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Validation of the TB indicators in Umzinyathi District

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Editorial

Tuberculosis was labeled as the “Forgotten Disease” by the former President Nelson Mandela when he spoke of his experience of being diagnosed with Tuberculosis on Robben Island. The decline of Tuberculosis in the developed world saw a waning of interest in the research initiatives into the diagnostic and therapeutic tools available to fight this disease. However, Tuberculosis has remained a constant feature in the disease landscape of the developing world and a persistent theme of the World Health Organisation with the Direct-Observed Treatment-Short Course (DOTS) Strategy.

The Tuberculosis Epidemic has received renewed impetus with the deadly alliance with HIV. This has forced a re-think on many of the tried and trusted strategies to fight the TB epidemic. An area that requires attention is that of the information system- the TB register forms one pillar upon which the programme rests. Current implementation, use and analysis of data in the register raise more questions than answers regarding patient and programme monitoring.

This edition of the Epidemiological Bulletin examines in detail the current pitfalls in the use of the TB register and the calculation of programme indicators. The decentralisation of the Tuberculosis Control Programme to the primary care level as part of the District Health System occurred to make services more accessible. In this scenario, greater attention to training and support of a vertical information system within a comprehensive primary care delivery environment is required to ensure data collection is accurate and can be validated.

The integration between the management of HIV and Tuberculosis is a matter of necessity to provide patients with comprehensive health care services and prevent duplication of scarce resources. Inherent in the integration would be a review of the information system to support patient care and management review. The need to move towards real time patient-centered data which can be aggregated and allow for the computation of composite accurate indicators of programme performance has dawned. Greater investment in the data derived from patient care is warranted to ensure patients are monitored and periodic evaluation of programme information results in appropriate information-led decisions.

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ACRONYMS & DEFINITION OF TERMS

<i>Case Finding</i>	The number of new and retreated TB cases sub-classified into smear+, smear- and no smear
<i>Categories</i>	This includes the following categories: (a) New patients. Those patients who have never been treated or who has been treated less than four weeks; and (b) Retreated patients. These include patients who return for treatment because they fell sick again with TB
<i>Completion Rate</i>	$\frac{\text{No. smear+ completing treatment without smear confirmation}^1}{\text{Total No. smear+}^2}$
<i>Cured</i>	A patient who complete treatment and had a negative sputum smear on at least two occasions, one of which was at completion of treatment
<i>Cure Rate</i>	$\frac{\text{No. Smear+ who turns smear-}}{\text{Total No. smear+}}$
<i>Death rate</i>	$\frac{\text{The number of deaths for any reason during treatment}}{\text{Total No. smear+}}$
<i>DOH</i>	Department of Health
<i>Drug resistance</i>	A patient with a culture of mycobacterium tuberculosis that is resistant to one or more antibiotics
<i>Failure rate</i>	$\frac{\text{Smear+ remaining smear+}}{\text{Total smear+}}$
<i>KZN</i>	KwaZulu-Natal
<i>Move</i>	Each patient moving across clinics within the same district is recorded more than once. For example, a patient moving from clinic 'A' to clinic 'B' in the same district is recorded first in the register of clinic 'A' and again in the register of clinic 'B'. The only way to avoid counting these records twice is to exclude all the records with the outcome "moved within the district"

¹ The numerators of the treatment rates consists of the number of smear+ who were smear- at, or 1 month prior to completion of treatment and on at least one previous occasion (cured), completed treatment without a bacteriological proof of cure, remaining or becoming again smear+ at 5 month or later (failed), interrupted for two or more months and died for any reason during treatment.

² The denominator consists of all the smear+ who were diagnosed in a defined period of time.

<i>Site of Disease</i>	Pulmonary or Extra pulmonary
<i>Success Rate</i>	$\frac{\text{No. cured} + \text{No. completed}}{\text{Total smear+}}$
<i>Transferred</i>	TB patients who are transferred between districts. According to WHO “This indicator should be close to zero since the treatment outcomes of all cases – except those leaving the country – should be known at national level, regardless of patients moving from one district to another”. These patients are counted as transfer in the originating clinic and as treatment outcome in the receiving clinic (i.e. cured). Therefore, transfers should not be included in the treatment outcome rates but they should be considered on their own.
<i>Treatment rates</i>	The proportion of new and retreated smear+, who were cured, completed, interrupted, failed and died.

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Abstract

This issue deals with the validation of the TB register of Umzinyathi. The introduction describes how the TB register works, and what the rationale is behind case finding and treatment outcomes. This rationale was used to validate the indicators of the TB control programme for 2004 in Umzinyathi. The survey team visited all the clinics between September and December 2005 to validate the registers and to collect information on the TB programme. While this Issue deals with the validation of the TB indicators, Issue 13 of the Bulletin will describe the TB programme.

Several coding and methodological problems caused an under-estimation of the cure rate. Due to coding problems the valid cure rate in Umzinyathi was 57% versus 48% of the electronic register. After tackling the methodological problems related to the transfers, the valid cure rate was 66% if the “not evaluated” were included and 71% if the “not evaluated” were excluded from the computation of the rates. The full rationale behind the above rates is explained and should be taken into account when taking decisions on the basis of the cure rates.

The main recommendations include:

- Compilation of clear guidelines on data collection, processing and use of TB indicators according to the rationale behind the TB register. These should include logical framework, objectives of each indicator (i.e. cure rate), differentiation between “treatment outcomes” and other outcomes related to movement of patients, introduction of a unique registration number, definition of terms, feasibility of reliably using the information from the register (i.e. extrapulmonary), interpretation of the statistical outputs and actions to be taken accordingly.
- Modification of the software of the electronic TB register to avoid double counting and to estimate treatment outcomes on smear+ cases only;
- Conduction of annual surveys in each district to provide more timely and reliable indicators compared to the present system, which is still finalizing the data for 2004. Besides validating the information of the TB register, the survey will provide the opportunity to collect management data to identify implementation problems and suggest solutions to be evaluated by the following annual survey.

Introduction

Since the last few years Tuberculosis has been increasing in KZN and in other provinces of South Africa, and the reported TB cure rate has remained very low. The increase of TB and the decline in TB cure rates in many countries is behind the recent initiative from WHO to urge the departments of health (DOH) of the most affected countries to increase their efforts against TB. In South Africa, the national and provincial DOH have recently launched an emergency TB programme, which will be carried out in the districts with the lowest cure rate. What is noticeable is that the same indicators, which were consistently low in the last few years and which were never validated, are now driving an emergency. This confirms that indicators are not a priority until the decision makers need them.

