

A CHANGE POINT ANALYSIS OF PERFORMANCE INDICATORS OF REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAM IN GUJARAT

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ABSTRACT

Background: In Asia, India is declared as High Tuberculosis/ High HIV/High MDR-TB burden country. The WHO estimates that there are 3100000 cases of TB at a rate of 256/1 lakh population, and the new cases are emerging at the rate of 185/ lakh population every year. To counter TB challenge, the country has implemented Revised National Tuberculosis Programme (RNTCP) since 1997. But, at which critical point of time the programme had significant success or failure in its indicators is important to analyze as this can help programme managers to detect measures that strengthen the impact of program.

Aims & Objective: To identify periods when the program indicators had significant change and to corroborate it with activities which may have led to this change.

Material and Methods: The RNTCP indicators – NSP case detection rate, NSP case notification rate, Cure rate etc. were analyzed from year 1998-2011. The change point analysis is the method used for this time series analysis.

Results: NSP case detection increased significantly from 2002, while cure rate improved from 2005. The sustained case holding is the key to better results. Same way, smear positive retreatment cases, though declining are not reduced to a change point.

Conclusion: The analysis suggests that the defaulter rate and failure rate among NSP is maintained in downward direction. It is indicative of better adherence, higher effectiveness and extending reach of the program.

Key-Words: Change Point Analysis; Cure Rate; NSP Detection Rate; RNTCP Indicators; Retreatment Cases

Introduction

The President of United States, Mr. Barack Obama in his historical speech had asked all American citizens for change. This speech is considered to be one of the best speeches ever delivered. And as we all know, the USA had got its first non-white President in White house. The people of the world, if asked, will also desire to get certain things changed. One such field, now paid attention to is quality of life. An important factor that helps improve this quality of life is the state of good health. Disease conditions, worldwide deteriorating the health are identified and their impact is measured using disease burden indicators.

The condition which is known for centuries and the causative organism of which is identified 130 years before is still one big challenge for public health. This condition known as, Tuberculosis, is one of the major cause of morbidity and mortality in several developing countries. Next to HIV/AIDS,

it is the greatest infectious killer worldwide by single infectious agent. Over 95% of deaths occur in low and middle income countries, being one of the top three killer among reproductive age women, generating about 10 million orphans. Tb mostly affects young adults in their most productive years.^[1]

The largest numbers of cases were from Asia in 2010. About 80% cases were reported from 22 countries, called as high burden countries. The condition is even more complicated by combination with HIV/AIDS and Multi-Drug resistance. In Asia, India is declared as High Tuberculosis/ High HIV/High MDR-TB burden country. The WHO estimates that there are 3100 000 cases of TB at a rate of 256/1 lakh population, and the new cases are emerging at the rate of 185/ lakh population every year.^[2] To counter TB challenge, the country has implemented Revised National Tuberculosis Programme (RNTCP) since 1997 after pilot testing in 1993-1996.^[3]

Gujarat, located in western part of India, is a state with a population of about 590.2 millions. The state has also implemented the RNTCP since 1998, in phased manner. By April 2004, all the districts of the state were covered under program geographically.^[4]

The concern is whether the program has made any visible change in Tuberculosis situation in Gujarat. Usually, trend in new case detection rate and other program performance indicators is evaluated to suggest change, using direction of line diagram. Sometimes, trend line is added in line diagram, with equation in $y = mx + c$ form. The slope, represented by m in the equation gives the direction of the trend, adds statistical value to interpretation of direction of change. But, still it is not certain from which exact point the direction started to change and with what level of confidence one can assure that the change has taken place.

Considering this issue of precision, an advanced format of analysis- change point analysis was used in the study.

Materials and Methods

Annual data of RNTCP performance indicators from year of implementation i.e. from 1998 to 2011 were collected and compiled from annual reports of each year. Each indicator was subjected to change point analysis. The change point analyser software was used for this analysis. The analysis output is in terms of graphs/plots of actual data, graphs/ plots of Cumulative Sum (CUSUM) of respective variable. The point of change is mentioned as per number of row of respective data. The range of period during which this change has taken place is mentioned in confidence Interval. The change point analyser performs Bootstrap analysis of the series of data and the confidence observed in that analysis i.e. in 1000 bootstraps is mentioned as confidence level like 90%, 99% etc. The yearly data which is having sequential effect, i.e. if one value changes than successive values of other yearly data also gets changed, is treated as error. For this kind of data larger sample is recommended which will require data of some more years. No ethical permission was required for the study.

