Economic incentives for improving clinical outcomes in patients with TB in South Africa: a study of feasibility and effectiveness

Symposium: Action on the Social Determinants of Tuberculosis

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Investigators

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Funders

- National Department of Health (South Africa) through the Research Directorate
- KNCV TB Foundation (the Netherlands), through the National TB Directorate (SA)
- Wellcome Trust (United Kingdom) through a training fellowship.

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Rationale for study

- Poverty has long been recognized as one of the factors predisposing to TB (Lancet 2005)
- Several studies have investigated use of economic incentives in patients with TB – only one RCT in a low income country investigating patients with active TB
- Several programmes have implemented economic support to improve health behaviour in people who are poor (CCTs)
- Incidence of TB in SA continues to rise (WHO 2011)
- TB was the most important cause of death in SA and in KwaZulu-Natal in 2009 (Statistics SA 2011)
- Extensive poverty in South Africa and in KwaZulu-Natal.

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Aim

To evaluate the feasibility and effectiveness of economic incentives in improving treatment outcomes in patients with TB in South Africa

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Methods

- Pragmatic, un-blinded two-arm cluster randomized controlled trial
- Public sector primary health care clinics as clusters
- Nested studies:
  - Qualitative
  - Survey of patients' household economies
  - Analysis of expenditure on voucher
  - Cost-effectiveness analysis

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Study setting

- KwaZulu-Natal, one of South Africa's poorest and most populous provinces (Barron et al 2007)
- Highest burden of TB in the country (Abdool Karrim 2009)
- Highest HIV prevalence rate nationally (UNAIDS 2008)
- One urban district (eThekwini, city of Durban) and one rural district (Uthungulu)
- Uthungulu has the second highest and eThekwini the 12th highest TB incidence of the 52 districts in the country (Day et al 2009)
- Cure rates relatively low: eThekwini ranked 41st, and Uthungulu 36th out of 52 districts in the country (Day et al 2009)

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Study setting

- In 2008, 71% of households in KwaZulu-Natal lived on less than 40% of the median per capita income of R569.00 per month (Hall 2010)
- In deprivation ranking, eThekwini lies within socio-economic quintile 4, and Uthungulu in socio-economic quintile 2 (where quintile 5 is least deprived, and quintile 1 is most deprived) (Day et al 2009: 2).
- Within eThekwini are large areas of poverty.

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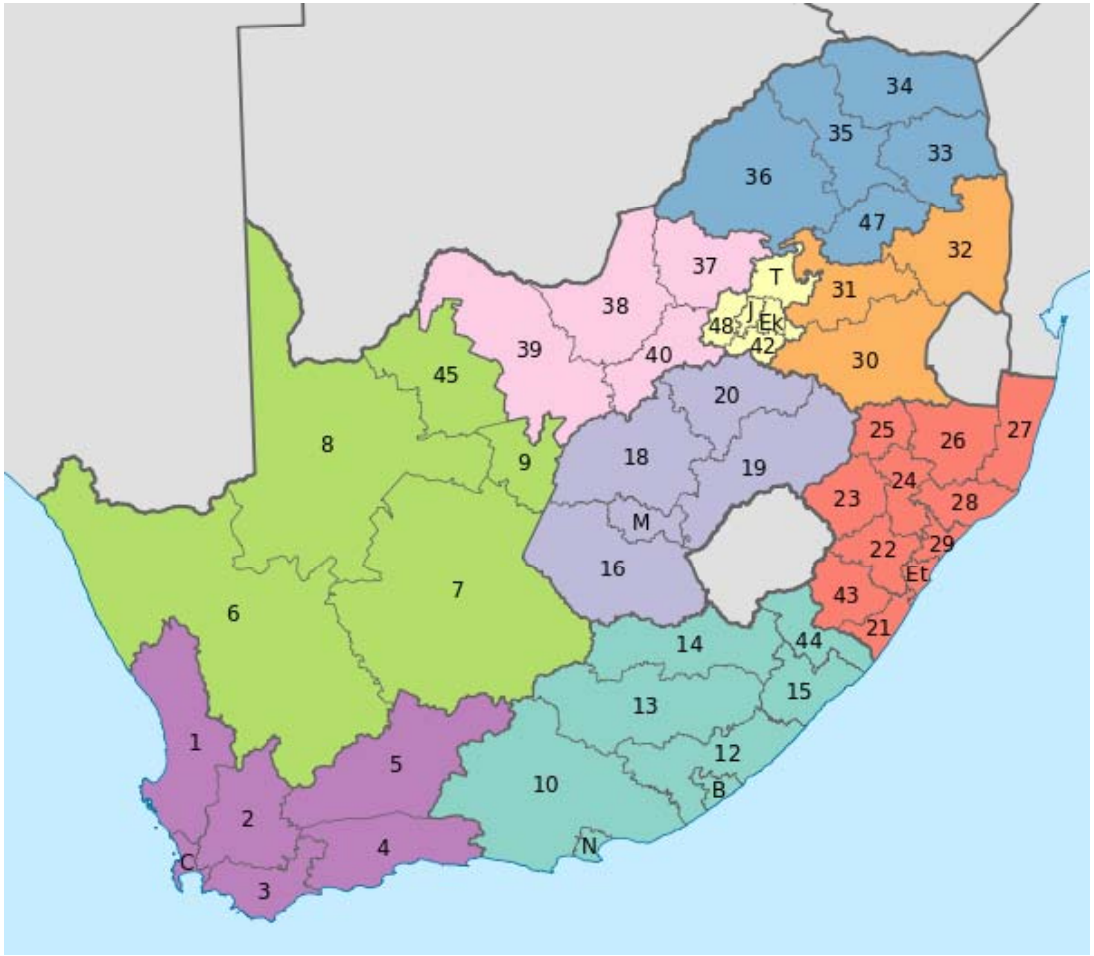
KwaZulu-Natal, South Africa



