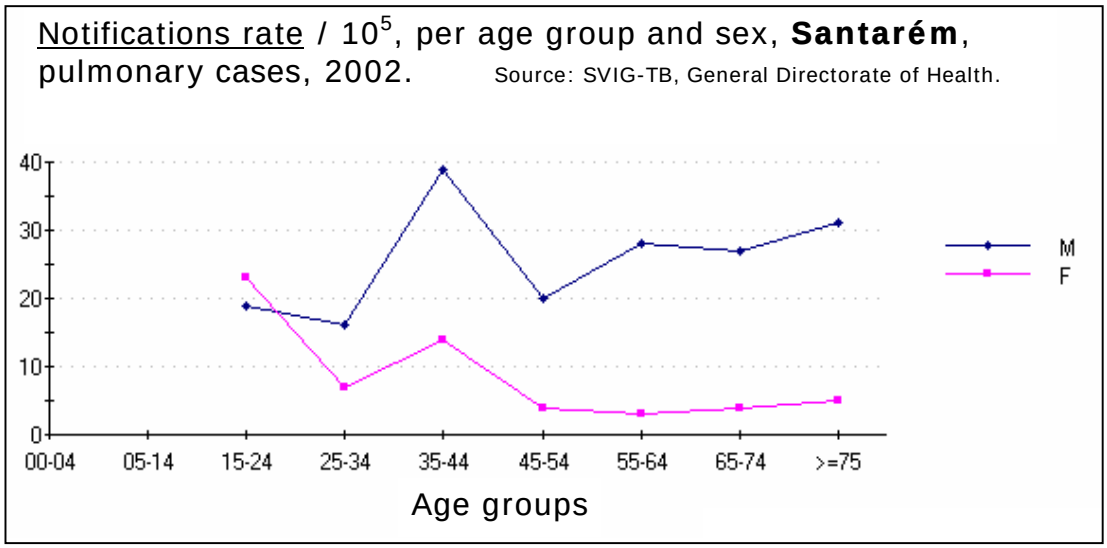

Fig. 21

Laboratory detection rates in notified pulmonary cases, being relatively homogeneous among subregions, suggest that heterogeneity in notified incidence results from not bringing new cases in the community to the contact of networked services, thus failing notification.

Multirresistance in new cases is a *proxy* both to low impact and to insufficient programme performance. The above mentioned bias, due to the practice of positively discriminating cases with co-morbidities and immigrants for antibiotics testing, will decrease and its interpretation will be easier as coverage by testing increases. Thus, multirresistance in new cases is most probably biased in favour of those having associated problems.

Internal validity of *SVIG* data following notification (and thus about follow-up events) couldn't be assessed yet. But this missing knowledge is of considerable importance, as its validity may be much influenced by the alertness and motivation of anyone measuring, recording and transferring data. So, it is only presumed as enough.

INTEREST AND USEFULNESS OF INDEPENDENT OBSERVATIONS

***PNT* progress reports**, issued by its coordination team yearly, have evolved in the observed period, showing increasing completeness, perspicuousness and epidemiologic perspective. The positive reinforcement brought by technical discussions between observer and observed teams, beyond concrete findings from

external, more analytic *OPSS* observations, may be producing some mutual constructive influence and promoting cooperation yield.

The **availability and cooperation of *PNT* coordination team** for providing the required information has been excellent. Its receptive attitude to external appraisals may partly explain the successive improvements in its reports and is a nice example for other intervention programmes.

Limitations imposed by available information were, naturally, the same as for *PNT* own reports, as it comes from the same sources. This weakness of external exercises demands additional cautiousness in critical judgements.

As **external observations are completely free from involvement** in any commitment with both running intervention and programme coordination, they ensure an independent view in evaluation judgements. This also eases external, finer, in depth analysis of specific aspects, relevant for a better understanding of the control image and *PNT* performance. Appraisal exercises have the proved potential to raise clues for complementary studies, whose results may be offered back to *PNT* team.

DISCUSSION

These are additional, general notes to comments made along the *Results* chapter:

Internal validity – No inconsistencies in information have been found, that may be attributed to study weaknesses, even considering its broad scope. Some initial incongruences were cleared up by replacing provisional data by definitive data. Net values were presented, as they regard the whole corresponding population or groups. Major concerns relate to error on measurements, transference and from small numbers.

External validity – This broad approach is of the same nature as that one used by W.H.O. for the same purposes and concerning the whole world; present findings at national level agree in general with the evidence provided by W.H.O. and Euro TB (in turn, elaborated on national data provided…). Evidence showed at subnational level can only be compared with subnational references and with national average values.

CONCLUSIONS and IMPLICATIONS

CONCLUSIONS

1. **Epidemiological evidence of *PNT* impact** should be looked at with much cautiousness, whatever the geographic level, and subnational comparisons

may be misleading, due to a possible geographically heterogeneous under-detection.

2. Subregion heterogeneity in notified incidence and corresponding age/sex notification profiles show some inconsistencies, raising additional difficulties in judging on the degree of control achieved; this control is probably weaker than it seems in lower incidence subregions, as they may be experiencing a heavier underreporting.

3. ***PNT* performance parameters** may be giving an insufficient image of *PNT* capability to stop transmission and to prevent antimicrobial resistance, mainly due to insufficient treatment success. Such capability seems too weak anyway, if emerging challenges to control are to be faced and because a low treatment success counteracts any acceptable detection rate, by bulking the number of resistant mycobateria. In several settings, time since first consultation through treatment start and length of standard treatment are unacceptably high, deserving special attention. "Small numbers" at subregional level data are hampering more confident judgements pertaining both to *PNT* impact and performance.

4. "Small numbers" at subregional level data are hampering more confident judgements pertaining both to *PNT* impact and performance.

5. **Independent appraisals** are confirming the valuable effort of services, add some light on the quality of evidence available, bring specific focus to some issues and raise useful clues for further research, in spite of using the same information sources as *PNT*. Additional analyses of remaining subregions will be useful in order to confirm present findings and to compose a complete picture.

6. Advantage taken from available information by ***PNT* team in its progress reports** is improving fast, presumably influenced by the constructive cooperation with independent appraisals by *OPSS*. This constructive and stimulating environment between "observed and observer" entities should be enhanced and divulged as a good practice for other intervention programmes.

IMPLICATIONS

1. **Notification-based impact evidence** should be complemented with parallel age/sex distribution-related parameters (including median age at diagnosis), National Inquiry on Health information, local key-informers expert opinions, or other relevant evidence which may help to interpret ongoing impact with less uncertainty.

2. **Complementary indicators** on laboratory detection and follow-up, on coverage by directly observed treatment and by case-contacts screening, on time since first consultation through treatment start and on length of total correct, confirmed treatment should be empowered in the board panel, at all levels, and their values improved.

3. **Geographic variation in notified incidence** and its discrepancies with age/sex notification curves must be approached with a finer ecological study, looking for organizational, psychocultural and economical reasonable explanations.

4. **Local evidence** deserves a further revision under the scope of "small numbers" techniques and results should be taken by local teams anyway, for a better adaptation and improvement of national *PNT* guidelines to their specific settings.

5. **Communication and operational cooperation** between networked institutions acting in the same subregion should be very highly promoted.

6. **Independent observation exercises** may act like a mirror and reinforcement for services. They do deserve to be promoted, even with other intervention programmes, because of their great usefulness as a source of learning and development opportunities

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