Now that the cure rate has been used to select the worst districts and to measure the impact of a new initiative, everybody should be concerned about its reliability. This means to be able to confidently rank districts according to their cure rates and to ensure that the increase in cure rate is indeed a sign of impact and not a vagary of reporting. Nobody should take for granted that an indicator is reflecting reality just because it is coming out from the electronic register, especially if there is only a superficial knowledge about the complexity of the TB treatment outcomes. The main issue is therefore to find out if the reported cure rates reflect the real cure rate.

Validation is particularly important when published TB statistics are problematic. The TB statistics reported before 2002 is not usable to estimate the annual rate of change in TB incidence and treatment rates. The poor reporting and the changes in the electronic register make numbers non comparable across years. This can be appreciated in Table 1, which represents the outcome rates for KwaZulu-Natal between 1999 and 2001. These numbers are unreliable because they are clearly an under-counting of the real number of expected TB cases and because of the high proportion of transferred and not evaluated.

Table 1 Treatment outcome rates

Treatment outcome	Number of cases			Rates (%)		
	1999	2000	2001	1999	2000	2001
Cured	4430	3482	3449	40%	33%	22%
Completed	2525	2767	7742	23%	26%	49%
Failure	163	283	76	1%	3%	0%
Interrupted	2995	2964	2888	27%	28%	18%
Died	1018	1050	1689	9%	10%	11%
Total known cases	11131	10546	15844	100%	100%	100%
Transferred	4271	3211	3071			
Not evaluated			18128			
Total	15402	13757	37043			

Source: Health Statistical Information, DOH

Now that the TB indicators are driving the emergency, it is important to avoid the problems of the past by creating a more solid baseline against which to compare changes. Because TB statistics is far from being straightforward, it can be incorrectly interpreted leading to wrong conclusions. The terms related to the case finding and the outcomes have to be fully understood to ensure that the treatment rates are based on the correct numerators and denominators.

The objective of this issue is to describe how the electronic TB register works and how it was validated in Umzinyathi. The selection of Umzinyathi was due to the presence of the Italian Cooperation in the district and to the interest of the district authorities to participate. Besides the reliability check, the survey provided the opportunity to collect information on each clinic to shed light on implementation problems. A survey team visited all the clinics to enter the data of the TB registers for 2004 and to interview the staff to collect information on the TB programme. The present Issue deals with the validation of the TB indicators while Issue 13 will present the analysis on the TB programme in Umzinyathi.

Methodology

The TB registers are filled by the clinics and are sent quarterly to the district office. Each page of the Register (see Annex) is composed of rows and columns, with each row representing a patient and each column representing a variable (i.e. diagnosis, outcome). Each page of the register has several carbon copies that are detached by the clinic's staff at the end of each quarter and are sent to the District Office, where the data is entered into the electronic register, which is used to produce quarterly reports.

The validation was organized in two phases. The first phase was spent by the survey team to trace the registers' carbon copies received at the District Office. The information was entered into excel spreadsheets and the missing pages were noted. During the second phase, the team visited the 44 fixed and 8 mobile clinics dealing with TB patients to trace the missing pages that were not received by the District Office. A questionnaire was also used to interview all the nurses in each clinic to collect data on their age, gender, length of service, training, supervision, knowledge about TB diagnosis and treatment, and constraints met during their daily activities. A second questionnaire was administered to the sister in charge to collect information on the clinic's infrastructure, staffing, strategies to trace defaulters, constraints met to trace defaulters and other variables that could shed light on the implementation of the TB programme.

The data collected was analyzed through SPSS. The data was cleaned for inconsistencies and organized in files containing the data related to the TB register, the staff and the clinics' characteristics. The analysis presented in this issue is related to the validation of the TB register, which was carried out by comparing the data entered through the survey with the data produced by the electronic register. The denominators of the treatment rates were based on the cohort of new and retreated smear+ cases that were registered between 1/1/04 and 31/12/04.

Results

Case Finding

Tables 2a-2b compare the number of TB cases found in 2004 according to the validation and to the electronic register. Although the grand totals are similar, the validation recorded only 11% of cases without a smear versus 28% on the electronic register. Although the register had information on the TB site, the proportion of extrapulmonary cases was too low and the diagnosis of the TB site was frequently inconsistent with the smear result. The validation used the remarks at the end of each record on the register to assign each case to pulmonary and extra pulmonary codes. The fact that the validation found 10% of extrapulmonary cases versus 2% of the electronic register, suggests that this statistics is unreliable and should not be used to compare districts.

Table 2a Case Finding, Validation

	smear+	smear-	No smear	Total	%
New	1630	1759	440	3829	84%
Re-treated	358	324	57	739	16%
Total	1988	2083	497	4568	100%
%	44%	46%	11%	100%	

Table 2b Case Finding, Register

	smear+	smear-	No smear	Total	%
New	1420	1384	1130	3934	86%
Re-treated	268	239	151	658	14%
Total	1688	1623	1281	4592	100%
%	37%	35%	28%	100%	

Treatment rates

Tables 3a and 3b show that the electronic register underestimated the cure rate of Umzinyathi for 2004. The cure rate among the new smear+ was 57% according to the validation versus 48% of the electronic TB register. The cure rate among the retreated was 23% according to the validation versus 18% according to the register. This under-estimation of the register is due to problems affecting the quality of recording and data processing.

Table 3a Outcomes, Umzinyathi 2004, Validation

	Cured	Completed	Failure	Dead	Interrupted	Transferred	Not Evaluated	Total
New smear+	924	67	14	250	45	230	95	1625
	56.9%	4.1%	0.9%	15.4%	2.8%	14.2%	5.8%	100.0%
Retreated+	80	12	2	85	9	63	100	351
	22.8%	3.4%	0.6%	24.2%	2.6%	17.9%	28.5%	100.0%
Total	1004	79	16	335	54	293	195	1976
all smear+	50.8%	4.0%	0.8%	17.0%	2.7%	14.8%	9.9%	100.0%

Table 3b Outcomes, Umzinyathi 2004, Electronic Register

	Cured	Completed	Failure	Dead	Interrupted	T/F	Not Evaluated	Total
New smear+	708	127	9	215	47	223	153	1482
	47.8%	8.6%	0.6%	14.5%	3.2%	15.0%	10.3%	100.0%
Retreated+	52	27	4	70	9	46	79	287
	18.1%	9.4%	1.4%	24.4%	3.1%	16.0%	27.5%	100.0%
Total	760	154	13	285	56	269	232	1769
all smear+	43.0%	8.7%	0.7%	16.1%	3.2%	15.2%	13.1%	100.0%

A critical issue needing full understanding is the improper use of the transfers. There are two types of outcomes: (a) treatment outcome and (b) movement outcome, which should not be mixed up because they have different meanings and objectives, and because they are duplicated records. According to WHO, transfers “should be close to zero since the treatment outcomes of all cases – except those leaving the country – should be known, regardless of patients moving from one district to another”. This is not the case in Table 3a and 3b, where transfers are 15% of the total outcomes. Any patient moving within the district or outside the district has two records, the first one represents the “movement outcome”, which is recorded by the transferring unit. The second record is compiled by the receiving unit, which duplicates the original diagnosis (i.e. smear+) of the transferring unit and at the end of treatment assign the “treatment outcome”. Therefore, the records with outcome “moved” or “transfer” are redundant and should be excluded from the statistics of the “treatment rates”. If statistics on moved and transferred is required this should be presented separately from the treatment rates.

