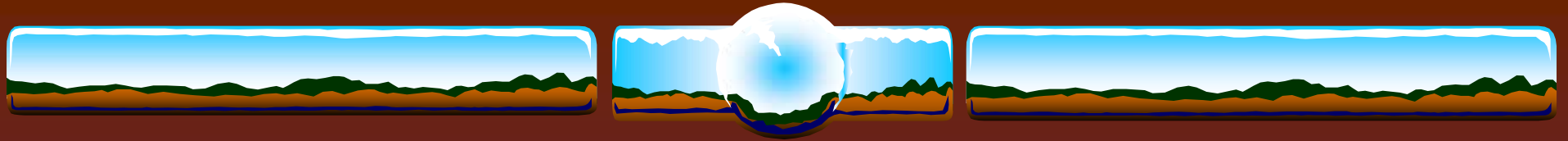


A comparative study of the
outcome of Category I &
Category II sputum smear
positive patients in a TB
unit implementing DOTS in
an urban setting in India

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Dr.Sanjay Kr. Sadhukhan



INTRODUCTION

EPIDEMIOLOGICAL SITUATION IN INDIA

- ❖ Total no. of patients infected with TB = 0.3 billion
- ❖ Total no. of active TB patients = 12 million
- ❖ Total no. of TB patients dying of TB/year = 5 lakhs
- ❖ N SSP patients / year (detected) = 1.5 million
- ❖ Patients put on treatment / year = 1.5 million



RNTCP IN INDIA

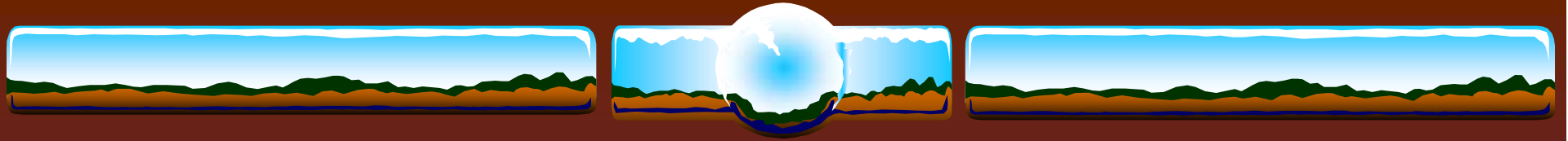
NTP - 1962

RNTCP - 1997

632 districts / 1114 m - 2007

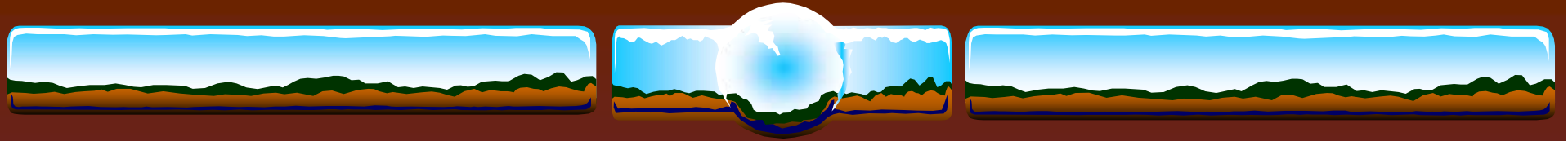
PROTOCOL

CATEGORY	SCHEDULE	INDICATION
CAT I	2(RHEZ) ₃ / 4(RH) ₃	NSSP Seriously ill sp. Smear -ve Seriously ill E-P TB
CAT II	2(SRHEZ) ₃ / 1(RHEZ) ₃ / 5(RHE) ₃	Sp. Smear +ve Relapse Sp. Smear +ve Faliure Sp. Smear +ve TAD Others (Sp. +ve or -ve)
CAT III	2(RHZ) ₃ / 4(RH) ₃	Sp.smear -ve not seriously ill E-P not seriously ill