Procedure for Performing a Change-Point Analysis^[5]:

The procedure used by Taylor for performing a change-point analysis iteratively uses a combination of cumulative sum charts (CUSUM) and bootstrapping to detect the changes.

CUSUM charts are constructed by calculating and plotting a cumulative sum based on the data. Let X_1, X_2, \dots, X_{14} represent the 14 data points. From this, the cumulative sums S_0, S_1, \dots, S_{14} are calculated. The cumulative sums are calculated as follows:

1. First calculate the average $\bar{X} = [X_1 + X_2 + \dots + X_{14}] / 14$
2. Start the cumulative sum at 0 by setting $S_0 = 0$.
3. Calculate the other cumulative sums by adding the difference between current value and the average to the previous sum, i.e.,

$$S_i = S_{i-1} + (X_i - \bar{X}) \quad \text{for } i = 1, 2, \dots, 14.$$

For the annual data of NSP cases:

Average $\bar{X} = 25866.93$

$S_0 = 0$

$S_1 = S_0 + X_1 - \bar{X} = 0 + 952 - 25866.93 = -24914.9$

$S_2 = S_1 + X_2 - \bar{X} = -24914.9 + 5910.00 - 25866.93 = -44871.9$

$S_{14} = S_{13} + X_{14} - \bar{X} = -9608.07 + 35475 - 25866.93 = 0$

The cumulative sums are not the cumulative sums of the values. Instead they are the cumulative sums of differences between the values and the average. These differences sum to zero so the cumulative sum always ends at zero ($S_{14}=0$).

Interpreting a CUSUM chart requires some practice. Suppose that during a period of time the values tend to be above the overall average. Most of the values added to the cumulative sum will be positive and the sum will steadily increase. A segment of the CUSUM chart with an upward slope indicates a period where the values tend to be above the overall average. Likewise a segment with a downward slope indicates a period of time where the values tend to be below the overall average. A sudden change in direction of the CUSUM indicates a sudden shift or change in the average. Periods where the CUSUM chart follows a relatively straight path indicate a period where the average did not change. A sudden change in

direction suggests that around this time, the average shifted. After the change, the CUSUM is relatively straight indicating no subsequent change occurred. It could be broken into two separate line segments. This gives an indication that a second change might have occurred.

The CUSUM chart may indicate that at least one and possibly two changes took place. A confidence level can be determined for the apparent change by performing a bootstrap analysis. Before performing the bootstrap analysis, an estimator of the magnitude of the change is required. One choice, which works well regardless of the distribution and despite multiple changes, is S_{diff} defined as:

$$S_{diff} = S_{max} - S_{min} , \text{ where, } S_{max} = S_i \text{ with maximum value; } S_{min} = S_i \text{ with minimum value}$$

Once the estimator of the magnitude of the change has been selected, the bootstrap analysis can be performed. A single bootstrap is performed by:

1. Generate a bootstrap sample of all units, denoted $X^0_1, X^0_2 \dots X^0_{14}$, by randomly reordering the original all values. This is called sampling without replacement.
2. Based on the bootstrap sample, calculate the bootstrap CUSUM, denoted $S^0_0, S^0_1, \dots, S^0_{14}$.
3. Calculate the maximum, minimum and difference of the bootstrap CUSUM, denoted S^0_{max}, S^0_{min} , and S^0_{diff} .
4. Determine whether the bootstrap difference S^0_{diff} is less than the original difference S_{diff} .

The idea behind bootstrapping is that the bootstrap samples represent random re-orderings of the data that mimic the behaviour of the CUSUM

if no change has occurred. By performing a large number of bootstrap samples, you can estimate how much S_{diff} would vary if no change took place. You can then compare this with the S_{diff} value calculated from the data in its original order to determine if this value is consistent with what you would expect if no change occurred.