Because there is no unique identification number, the only way to avoid double counting is to exclude the records where outcome is coded as “moved” or “transfer”. This is partially done for the district statistics shown in Tables 3a and 3b, where the records coded as “moved” are excluded but the records coded as “transferred” are instead kept in the computation of the treatment rates.

The reason for including the number of transfers across district in the computation of the treatment outcomes is unclear. Including transfers in the treatment rates is incorrect because of the following reasons:

- (a) Although the transfers are outcomes, they are not “treatment outcomes”;
- (b) These patients leave the district to continue treatment in another district, where the receiving unit opens a new record. This means that if Umzinyathi transfers a patient to another district, this patient should be counted for the sake of case finding only because it was diagnosed in Umzinyathi. Including this transfer for the estimation of the treatment outcome of Umzinyathi will penalize the cure rate of this district. If the proportion of the transfers is small the underestimation will be minimal but in Umzinyathi the district transfers were 15% of the total patients, producing a substantial inflation of the denominator with under-estimation of the real treatment rates.
- (c) The same concept is valid when transfers are included in the estimation of the provincial treatment rates. Any patient who is transferred between districts is entered twice in the TB electronic register of KZN. The first time, the patient is recorded in the TB register of the clinic of the originating district where the record will include the diagnosis and the outcome as “transfer”. The clinic in the receiving district will open a second record, repeating the same diagnosis recorded in the TB register of the transferring clinic, while the outcome will be the real treatment outcome. When the data from the districts are aggregated to produce the provincial statistics, each of these cases will contribute two identical diagnosis, one transfer and one real treatment outcome.

The only justification for including the number related to the “transfers” is the estimation of the case finding in the originating district and the movement of patients across districts. Because the original diagnoses of the transfers occurred in Umzinyathi, it is correct to include these records to compute the statistics related to the case finding of Umzinyathi for 2004. It is also correct to use the records of the transfers to produce separate statistics on the movements of patients. But it is incorrect to include the transfers in the treatment rates, which should be based only on the record with a valid “treatment outcome”. This is presented in Tables 4a and 4b, which should be considered the real treatment rates for Umzinyathi. This is the only way to prevent the “transfers” from inflating the denominator and causing an under-estimation of all treatment rates. Further arguments for taking out these duplicated records are in the Annex.

Table 4a Treatment rates, Umzinyathi 2004, Validation

	Cured	Completed	Failure	Dead	Interrupted	Not evaluated	Total
New smear+	924	67	14	250	45	95	1395
	66.2%	4.8%	1.0%	17.9%	3.2%	6.8%	100.0%
Retreated+	80	12	2	85	9	100	288
	22.8%	3.4%	0.6%	24.2%	2.6%	28.5%	82.1%
Total	1004	79	16	335	54	195	1683
All smear+	59.7%	4.7%	1.0%	19.9%	3.2%	11.6%	100.0%

Table 4b Treatment rates, Umzinyathi 2004, Register

	Cured	Completed	Failure	Dead	Interrupted	Not evaluated	Total
New smear+	708	127	9	215	47	153	1259
	56.2%	10.1%	0.7%	17.1%	3.7%	12.2%	100.0%
Retreated+	52	27	4	70	9	79	241
	21.6%	11.2%	1.7%	29.0%	3.7%	32.8%	100.0%
Total	760	154	13	285	56	232	1500
All smear+	50.7%	10.3%	0.9%	19.0%	3.7%	15.5%	100.0%

Further under-estimation is caused by the inclusion of the “not evaluated”. It can be argued that the “not evaluated” are per se negative outcomes because all the patients should be followed up till the end. However, these records should be treated as missing values, which are usually excluded from the estimation of rates. According to WHO the not evaluated “should be closed to zero, showing that all registered cases have been evaluated for treatment outcome”. This is not the case in Tables 4a and 4b where these missing values are a sizable number, inflating the denominator without contributing to the numerator. In other words, when estimating the treatment rates, the “non evaluated” inflate the denominator, which is tantamount to say that all patients who were not evaluated did not smear convert, did not complete, did not fail, did not interrupt and did not die but they are still to be counted at the denominator of the treatment rates, biasing all the treatment rates downwards. It has to be considered that the fate of those patients who were not evaluated is unknown and like any missing records they require to be taken out of the estimation of rates. Although missing information can be considered undesirable and therefore a negative outcome, the number of missing should not mixed with the number of known outcome.

Because of the above problem, missing values should be excluded from the estimation of treatment outcome rates. Keeping the missing values in the computation produces more biased estimates compared with taking them out. If the TB programme decides to keep the not evaluated in the computation, it is suggested to present the rates with the “not evaluated”, as in Table 4a and 4b, and without the “not evaluated” as in Tables 5a and 5b, which represent the “known treatment rates”.

Table 5a Known treatment rates, Umzinyathi 2004, Validation

	Known					Total
	Cure rate	Completed rate	Failure rate	Dead rate	Interrupted rate	
New smear+ known rates	924 71%	67 5%	14 1%	250 19%	45 3%	1300 100%
Retreated+ known rates	80 43%	12 6%	2 1%	85 45%	9 5%	188 100%
Total known Rates	1004 67%	79 5%	16 1%	335 23%	54 4%	1488 100%