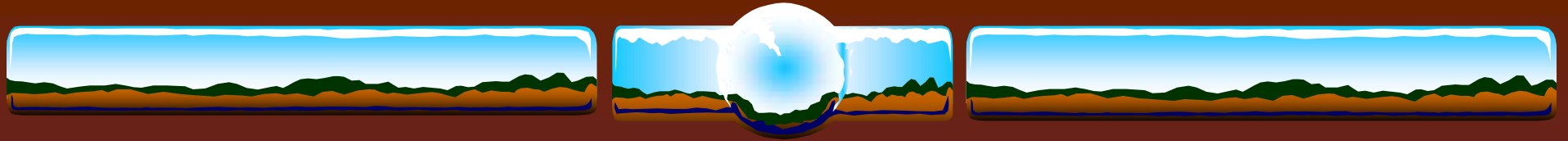
WHO Targets

1. Cure of at least 85% of NSSP patients.
2. Detection of at least 70% of NSSP patients.



OBJECTIVES OF THE STUDY

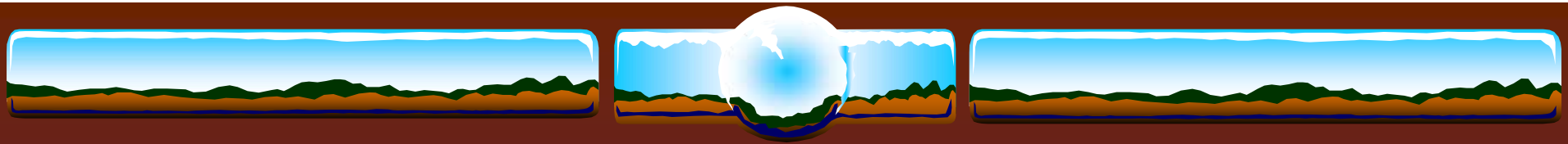
- ❖ To detect any significant difference in the outcome of Cat I & Cat II patients.
- ❖ To find out the adequacy of management of retreatment cases



MATERIALS & METHODS

STUDY SETTING :-

- ❖ A retrospective data based study (TB register) of NSSP Cat I & SSP Cat II patients enrolled at Sagore Dutta TU.
- ❖ Catchment population : 10.1 lakhs
- ❖ Period of study : 2003 – 2004
- ❖ Supervision during IP : TBHV / DOT Provider
Supervision during CP : 1st day – TBHV, other days – Family members.



FOLLOW UP

Sputum microscopy in the DMC

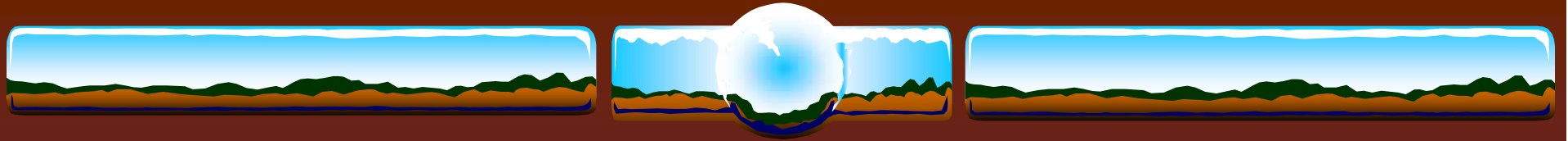
Categorization of results of sputum microscopy

IF SLIDE HAS	RESULTS	GRADING	NO. OF FIELDS
> 10 / 0IF	Pos.	3+	20
1 – 10 / 0IF	Pos.	2+	50
10 – 99 / 100 0IF	Pos.	1+	100
1 – 9 / 100 0IF	Scanty	No./ 200	200
No AFB	Neg	-	100