A bootstrap analysis consists of performing a large number of bootstraps and counting the number of bootstraps for which S^0_{diff} is less than S_{diff} . Let N be the number of bootstrap samples performed and let X be the number of bootstraps for which $S^0_{diff} < S_{diff}$. Then the confidence level that a change occurred as a percentage is calculated as follows:

$$\text{Confidence Level} = 100 [X/N] \%$$

Typically 90% or 95% confidence is required before one states that a significant change has been detected.

Results

The National TB control Program attempts to catch the possible cases of tuberculosis by examining patients attending Out Patient Departments (OPDs). The suspected TB cases are subjected to sputum smear microscopy. Those found to be smear positive on any of the two samples are labelled as new smear positive (NSP) cases. Those found to be positive, who were treated under program are labelled as previously treated or Re-treatment (PT or RT) positive. The program protocols defined outcome as Cured, Failure and defaulter depending on sputum smear result and adherence of patient to program.^[6]

Table-1: Annual NSP Cases, Cure Rate, Failure Rate, Defaulter Rate in NSP Patients

Year	Row No.	Patient Reporting	Cured		Failure		Defaulted	
			No.	%	No.	%	No.	%
1998 Annual	1	952	759	79.7%	46	4.8%	76	8.0%
1999 Annual	2	5910	4070	68.9%	268	4.5%	1064	18.0%
2000 Annual	3	14082	10809	76.8%	647	4.6%	1615	11.5%
2001 Annual	4	19635	15907	81.0%	862	4.4%	1677	8.5%
2002 Annual	5	22974	19331	84.1%	877	3.8%	1481	6.4%
2003 Annual	6	26471	22462	84.9%	893	3.4%	1605	6.1%
2004 Annual	7	30614	26010	85.0%	925	3.0%	1960	6.4%
2005 Annual	8	30289	26103	86.2%	844	2.8%	1622	5.4%
2006 Annual	9	33603	29259	87.1%	828	2.5%	1561	4.6%
2007 Annual	10	34925	30335	86.9%	838	2.4%	1630	4.7%
2008 Annual	11	35588	31027	87.2%	910	2.6%	1663	4.7%
2009 Annual	12	35200	30932	87.9%	901	2.6%	1504	4.3%
2010 Annual	13	36419	31968	87.7%	872	2.4%	1609	4.4%
2011	14	35475						

Table 1 provides the year wise data of new smear positive cases, cure rate, failure rate and defaulter rate in NSP cases. The NSP cases are the most important one from epidemiological point of view. As the infection is transmitted by droplet infection and NSP cases can transmit infection to 10-15 contacts in a year, more than any other type of TB patient can transmit, to evaluate performance in context of NSP cases is very much useful.^[7-9]

The annual data suggests that the point of change in NSP cases reported annually, lies in year 2002, with 99% confidence limit, on bootstrap analysis of CUSUM data. As the program was scaled up in the state in a phased manner and by 2002, most of the geographic coverage was achieved, this significant improvement is appreciable.

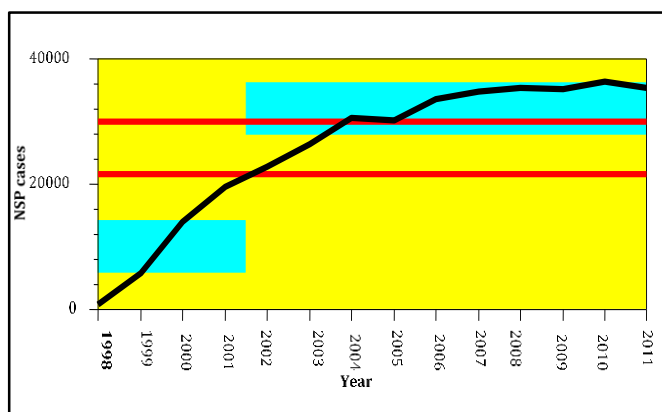


Figure-1: Plot of NSP Cases Annual

The NSP case notification rate is ratio of number of NSP cases reported to total population in millions. The change -point for NSP notification lies in the year 2001, with full 100% bootstrap support. This finding supports the earlier finding of absolute number rising from 2002. Following rise in notification rate, the actual numbers are rising, a well understandable phenomena.