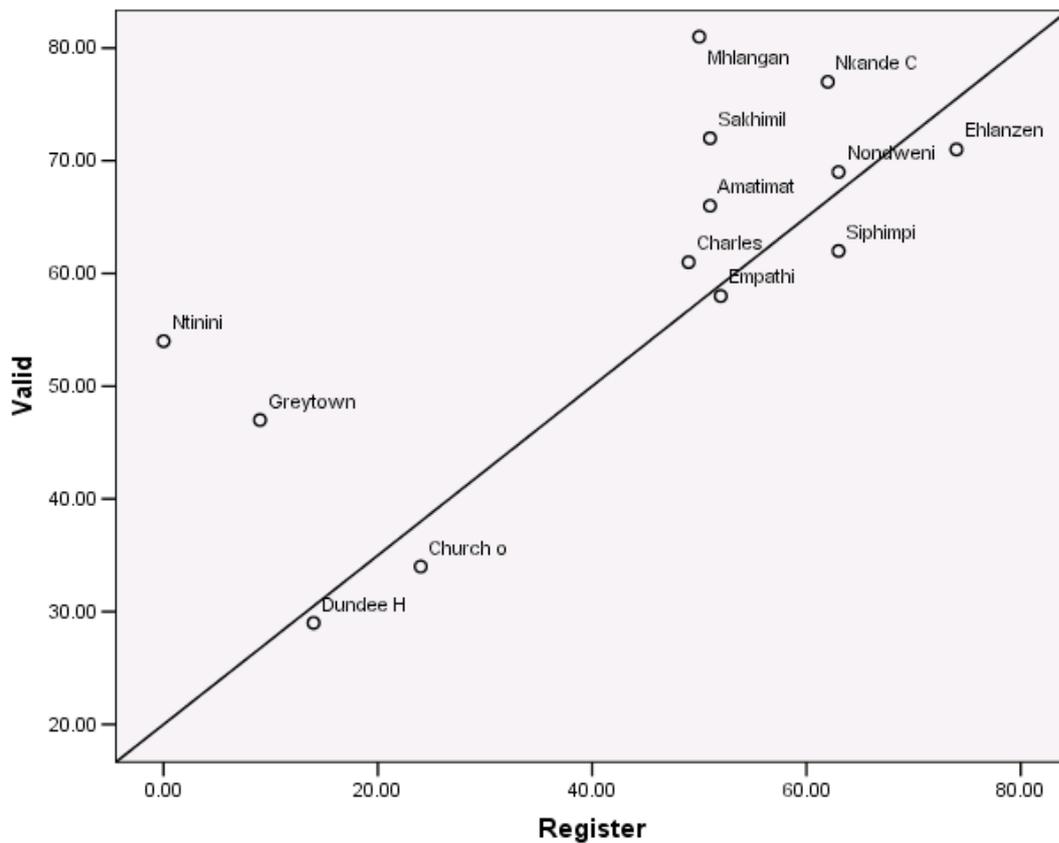
Table 5b Known treatment rates, Umzinyathi 2004, Register

	Known					Total
	Cure rate	Completed rate	Failure rate	Dead rate	Interrupted rate	
New smear+ known rates	708 64%	127 11%	9 1%	215 19%	47 4%	1106 100%
Retreated+ known rates	52 32%	27 17%	4 2%	70 43%	9 6%	162 100%
Total known Rates	760 60%	154 12%	13 1%	285 22%	56 4%	1268 100%

The treatment rates were also validated at the individual clinic level. In Figure 1 each clinic with more than 30 patients is plotted according to the cure rate of the validation (Y axis) and the register (X axis). For example Empathi had similar values according to the validation and the register and therefore it was on the 45-degree line. The clinics on the left of the line had higher valid values compared with the register and therefore the register produced underestimation of their cure rates. Vice versa, the clinics at the right of the line had lower valid values than the reported cure rate (overestimation). The reason why most clinics fell at the left of the diagonal line and therefore had an underestimated cure rate was due to a mix of poor recording and duplication of records due to the fact that both the “moved” and the “transfers” were considered in the computation of the rates.

While the electronic register excluded the “moved” when computing the treatment outcome rates for the district level, it included the “moved” when computing the same rate for individual clinics. This produced a worst double counting compared with the statistics extracted for the district level as it can be seen by the total at the bottom of Table A1 in the Annex where the total TB records for Umzinyathi was 6749 compared with 4562 TB cases and the cure rate for the district was 11% as shown at the bottom of Table A1 in the Annex.

Figure 1 Comparison between valid and reported treatment outcomes



The above considerations show that caution should be exercised before interpreting the rates coming out from the electronic register. The electronic register is programmed according to what it was instructed to do with the data, but this does not mean that this is meeting the original objectives, which was to measure the treatment rates. If there is lack of clarity on what these indicators mean or how they should be used it is not surprising that the software produces underestimated cure rates.

TB mortality

The exclusion of transfers and “not evaluated” provides more reliable estimates on the TB mortality. When transfers are included (Tables 3a-3b), mortality among the new and retreated cases is respectively 14% and 18% according to the validation and 15% versus 16% according to the register. One would expect to find a much higher difference in mortality between these two types of patients, considering that the retreated have much less chance of survival than the new cases. When transfers are taken out (Tables 4a-4b) the difference in mortality between new and retreated increases. When the “not evaluated” are taken out, this difference increases further (Table 5a-5b) and mortality among the retreated is double than among the new cases. This confirms that the inclusion of transfers and not evaluated bias the result of mortality too.

The age and gender proportional distribution of the number of TB deaths reminds that of AIDS deaths. Figure 2a shows the proportional distribution of all TB deaths in 2004 for Umzinyathi in terms of the percentage of total deaths that occurred in certain age groups for males and females. The two curves show that about 45% of all the TB deaths occurred between 25 and 34 years of age among females versus about 35% among males. Figure 2b shows the prediction of the proportional distribution of the expected AIDS deaths for KZN according to ASSA2003. The two mortality curves are very similar because they show that the female curve rises and declines before the male curve both for TB and AIDS mortality. This is a well-known pattern of HIV infection, which infects females at a younger age than males.

Figure 2a Proportional distribution of TB deaths, Umzinyathi 2004, validation

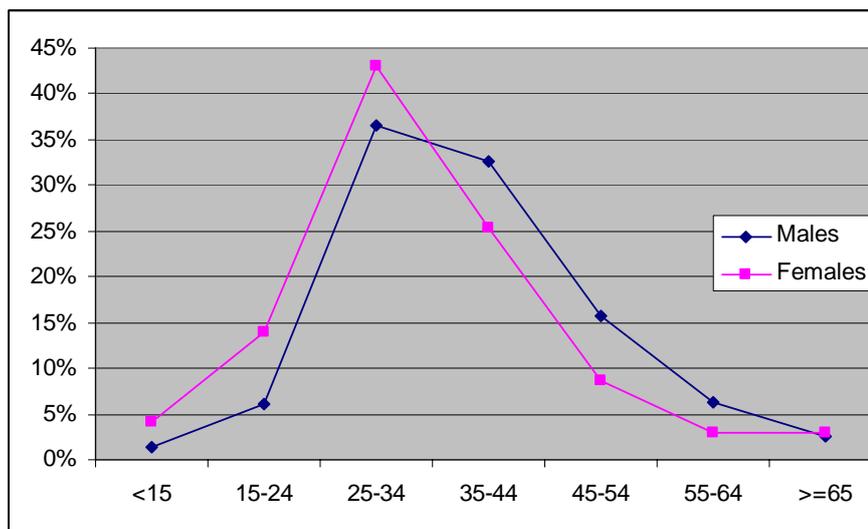
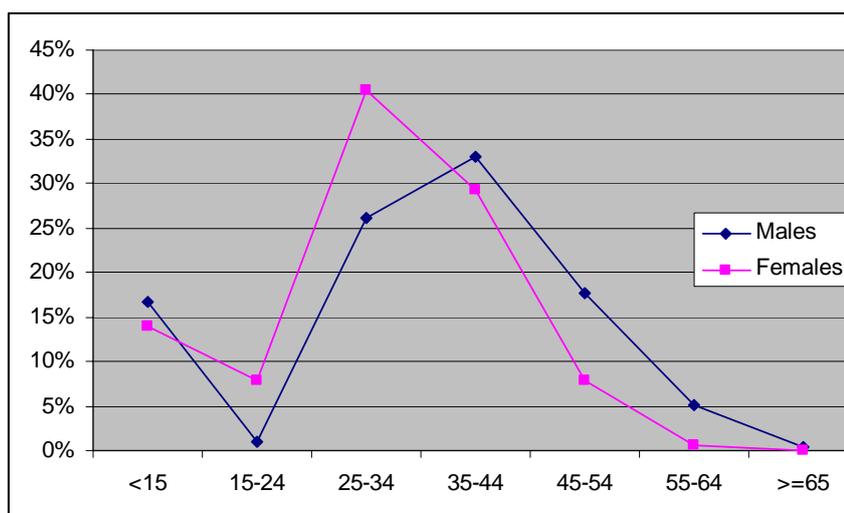


