Current barriers to treatment adherence

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Overview

- DR-TB treatment adherence – what's the problem?
- Experience in Khayelitsha
- Adherence strategies

Advances in DR-TB in SA

- Improved standard regimen
  - addition of Tzd and Moxi
- Rapid diagnostics
  - LPA – rapid RIF/INH resistance
  - GXP – screening of all TB suspects
- 2011 National Policy Framework for Decentralised Management of DR-TB

- But what happens after successful diagnosis and treatment initiation...?

A few difficulties...

- **Pill burden** and many **SEs**
- **Long duration** – Tx daily for 2 years under DOT in local clinic – expense and disruption of ADLs
- **Access to drugs –** potentially prolonged hospital admission even if clinically stable and ambulant
- **Patient beliefs** / understanding of disease severity and importance of Tx completion
- **Social stigma** – mask, separation, perceptions
- **Low Tx success** rates – ltd efficacy of Tx
- **IC risk** – loss of employment, social isolation
- **HIV** co-infection – ?integration of TB/HIV care
- **External challenges** – subs abuse, poverty

Treatment Interruption and Default – definitions:

- **Default** from DR-TB treatment is defined as a break in treatment of two or more consecutive months

- Any period less than two months is described as **treatment interruption** and therefore if patients return to treatment within this time they are not classified as defaulters

  - Bad connotations and stigma, i.e. defaulters = delinquent / recalcitrant / socially irresponsible

2011 SA National DR-TB Guidelines

- Acknowledges difficulties of treatment
  - emphasises need for adequate counselling, DOT, psychosocial and financial support
- Decision on whether to restart treatment and which regimen is based on:
  - smear status, period of default, stage of treatment, clinical condition, commitment to treatment
- Chronic defaulters
  - may have Tx suspended / terminated if likely to be ineffective or chance of further resistance developing

In practical terms...

- Acknowledges difficulties of treatment
  - emphasises need for adequate counselling, DOT, psychosocial and financial support

- What is adequate counselling? Who should do it? With what resources? How much training?
- Is DOT a barrier to adherence in later stages (feeling better, non-infective, need to get back to ADLs)?
- Psychological assessment and support – who and when to screen, where to refer to?
- Financial support – DGs – delays in access; sufficient to cover regular income?

In practical terms...

- Decision on whether to restart treatment and which regimen is based on:
  - smear status, period of default, stage of treatment, clinical condition, commitment to treatment

- How many times can you restart treatment?
- Should patients be hospitalised each time?
- Some hospitals don't accept defaulters, or culture negative patients with social issues – then what?

In practical terms...

- Chronic defaulters
  - may have Tx suspended / terminated if likely to be ineffective or chance of further resistance developing

- Who decides whether chronic defaulters should have treatment suspended? When should this happen?
- Should all of these patients brought to the attention of the provincial review boards?

Ethical Considerations

- Can patient be blamed for stopping drugs with significant SEs or treatment which doesn't appear to be working?
- Treatment adherence is a social responsibility – not just the individual at risk – consider IC risk and rights of others
- Can Rx be withheld if effective Rx is available and patient is requesting it, even after multiple previous default episodes?
- Will Rx still be effective after default – possible development of resistance? Also consider high cost of Rx and others in need – adequate limited resource allocation

Khayelitsha DR-TB Programme

- Community based, patient-centred
- Access to DR-TB treatment in local PHC facilities within sub-district

Khayelitsha DR-TB Programme

Extensive patient support:

- individual and family counselling
- home visits
- weekly support groups
- social assistance (psych support, DG applications, access to social services and other NGOs)
- local audiometry screening
- local short term inpatient facility
- IC support in homes