FREQUENCY OF SPUTUM EXAMINATION

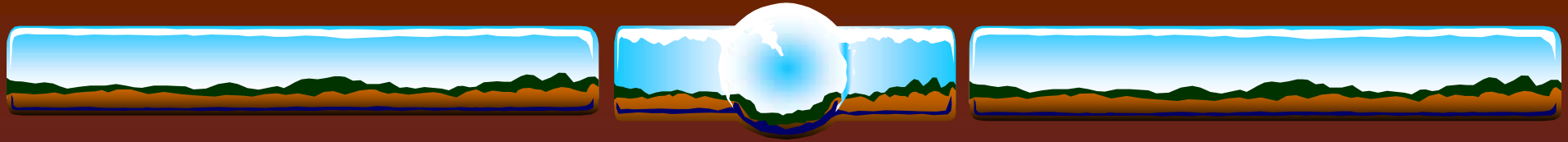
CATEGORY OF Tt.	TYPE OF PATIENT	REGIMEN	PRE – Tt. SPUTUM	FU AT MONTH	IF RESULT	THEN
I	NSSP	2(RHEZ) ₃ / 4(RH) ₃	+	2	-	Start CP, test at 4,6 mths.
					+	IP x 1 more month test at 3,5,7 mths.
II	SSP	2(SRHEZ) ₃ / 1(RHEZ) ₃ / 5(RHE) ₃	+	3	-	Start CP, test at 5, 8 mths.
					+	IP x 1 more month, test at 4,6,9 mths.

Outcome – Cured / TC / Died / Failure / Defaulted / Tr. out



DATA COLLECTION & ANALYSIS

1. Patients carefully categorized.
2. Data analyzed by tabulation & proportion (%).
3. Suitable statistical tests (χ^2 , Z) to compare variables of the 2 groups & their outcomes.
4. $p < 0.05$ is taken as significant.



RESULTS

Total no. of patients = 757 (100%)

Cat I NSSP = 551 (73%)

Cat II SSP = 206 (27%)



Table 1. Sex distribution of study subjects

SEX	CATEGORY I	CATEGORY II	TOTAL NO. OF PATIENTS
MALE	366 (66.42)	161 (78.15)	527 (69.62)
FEMALE	185 (33.58)	45 (25.85)	230 (30.78)
TOTAL	551 (73.58)	206 (26.42)	757 (100)

Note : Figures in parentheses indicate percentage .



Table 2. AGE DISTRIBUTION OF STUDY SUBJECTS

AGE GROUP (years)	CAT I	CAT II	TOTAL NO. OF PATIENTS
0 – 10	1 (0.18)	1 (0.49)	2 (0.29)
11 – 20	128 (23.23)	20 (9.71)	148 (19.42)
21 – 30	153 (27.77)	55 (26.70)	208 (27.50)
31 – 40	93 (16.88)	52 (25.24)	145 (19.20)
41 – 50	96 (17.42)	46 (19.42)	136 (17.99)
51 – 60	42 (7.62)	17 (8.25)	59 (7.80)
> 60	38 (6.90)	21 (10.19)	59 (7.80)
Total	551 (73.58)	206 (26.42)	757 (100)

Note : Figures in parentheses indicate percentage .



TABLE 4. DIFFERENT TYPES OF SSP CAT II PATIENTS

TYPE	TOTAL NO. OF PTS.
Relapse	119 (57.76)
Faliure	16 (7.77)
TAD	70 (33.98)
Others +ve	1 (0.49)
Total	206 (100)

Note : Figures in parentheses indicate percentage .



Table 3. Sputum grades of study subjects

SPUTUM GRADES	CAT I	CAT II	TOTAL NO. OF PATIENTS
1 +	155 (28.13)	73 (35.44)	228 (30.12)
2 +	139 (25.23)	54 (26.21)	193 (25.50)
3 +	201 (36.48)	59 (28.64)	260 (34.35)
Scanty	56 (10.16)	20 (9.71)	76 (10.03)
Total	551 (73.58)	206 (26.42)	757 (100)

Note : Figures in parentheses indicate percentage .