Figure 2b Proportional distribution of AIDS estimated deaths for KZN, ASSA2003



Discussion

The good news is that the real cure rate for 2004 in Umzinyathi was about 71% versus the reported 47% among the new cases, the bad news is that several changes are required in the reporting system. The unreliability caused by recording and data processing was responsible for about 9% underestimate of the cure rate among new cases. The methodological problems related to the transfers and not evaluated were responsible respectively for another 10% and 5% underestimate of cure rate among the new cases. The data recording and processing can be improved through the provision of guidelines on how to record the information on the register and by implementing annual surveys like that conducted in Umzinyathi. The methodological problems are much more difficult to tackle because they need clarification of the rationale behind the register and changes in ingrained modus operandi when interpreting and using the estimates. When the top level has always instructed the lower level to equate the “transfers” to “treatment outcomes”, and to include the “not evaluated” in the estimation of rates, any change requires substantial efforts.

The problem is also complicated by the interpretation of the WHO directives. The fact that the WHO control programme keeps transfers and “not evaluated” in their statistics, even if they admit that they should be near zero, does not help. The question is therefore how to begin a discussion at the highest level to sensitize the top decision makers to accept that there are problems and that these problems are affecting all the treatment rates.

The national and provincial Department of Health should become more aware about the problems affecting TB statistics. Besides the problem of under-estimation of the treatment outcome rates another problem is the inconsistency of the statistics produced by the electronic register. Cure rates are estimated on both smear+ and on all TB cases (including smear-), causing different cure rates. The cure rates estimated at clinic level include movements within the district which brings the total to more than 6000, causing the worst underestimate of cure rate for Umzinyathi (11%).

The reason why most decision makers consider further efforts in improving the reliability of the indicators as an academic exercise is due to poor knowledge about statistics. The matter is not to improve precision but validity and comparability so that the huge amount of resources invested in the health information system are not wasted in producing misleading statistics. The relatively small cost of conducting a district survey allows decision makers to have a clearer idea of where the TB programme stands. This allows to efficiently use the human and other resources invested in the TB register which otherwise would have been wasted in producing unreliable statistics. After all, although the reported cure rates were extremely low, nobody took actions to check if this was indeed the case. Without a proper reliability check on the indicators there is no valid yardstick against which to select the worst district or to measure the changes in terms of impact.

The original good intentions at the basis of the production of the quarterly reports are nullified by the inconsistencies of the data. Because of the delay with which the carbon copies are received at the district office, the numbers are always changing across reports causing inconsistencies. Furthermore, the electronic register produces cure rates for both smear+ and for all TB cases, including smear- and no smear, which is incorrect and creates confusion. These different numbers and rates should be presented in a more standardized way and there should be a clear rationale between the statistics and its link to management actions. As they are at present the quarterly reports are unlikely to meet the original objectives of producing such routine statistics because it is unclear if the meaning of the numbers presented in the tables is understood and if the statistics is used to improve programme activities.

Improving the reliability of the statistics produced by the TB control programme requires a better understanding of the logic behind the TB register. The registration is of no use if each patient is not assigned a unique Identification number so that the electronic register can trace the double counted patients. This could be done through the printing process of the green treatment card, which is given to each new patient. The printing process could be used to provide each card with sequential numbers, which could then be used as registration numbers. The logic behind the TB register should help to understand the difference between movements of patients within and outside the district, treatment outcomes and duplication of records.

The “not evaluated” records should be considered as any other missing records and treated accordingly. The districts having a high proportion of “not evaluated” can bias the rates downwards impairing comparison with districts with lower proportion of “not evaluated”. For example, Ethekewini and Zululand have been frequently characterized by high numbers of “not evaluated”, which are likely to have affected the estimation of the real rates and their comparability across districts. Districts like Umzinyathi, having a much lower proportion of “not evaluated” are likely to produce less biased estimates because it is more likely that the known outcomes represent the whole sample. In this case, taking out the missing values creates fewer problems compared to keeping them in the computation.

Last but not least the production of statistics should be better standardized and reduced to the minimum essential. At the moment there are several opportunities to produce incorrect or inconsistent statistics because there is no clear guidelines on the data collection, data processing and interpretation of the statistical outputs. The footnotes of the page of the register are insufficient to grasp the meaning, importance and function of technical terms and relative codes. For example, it is insufficient to put a few codes under “site of disease” hoping that the nurse correctly assigns a case to pulmonary and extrapulmonary codes. The unlikely small proportion of extrapulmonary cases in Umzinyathi in 2004 confirms that the diagnosis of extrapulmonary TB is a problem. Furthermore, it is unlikely that the seven different ICD10 codes (i.e. A16.3, A16.5) of extrapulmonary sites of TB are achieving any objective, considering that a nurse will be able to differentiate between them. The nurses are doing a commendable job in recording the information but they should be guided on how to properly fill the

information in the register. A better clarification of the logical framework behind the register should highlight the role of each variable, the way to collect the information and the link with management of TB control programme.

The major recommendations include:

- Compilation of guidelines on data recording and processing according to the rationale behind the TB electronic register. These should include logical framework, objectives of each indicator (i.e. cure rate), differentiation between “treatment outcomes” and other outcomes due to movement, justification of numerators and denominators and problems related to double counting, introduction of a unique registration number and date, definition of terms, interpretation of the statistical outputs and actions to be taken accordingly;
- Understanding the role of each variable collected on the register, feasibility of correctly recording the information and risk of misuse. For example, the collection of information on extrapulmonary cases should be judged according to its potential use to improve programme’s activities, feasibility of reliably collecting this diagnostic information, risk of misusing unreliable information to compare districts in the proportion of extrapulmonary cases.
- Modification of the software of the electronic register to avoid double counting and to estimate the treatment rates on smear+ only;
- Conduction of annual surveys in each district to provide more timely and reliable indicators compared to the present system, which is still finalizing the data for 2004. Besides validating the TB register, the survey provides the opportunity to begin a monitoring and evaluation system by collecting management data to identify implementation problems and suggest solutions to be evaluated by the following surveys.