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eThekwini, City of Durban

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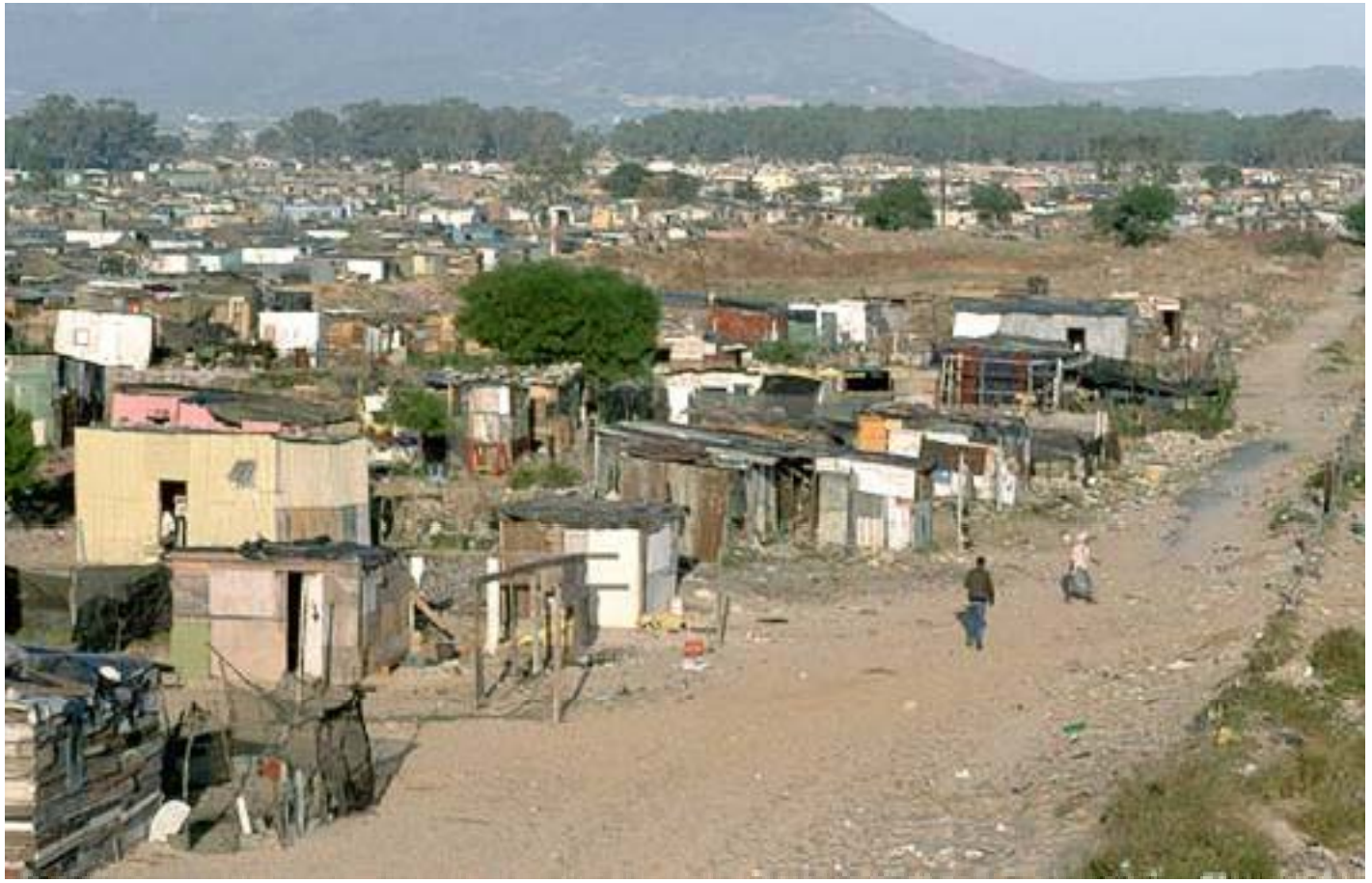
Mlazi, township in eThekwini