$$\chi^2 \text{ (df3)} = 5.428 \quad p = 0.143$$

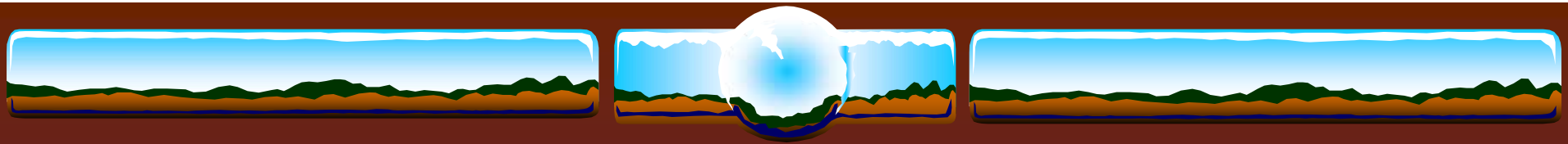


Table 5. OUTCOME OF SSP CAT II PATIENTS ACC. TO TYPE

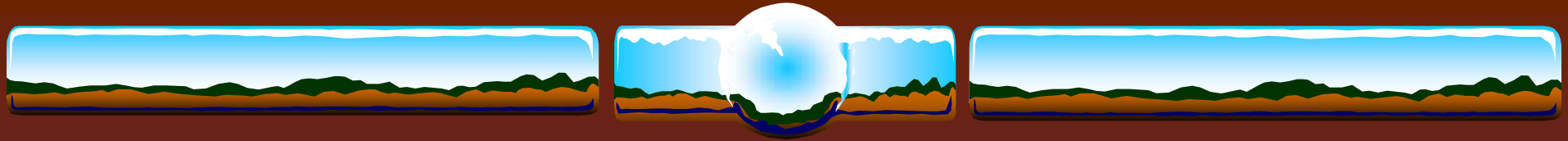
TYPE	CURED	TC	FAV.	DIED	FAILURE	DEFAULT	UNFAV.	TOTAL
Relapse	83 (69.24%)	-	83	8	8	20	36	119
Failure	13 (81.25%)	-	13	-	-	3	3	16
TAD	44 (62.86%)	-	44	8	4	14	26	70
Other s +ve	-	1	1	-	-	-	-	1
Total	140 (67.96%)	1	141	16	12	37	65	206



Table 6. TREATMENT OUTCOME IN CAT I & CAT II PATIENTS

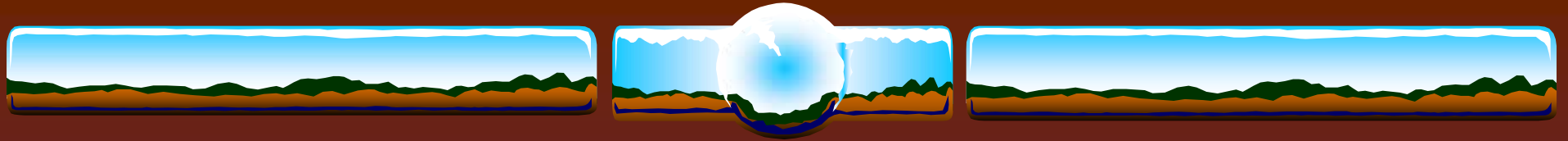
OUTCOME	CAT I	CAT II	TOTAL NO. OF PTS.
Cured	476 (86.39)	140 (67.96)	616 (81.37)
TC	0	1 (0.49)	1(0.13)
Died	22 (4.00)	16 (7.76)	38 (5.02)
Failure	27 (4.90)	12 (5.83)	39 (5.15)
Defaulter	26 (4.71)	37 (17.96)	63 (8.33)
Total	551 (73.58)	206 (26.42)	757 (100)

Note : Figures in parentheses indicate percentage .



SIGNIFICANT DIFFERENCES IN FINAL OUTCOME

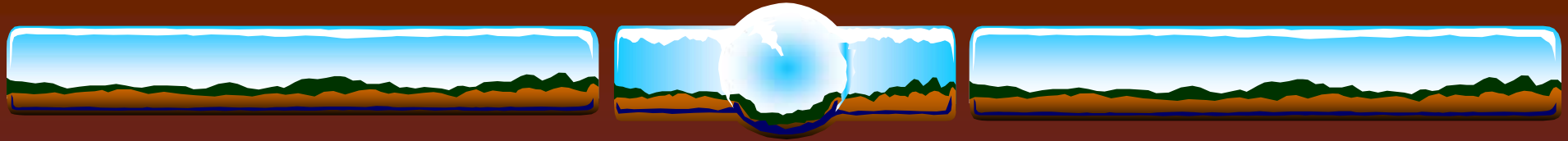
- Cured $\textcircled{Z} = 5.69$ $p = 0.000\dots\dots$
- Defaulter $\textcircled{Z} = 5.73$ $p = 0.000\dots\dots$
- Favourable $\textcircled{Z} = 5.77$ $p = 0.000\dots\dots$
- Unfavourable $\textcircled{Z} = 5.55$ $p = 0.000\dots\dots$