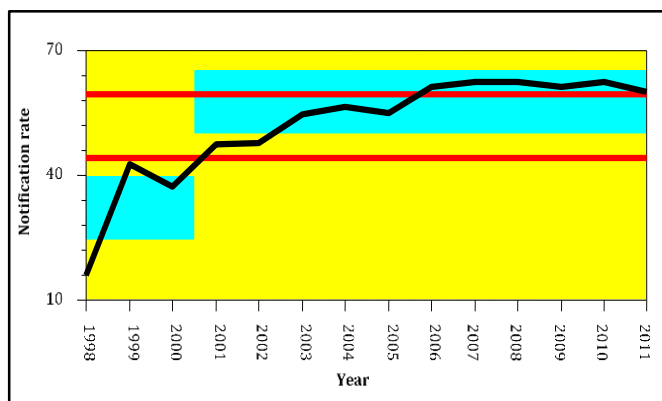


Figure-2: Plot of NSP Notification Rate

When we go for analysis of outcome of NSP

patients coherent results are found on change point analysis. The analysis suggests two points of change. The first point of change is in 2001 with 91% confidence interval, range being 1999-2001. The second point of change is in year 2005, with 97% confidence interval. The direction of change is upwards. Thus, after an initial peak during expansion phase the cure rate is significantly increased one year after complete coverage. This is indicating improvement in performance.

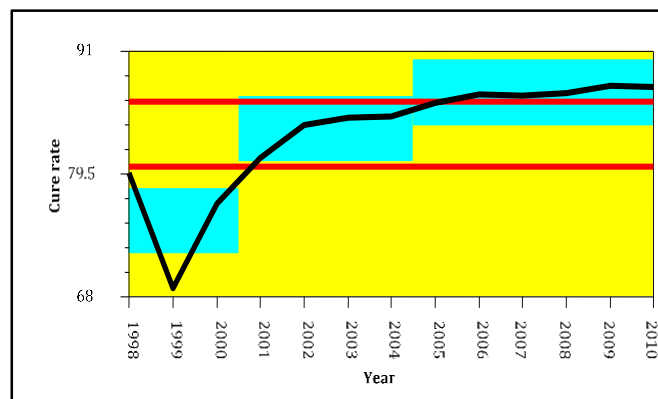


Figure-3: Plot of Cure Rate

The program defines that those NSP cases that are smear positive at 5 months or later of treatment course, as Failure cases. The annual data is suggestive of continuous downward change in failure rate, with point of change being in year 2003. Thus, the failure rate is significantly reduced since 2003, with 100% bootstraps supporting the result. This is an important finding in context of earlier finding of cure rate, which significantly improved in 2005. Thus, both findings corroborate well with each other.

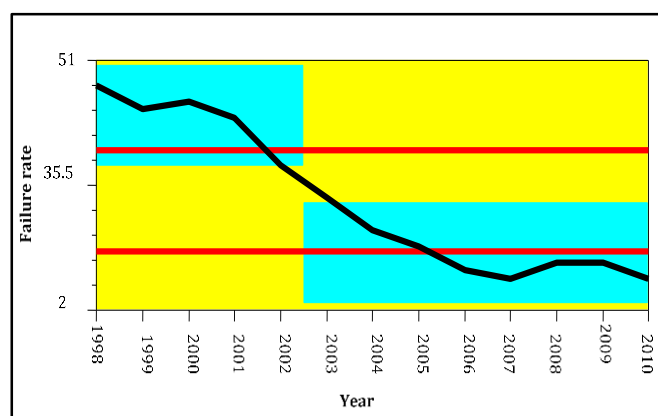


Figure-4: Plot of Annual Failure Rate

The adherence of patients to treatment is very important. Thus rate of defaulter is proxy of patient compliance to program and in other words, accessibility of program to the patient. If the cases are reported more but lost as defaulter,

the program loses its impact on the disease. So, it is necessary to reduce the defaulter rate with time. The annual data is suggesting that the defaulter rate in NSP patients is falling significantly, with 98% confidence limit in year 2001. It is suggestive of increasing program acceptance in the community.