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Rural KwaZulu-Natal

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Sample

- Sample size:
  - 15% difference in treatment success rates
  - Power of 90%
  - Significance level of 5% (two sided test)
  - Average cluster size of 100
  - 18 clinics necessary
  - Twenty clinics included
- Inclusion criteria:
- Clinics
  - Cure rates of between 40% and 70% (to make ICC smaller – 0.03 – and study more feasible)
  - 20 and 150 new smear positive TB patients per year
- Patients
  - Pulmonary, drug sensitive TB

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Intervention

- A voucher, valued at R120 (approximately US $ 15) was offered to patients by nurses every month on collection of their treatment, to a maximum of eight months
- Conditional on adherence
- Voucher could be redeemed at shop close to clinic for any goods, although healthy food stuffs suggested
- Patients presented ID books and clinic cards when redeeming voucher.

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Ethical considerations

- Ethical approval received from the Committee for Human Research at the University of Stellenbosch (N07/10/245)
- Permission to conduct trial received from
  - Provincial and district health authorities
  - Tribal authorities in rural areas
  - Individual intervention clinics.
- Individual consent verbal (written for nested studies)
- Trial registered with South African and international registries.

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Data collection and analysis

- Primary outcome treatment success (cure + treatment completion)
- Outcome data collected from clinic registers and individual patient files
- Sample checked for accuracy
- Analysis was intention to treat
- Patient level data used
- Multivariate analysis for selected covariates
- Dose response analysis.

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Results

- Trial duration: 01 July 2009 to 30 September 2010
- Total participants: 4091 (1 984 in the control arm and 2 107 in the intervention arm)
- No clinics lost
- Loss to follow up: 18 patients (0.4%).

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Intention to treat analysis

Outcome	Intervention group (%)	Control group (%)	Risk difference (95% confidence interval)	p-value
Treatment success	1 606/2107 (76.2)	1 402/1984 (70.8)	0.06 (-0.01; 0.12)	0.107

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Secondary outcomes

Treatment outcome	Intervention group (%)	Control group (%)
Defaulted	158 (7.5)	202 (10.18)
Treatment interrupted	0 (0.0)	15 (0.76)
Treatment failure	79 (3.75)	113 (5.7)

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Ancillary analysis

- Higher treatment success rates in:
  - Patients who were employed
  - Children under the age of 13
  - Women
  - Patients with smear positive TB had significantly better rates
  - No significant interactions between any sub-groups.

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Fidelity

- 813 patients (38.6%) did not receive a voucher at all
- 671 (31.8%) received a voucher for between one and three months
- 623 (29.5%) received a voucher for between 4 and 8 months
- Explanation:
  - Vouchers not always available at clinics
  - Nurses gave to more needy patients.