ANNEX Electronic Register

The objective of the TB register is to follow up each patient from registration to the treatment outcome related to cure, completion, failure, interruption and death. Each row of the register in Figure A1 represents a patient and the columns represent the following variables: registration number and date (a-b); newly registered or coming from another unit (c); name, sex age, race, address (d-h); category in terms of new patient or retreated (i) site of disease as pulmonary and extra pulmonary (j); treatment regimen and date (k); date and result of smear at pretreatment, 2 month, 3 month, 6 month (l-o); date and culture results for those patients still having a positive sputum after 6 months (p); treatment stop date (q); outcome (r) and remarks (s).

Data Recording

Although the above terms might seem straightforward, there are many opportunities for mistakes. The simplest case is a patient beginning and ending in the same clinic because the complete history is easy to follow chronologically on one row of the register from left to right. A patient entering the system in one clinic and moving to another clinic within the same district is coded as “moved” under the outcome (r) of the register of the transferring unit and as a “moved in from facility in this district” under the column related to “transfer/moved” (c) in the register of the receiving unit which, if no other movements occur, follows the patient till the “treatment outcome” is coded (r). In this case, the patient is registered twice in the same district and because there is no unique registration number the only way to avoid duplication is to exclude the first record coded as “moved” under the outcome and keep only the record with a “treatment outcome”. If the patient is transferred out of the district from clinic A to C, the code of the outcome is “transferred” and the record should be taken into account in the originating district only for the estimation of the case finding but not for “treatment outcome”. In the production of the provincial statistics, the records “transfer” are duplicates because the same patient has one record in the originating district and another one in the receiving district. If these records are not excluded each patient moving across the district contributes for two identical diagnoses (i.e. smear+) one “transfer” and one “treatment outcome”.

Statistics on case finding

The statistics produced by the register includes the case finding and the treatment outcomes. The case finding is related to the number of new and retreated cases identified in a defined period of time. These are then disaggregated according to the results of the pretreatment smear (l). At least in Umzinyathi the coding related to pulmonary and extrapulmonary TB (j) was unreliable and the case finding was therefore limited to the number of new and retreated smear+, smear- and no smear.

Statistics on treatment rates

The treatment rates should be calculated taking into account the smear+ only. The logic behind the register is to follow a cohort of new and retreated patients who are registered during a period of time such as between 1/1/04 – 31/12/04. Because the treatment lasts six months, the pages of the register related to the last patients registered in the last few days of 2004 were completed around the middle of 2005. The treatment outcome rates are based on the proportion of smear+ turning smear- (cure), completing the treatment without a smear test (complete), remaining smear+ (failure), dying for any reason and interrupting during treatment. Even if estimation of completion, death and interruption could theoretically be based on all TB patients (including the smear-), the treatment outcome rates should be based only on the smear+. This is related to the fact that smear+ are infectious and smear- are not, and therefore their treatment outcome is prioritized, but another reason is that the smear+ treatment rates provide a proxy of the treatment rates of all TB cases. Furthermore producing different treatment rates for all TB cases would only add confusion.

How the electronic register works

Each sheet of the register in the clinics has carbon copies that are detached and sent to the district office where the information is entered into the electronic register. The statistics extracted from the electronic register is based on the correct coding of each record and on the right use of numerators and denominators.

New and retreated

The new and retreated TB cases are derived from the variable “treatment category” in Column (i). New patients have never been treated or have been treated for less than four weeks. Retreated patients are falling sick again after they were considered cured (negative smear), completed treatment (without smear confirmation), failed treatment (still smear positive after six months) and interrupted.

Treatment rates

The outcomes are derived from column ® where two different types of outcomes are coded: (a) “treatment” and (b) “movement”. The treatment outcomes include: (i) cure, smear negative at or one month prior to completion of treatment; (ii) completion of treatment without smear confirmation; (iii) failure, remained or became smear+ at five months or later during treatment; (iv) death for any reason during treatment and (v) interruption for two or more months. The treatment outcome rates are based on the cohort of smear+, which was followed up from diagnosis until the treatment outcome was recorded. The movement outcomes include “moved” between clinics within the same district and “transferred” to another district. These records duplicate the information of other records and should not be included in the formulae of the treatment rates.

The reason why the moved and the transferred should be excluded from the formulae of the treatment rates is described in Box 1. Box 1 represents an over-simplification of what happens to the cure rate in the hypothetical scenario where the whole population of smear+ patients is represented by the three smear+ cases in clinic A. In this hypothetical case the objective is to estimate the valid cure rate, which is 100% because at the end of treatment all patients get cured. Of the three smear+ beginning the registration in Clinic A, patient 1 does not move and occupies only one record, with one diagnosis (smear+) and one “treatment outcome” (cured). Patient 2 begins diagnosis and treatment in Clinic A but moves to Clinic B within Umzinyathi. This patient has two records, the first record in clinic A contain the original diagnosis (smear+) and one movement outcome (moved), while the second record in Clinic B reports the same original diagnosis of Clinic A and the treatment outcome (cured). Patient 3 is similar to Patient 2 but instead of moving within the district is transferred to Clinic C outside the district where the “treatment outcome” is recorded (cured).

The correct estimation of the treatment rates depends on the inclusion and exclusion criteria of the software of the electronic register. When the registers of clinics A (3 records) and B (1 record) are sent to the district office, four records are entered into the electronic register of Umzinyathi. If the inclusion criteria are correct and only the records with “treatment outcomes” are included and the records with “movements outcomes” are excluded, the cure rate for Clinics A and B is 1/1 (100%) because each clinic has one valid record characterized by a “treatment outcome” while the other records of Clinic A are related to “movement outcomes”. If the same inclusion criteria are applied at the district level, again the cure rate is 100% because two cured are divided by two smear+. Finally the cure rate is 100% also at the provincial level where three cured are divided by three smear+.

But the electronic register uses different inclusion criteria, which affect the correct estimation of the cure rate at different levels. At the clinic level, because both transfers and moved are included, Clinic A has a cure rate of 1/3 (33%) because all the three smear+, including movements are taken into account. Clinic B has a cure rate of 1/1 (100%) because the only cured is divided by the only smear+. At the district level, the software excludes the records with outcome “move” but keeps the “transfers”, thus the cure rate is 66% because the two cured from Clinics A and B are divided by four smear+. At the provincial level, again the transfers are kept in the computation and the cure rate is 75% because the three cured from all the clinics are divided by four smear+.