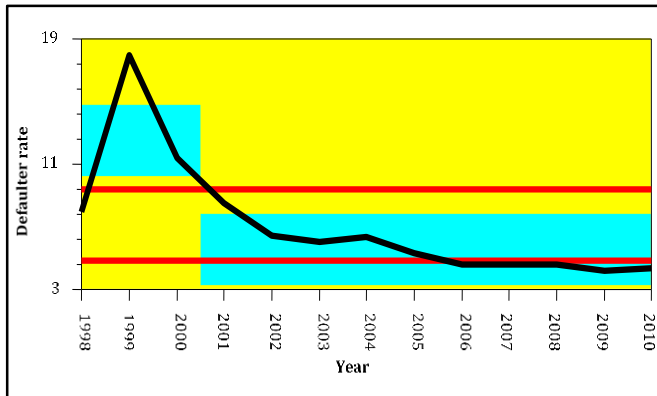


Figure-5: Plot of Defaulter Rate in NSP

The patients already treated by the Anti-TB treatment but returning as smear positive are called re-treatment positive cases. The program expects that with increasing impact of program, gradually this rate should have a downward trend. The annual data analysis suggests that the RT case detection rate is having upward direction. The rise is significant in year 2002. This can be due to initial expansion phase of the program as well the cases coming from private sector. However, the RT +ve annual detection rate shows a declining trend since 2010. A sign suggestive of successful program implementation.

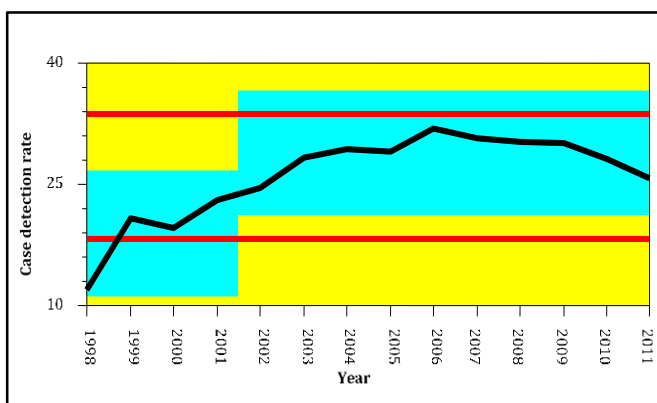


Figure-6: Plot of Sm +ve RTDR

Discussion

The data of New Sputum Smear positive cases are routinely reviewed in national programs for Tuberculosis control throughout the world, particularly in high burden countries by WHO. The

SS+ notification rate is used to evaluate the program as one of the important indicator.

The Change point analysis suggests that reporting of NSP cases increased from 2002. In an empirical assessment of DOTS carried out by Obermeyer Z et al. had revealed that NSP case notification was found to be rising with expansion of DOTS implementation in china, Indonesia, Korea, Philippines and South Africa also during 1995-2005, depending upon when the DOTs was implemented as national strategy.^[10] However, the exact year to be considered as year of change is not mentioned.

The country profile of Uganda in 2008 revealed a little different picture. It showed that though the SS+ case notification rates inclined till 2003, peaked in 2003 and then has shown a decline after that. In Gujarat, significant increase is observed in year 2001, followed by continuous rise in the coming years.^[11] The DOTS coverage in Uganda was 100% in those years, while Gujarat reached it in 2004. But, even there after the NSP case notification rate has shown upward trend. In their baseline data for mathematical modelling for dynamics of TB, Daniel Okuonghae and Andrei Korobeinikov, has noted that, in Nigeria, with expansion of DOTS, NSP case notification rate also increases.^[12] This supports the trend observed in Gujarat.

The cure rate in Gujarat shows an upward trend, with significant changes observed in year 2005. N. Ravichandran, in his community health worker based model has mentioned that, in Bangladesh, similar trend is observed.^[13] However, year of significant change is not available in literature. However, in Nigeria, treatment success rate declined in year 2003, after a sustained rise from 1996 to 2002 despite of increased DOTS coverage and NSP case detection rate in 2003. This probably suggests that sustained efforts for patient holding are equally important while increasing geographical coverage.

Conclusion

The analysis suggests that the defaulter rate and failure rate among NSP is maintained in downward direction. It is indicative of better

adherence, higher effectiveness and extending reach of the program. However, the program needs to strengthen its coalition with private practitioners. The rising trend of smear positive re-treatment cases, majority from private sector indicates the necessity of it.^[14] It is declining since 2010, but the decline has still not reached to be called as change point. The stronger implementation can lead to it and the attempts are already started to have stronger bonding with Non-Government sector by the program.

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