DISCUSSION

- ❖ Setting : Mariinsk, Kemerovo Region (Siberia)
- ❖ Period : June 1996 to March 1997
- ❖ Failure : 35%
- ❖ MDR : 22.6%

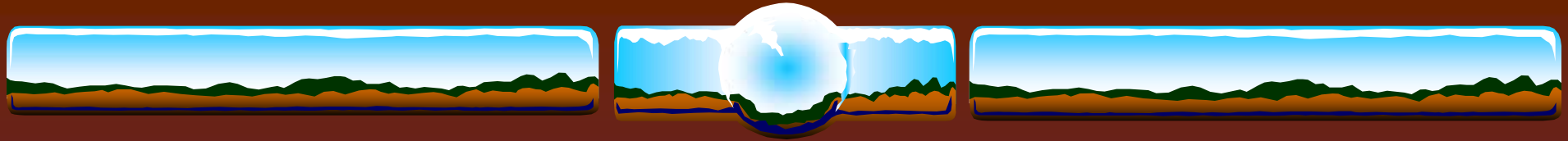
Inadequacy of the current WHO re-treatment regimen in a central Siberian prison : treatment failure and MDR-TB
M.E.Kimerling et al – IJTLD 1999; 3(5): 451 - 453



Contd....

- ❖ Setting : Northern Lima, Peru
- ❖ Period : Feb. 1997 to Oct. 2001
- ❖ Cat I failure pts. Included : 125
- ❖ Strategy A (Cat II) : 73 Favourable : 38%
- ❖ Strategy B (DST) : 52 Favourable : 79%

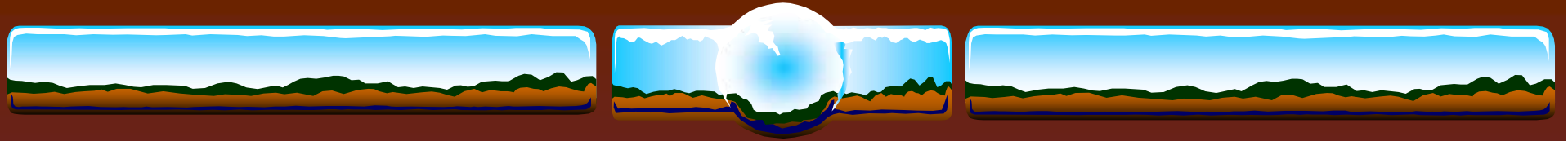
Retreatment management strategies when first line tuberculosis therapy fails
J.C.Saravia et al – IJTLD2005; 9(4): 421 - 429



Contd.....

- ❖ Setting : Cotonou, Benin
- ❖ Period : 1992
- ❖ Total no. of pts. (with Tt H/O) : 8103
- ❖ Cat II (2SRHEZ/1RHEZ/5R₃H₃E₃) : 642
- ❖ Favourable with Cat II : 78%
- ❖ Favourable with Cat I : 82%

Outcome of tuberculosis retreatment in routine conditions in Cotonou, Benin
M.Gninafon et al – IJTLD 2004; 8(10); 1242 - 1247



Present study

- ❖ Setting : Urban TU, West Bengal, India
- ❖ Total no. of pts. : 757
- ❖ Cat I NSSP : 551 Cat II SSP : 206
- ❖ Cat I cure rate : 86.39% Cat I failure rate : 13.61%
- ❖ Cat II cure rate : 68.45% Cat II failure rate : 31.55%



CONCLUSION

Revision of Cat II protocol by :

Curative – DOTS PLUS

Preventive – retrieval of Cat I / Cat III patients
with recc. drug interruption.



Thank you