Because of the mixing between movement and treatment outcomes, cure rate is driven down. The above simplification shows why the real cure rate of 100% is underestimated at different levels. The inclusion of both move and transfer at the clinic level produced the highest underestimation in Clinic A because this clinic has patients moving and transferring to other clinics. The exclusion of the move at the district level and provincial level reduces the underestimation compared to the clinic level. Therefore, the way the data are used causes different degree of underestimation according to the different level, producing both poor validity and poor reliability. This is due to the fact that treatment outcomes are mixed with movement outcomes, which is like mixing apples with oranges.

BOX 1 Example of how the electronic register works

The under-estimate is represented by this over-simplification in which all the smear+ in KZN are represented by three smear+ which are all cured (cure rate= 100%) but the reporting tells a different story.

AT PROVINCIAL LEVEL (Aggregation of Records from Clinics A, B, C)

KZN Register = 5 records of which 4 are used because “move” is excluded but transfer” is included.
3 valid records with diagnosis & treatment outcomes, 2 duplicated records due to move and transfer
4 records kept in the computation of cure rate

Valid Cure Rate= 3 cured / 3 smear+ = 100%

Reported Cure Rate = 3 cured / 4 smear+ = 75%

Provincial register

Patient	Diagnosis	Outcome	Record kept	Valid or Duplicate
1	smear+	cured	Yes	Valid
2	smear+	cured	Yes	Valid
3	smear+	cured	Yes	Valid
2	smear+	moved	No	Duplicate
3	smear+	transfer	Yes	Duplicate

AT DISTRICT LEVEL (Aggregation of Clinic A and B in Umzinyathi District Register).

Umzinyathi Register = 4 records of which 3 are used because transfer is not excluded.

2 valid records with diagnosis & treatment outcomes
2 duplicated records due to move and transfer
3 records kept in the computation of cure rate

Valid Cure Rate= 2 cured / 2 smear+ = 100%

Reported Cure Rate = 2 cured / 3 smear + = 66%

Umzinyathi Register

Patient	Diagnosis	Outcome	Record kept	Valid/ Duplicate
1	smear+	cured	Yes	Valid
2	smear+	cured	Yes	Valid
2	smear+	moved	No	Duplicate
3	smear+	transfer	Yes	Duplicate

AT CLINIC LEVEL IN

UMZINYATHI

The software estimates the cure rate for each clinic by taking into account all records including duplicates due to move & transfer

Register Clinic A = 3 Records of which all 3 are included

1 Valid record with diagnosis & treatment outcome
2 Duplicated records due to move and transfer

All 3 records are kept

True Cure Rate = 1 cure / 1 smear+ = 100%

Reported Cure Rate = 1 cure / 3 smear+ = 33%

Register of Clinic A

Patient	Diagnosis	Outcome	Record kept	Valid or Duplicate
1	smear+	cure	Yes	Valid
2	smear+	move	Yes	Duplicate
3	smear+	transfer	Yes	Duplicate

The second patient moves in clinic B within Umzinyathi

The third patient is transfer in another district to Clinic C

Other District

Clinic C receives and cure patient 3 from Umzinyathi

Register C = 1 Record which duplicates the diagnosis from Clinic A and record the treatment outcome

Patient	Diagnosis	Outcome
3	smear+	cured

Register Clinic B = 1 record

Duplicated diagnosis = 1

Treatment outcome = 1

Register of Clinic B

Patient	Diagnosis	Outcome
2	smear+	cured

The diagnosis is already recorded in register A while there is a valid outcome.

True Cure Rate = 1/1 (100%)

Reported cure rate = 1/1 (100%)

Table A1 Treatment rates at the clinic level, Umzinyathi 2004, Electronic Register

KWAZULU NATAL Tuberculosis Programme DC24 – UMZINYATHI 2004/1/1 to 2004/12/31

Summary by Facility Performance of facilities, according to Number of cases, Smear Conversion and Treatment Outcomes

Facility	Cases Reported			Smear Conversion (New Sm+ve)				Treatment Outcome (New Sm+ve)					
	All TB	New sm+ve PTB		Converted		No results available		Cured		Defaulted		Not evaluated	
	N	N	%	N	%	N	%	N	%	N	%	N	%
AMAKHABELA PROV CLINIC	16	10	62.5	6	60.0	1	10.0	6	60.0	-	0.0	1	10.0
AMANDLALATHI PROV CLINIC	-	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0
AMATIMATOLO PROV CLINIC	97	37	38.1	27	73.0	2	5.4	19	51.4	1	2.7	6	16.2
CH. OF SCOTLAND PROV HOSPITAL	2053	258	12.6	131	50.8	9	3.5	61	23.6	1	0.4	18	7.0
CH.J. MEMORIAL PROV HOSPITAL	517	278	53.8	201	72.3	11	4.0	136	48.9	13	4.7	20	7.2
CJM MOBILE A	2	2	100.0	1	50.0	-	0.0	-	0.0	-	0.0	-	0.0
CJM MOBILE B	2	2	100.0	1	50.0	-	0.0	-	0.0	-	0.0	-	0.0
CJM MOBILE C	3	2	66.7	2	100.0	-	0.0	1	50.0	-	0.0	-	0.0
COLLESIE PROV CLINIC	74	11	14.9	7	63.6	2	18.2	3	27.3	-	0.0	6	54.5
COSH MOBILE I	127	11	8.7	9	81.8	2	18.2	10	90.9	-	0.0	-	0.0
COSH MOBILE II	144	14	9.7	13	92.9	-	0.0	11	78.6	1	7.1	-	0.0
CWAKA PROV CLINIC	93	17	18.3	14	82.4	1	5.9	9	52.9	1	5.9	2	11.8
DOUGLAS PROV CLINIC	88	24	27.3	22	91.7	1	4.2	9	37.5	1	4.2	10	41.7
DUNDEE LA CLINIC	-	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0
DUNDEE MOBILE I	32	17	53.1	12	70.6	2	11.8	7	41.2	-	0.0	4	23.5
DUNDEE MOBILE II	47	16	34.0	11	68.8	1	6.3	8	50.0	1	6.3	2	12.5
DUNDEE PROV HOSPITAL	675	268	39.7	75	28.0	20	7.5	38	14.2	6	2.2	4	1.5
EHLANZENI PROV CLINIC	57	34	59.6	25	73.5	1	2.9	25	73.5	1	2.9	-	0.0
ELANSKRAAL SA CLINIC	-	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0
EMPATHI/VICTORIA ST LA CLINIC	136	58	42.6	41	70.7	3	5.2	30	51.7	5	8.6	3	5.2
ESHANE PROV CLINIC	43	12	27.9	9	75.0	2	16.7	4	33.3	1	8.3	1	8.3
ETHEMBENI PROV CLINIC	145	25	17.2	19	76.0	2	8.0	12	48.0	-	0.0	6	24.0
FELANI PROV CLINIC	20	16	80.0	13	81.3	1	6.3	12	75.0	-	0.0	1	6.3
GLENCOE PRISON	30	7	23.3	5	71.4	1	14.3	3	42.9	-	0.0	1	14.3
GLENRIDGE CLINIC	42	26	61.9	14	53.8	3	11.5	13	50.0	5	19.2	3	11.5
GREYTOWN CIVIC LA CLINIC	-	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0
GREYTOWN MOBILE I	73	22	30.1	17	77.3	1	4.5	11	50.0	-	0.0	7	31.8
GREYTOWN MOBILE II	82	27	32.9	23	85.2	1	3.7	13	48.1	-	0.0	7	25.9
GREYTOWN PRIVATE HOSPITAL	-	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0
GREYTOWN PROV HOSPITAL	522	188	36.0	92	48.9	2	1.1	17	9.0	1	0.5	1	0.5
GUNJANA PROV CLINIC	84	3	3.6	3	100.0	-	0.0	3	100.0	-	0.0	-	0.0
HLATHI DAM PROV CLINIC	58	25	43.1	17	68.0	3	12.0	17	68.0	-	0.0	-	0.0