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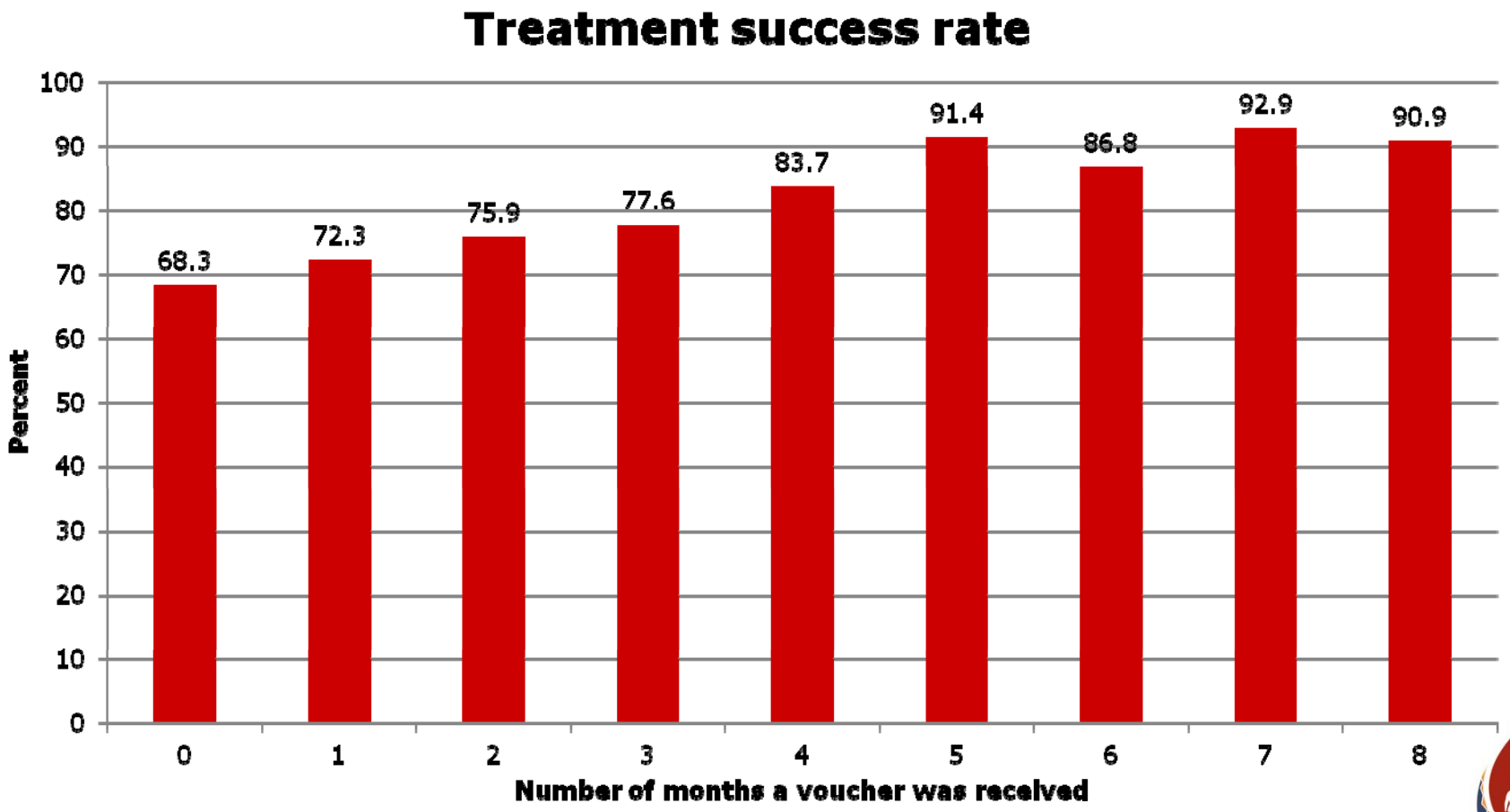
Dose response analysis



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Expenditure of vouchers

Category	Female expenditure (%)	Male expenditure (%)
Deserts/sweets/cakes percentage	4.34	3.68
Dairy percentage	**10.45**	**10.64**
Meat percentage	**25.80**	**31.18**
Veges percentage	8.91	7.74
Grains percentage	**17.69**	**15.77**
Fruits percentage	1.07	.83
Spices percentage	3.30	3.37
Fats percentage	4.18	4.83
Beverages/juice percentage	8.46	7.77
Alcohol/cigarette percentage	.10	.22
Cleaning percentage	4.83	5.28
Other percentage	10.88	8.68

Conclusions

- ITT analysis inconclusive
- Low fidelity
- Low power
- Chance
- Very little unhealthy expenditure
- Potential beneficial effect
- Further research to investigate better implementation.

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Thank you!

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