HOSPITAL GATE CLINIC	84	30	35.7	16	53.3	5	16.7	12	40.0	3	10.0	2	6.7
ISANDLWANA PROV CLINIC	20	17	85.0	14	82.4	-	0.0	10	58.8	-	0.0	1	5.9
ISITHUNDO PROV CLINIC	-	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0
KRANSKOP	-	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0
KWANYEZI PROV CLINIC	26	19	73.1	14	73.7	1	5.3	8	42.1	-	0.0	6	31.6
MANDLENI PROV CLINIC	66	10	15.2	8	80.0	-	0.0	4	40.0	-	0.0	3	30.0
MANGENI PROV CLINIC	25	19	76.0	11	57.9	6	31.6	7	36.8	-	0.0	7	36.8
MASOTSHENI PROV CLINIC	32	19	59.4	16	84.2	1	5.3	15	78.9	-	0.0	1	5.3
MAWELE PROV CLINIC	28	11	39.3	10	90.9	-	0.0	10	90.9	-	0.0	-	0.0
MAZABEKO PROV CLINIC	31	5	16.1	4	80.0	1	20.0	1	20.0	-	0.0	1	20.0
MBANGWENI PROV CLINIC	71	10	14.1	8	80.0	2	20.0	7	70.0	-	0.0	1	10.0
MDR PARKING LOT	-	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0
MHLANGANA PROV CLINIC	129	32	24.8	30	93.8	-	0.0	16	50.0	-	0.0	9	28.1
MKHONJANE PROV CLINIC	22	17	77.3	10	58.8	1	5.9	8	47.1	-	0.0	-	0.0
MPISE PROV CLINIC	-	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0
NGUBEVU PROV CLINIC	27	5	18.5	5	100.0	-	0.0	4	80.0	-	0.0	-	0.0
NKANDE PROV CLINIC	107	52	48.6	36	69.2	12	23.1	32	61.5	1	1.9	1	1.9
NOCOMBOSCHE PROV CLINIC	47	7	14.9	7	100.0	-	0.0	5	71.4	-	0.0	2	28.6
NONDWENI PROV CLINIC	125	65	52.0	56	86.2	6	9.2	41	63.1	-	0.0	5	7.7
NOYIBAZI CLINIC	86	11	12.8	9	81.8	1	9.1	7	63.6	-	0.0	1	9.1
NTEMBISWENI PROV CLINIC	69	27	39.1	20	74.1	2	7.4	8	29.6	1	3.7	4	14.8
NTININI CLINIC	1	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0
PHC GATE CLINIC	-	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0
PINE STREET/GREYTOWN LA CLINIC	80	27	33.8	19	70.4	5	18.5	7	25.9	2	7.4	12	44.4
QINELANI PROV CLINIC	66	8	12.1	8	100.0	-	0.0	6	75.0	-	0.0	1	12.5
RICHMOND CHEST SA HOSPITAL	-	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0
RORKES DRIFT PROV CLINIC	22	14	63.6	10	71.4	1	7.1	9	64.3	1	7.1	1	7.1
SAKHIMPILO LA CLINIC	120	49	40.8	32	65.3	3	6.1	25	51.0	2	4.1	4	8.2
SIBUYANE PROV CLINIC	-	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0
SIPHIMPILO LA CLINIC	119	48	40.3	39	81.3	3	6.3	30	62.5	3	6.3	5	10.4
SPRINGLAKE COLLERY	-	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0
UKUTHULA LA CLINIC	84	28	33.3	26	92.9	1	3.6	23	82.1	1	3.6	1	3.6
UNNAMED FACILITY 02	-	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0
UNNAMED FACILITY 03	-	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0	-	0.0
Total	6749	1940	28.7	1218	18.0	123	1.8	773	11.5	52	0.8	171	2.5

1. Caution must be exercised when interpreting percentages, especially when the number of cases seen at a facility is low (less than 30).
2. Cases reported include all patients seen at the facility, i.e. newly registered plus moved or transferred in. Therefore the 'Total' in this report (as a total of all facilities) is not a cohort and will not equal the numbers in your (Sub)-district/LSA reports.
3. The total for each row and indicator do not equal 100% as only selected performance data (smear conversion, cure and default) are highlighted in this report.

What was over-simplified in Box 1 is represented in Table A1, which is the statistical output of the electronic register at clinic level for 2004 for Umzinyathi. The columns represent the name of the clinics; the TB cases and the new smear+; the smear conversion; and the number and proportions of cured, defaulted and not evaluated. For example, the fourth clinic had 258 new smear+ and the cure rate was obtained by dividing the 61 cured by the initial 258 new smear+, which is equal to 24%. However, according to the analysis of the validation, 111 of the 258 initial smear+ moved to other clinics in the districts, where the same diagnosis was repeated and the final treatment outcome was recorded. Therefore the real cure rate should have been estimated by dividing the 61 cured which remained until the end attached to the clinic by the net smear+ patients followed up until the end which is $61/(258-111) = 41\%$. As already described in Box A1, if those moving within the districts are taken into account in the computation, the duplicated diagnoses inflate the denominator and cause underestimation of the real cure rate. The effect of this duplication can be seen at the bottom of Table A1 where in the first column the total number of TB patients for Umzinyathi is a staggering 6749 TB patients against the 4562 TB patients of Table 2a. In the 9th column, the cure rate for the district becomes a meager 11.5% versus 48% of table 2b. This shows how the same data have been extracted differently by the electronic register, producing inconsistent cure rates for the whole district.

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