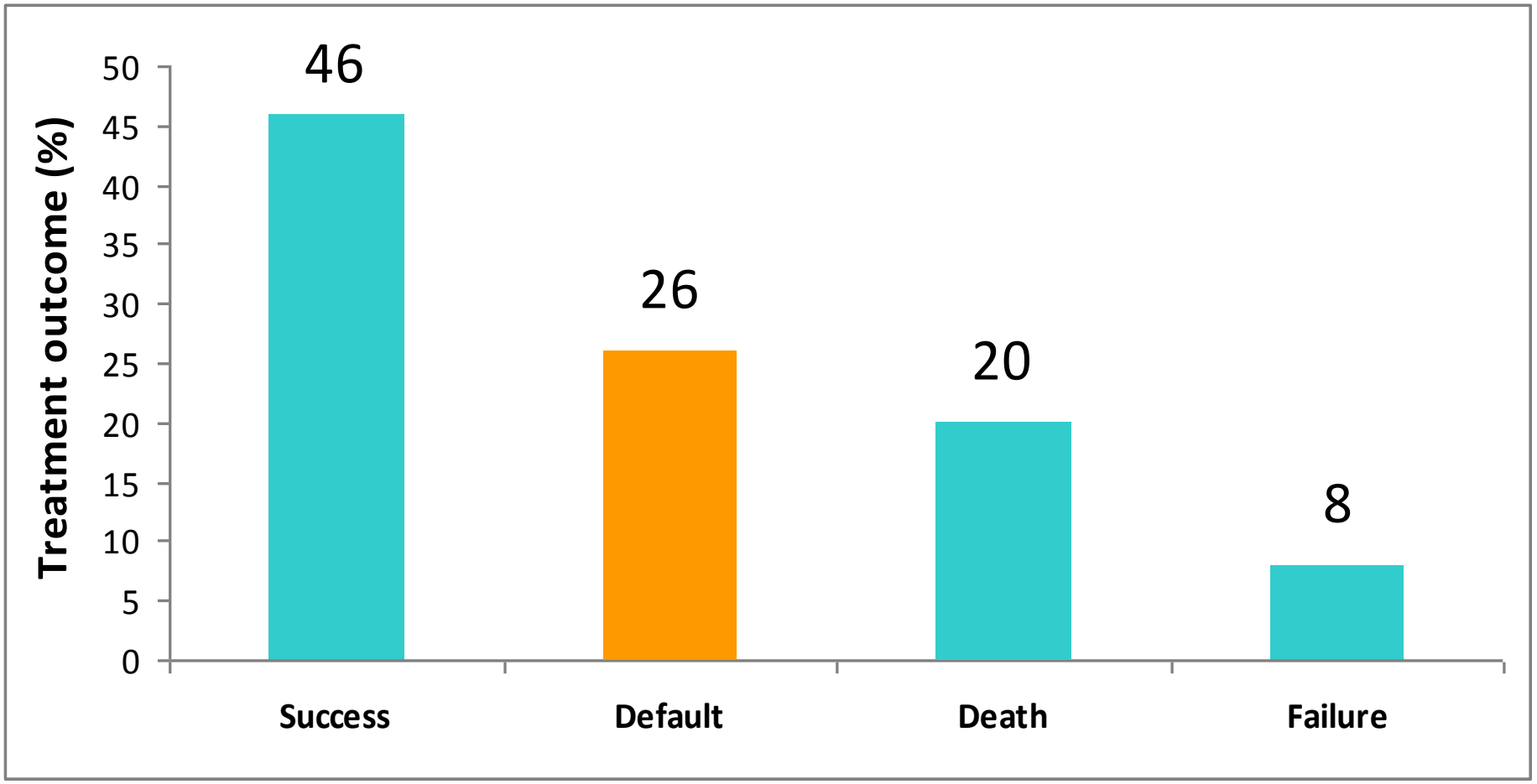
How much does the patient understand?

- Counselling counselling counselling
  - Who is responsible?
  - Is there any training?
- Video on patient support provided in Khayelitsha

Successes of Programme

	Before pilot program	With decentralised, community based treatment
DR-TB case notification/year	20/100,000	46/100,000
Average DR-TB cases initiating treatment/year	60	220
Case detection	30%	60%
Treatment success	42%	44%
DR-TB burden successfully treated	11%	25%

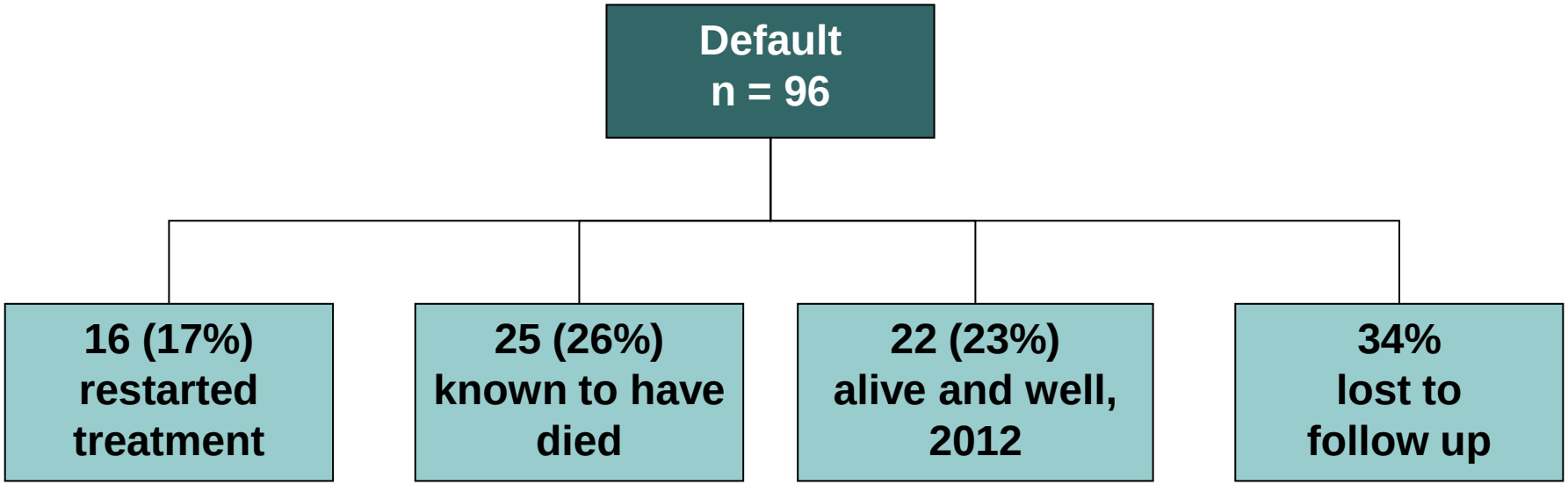
2009 Treatment Outcomes



(n=190, excluding Transfers Out)

Analysis of Defaulters

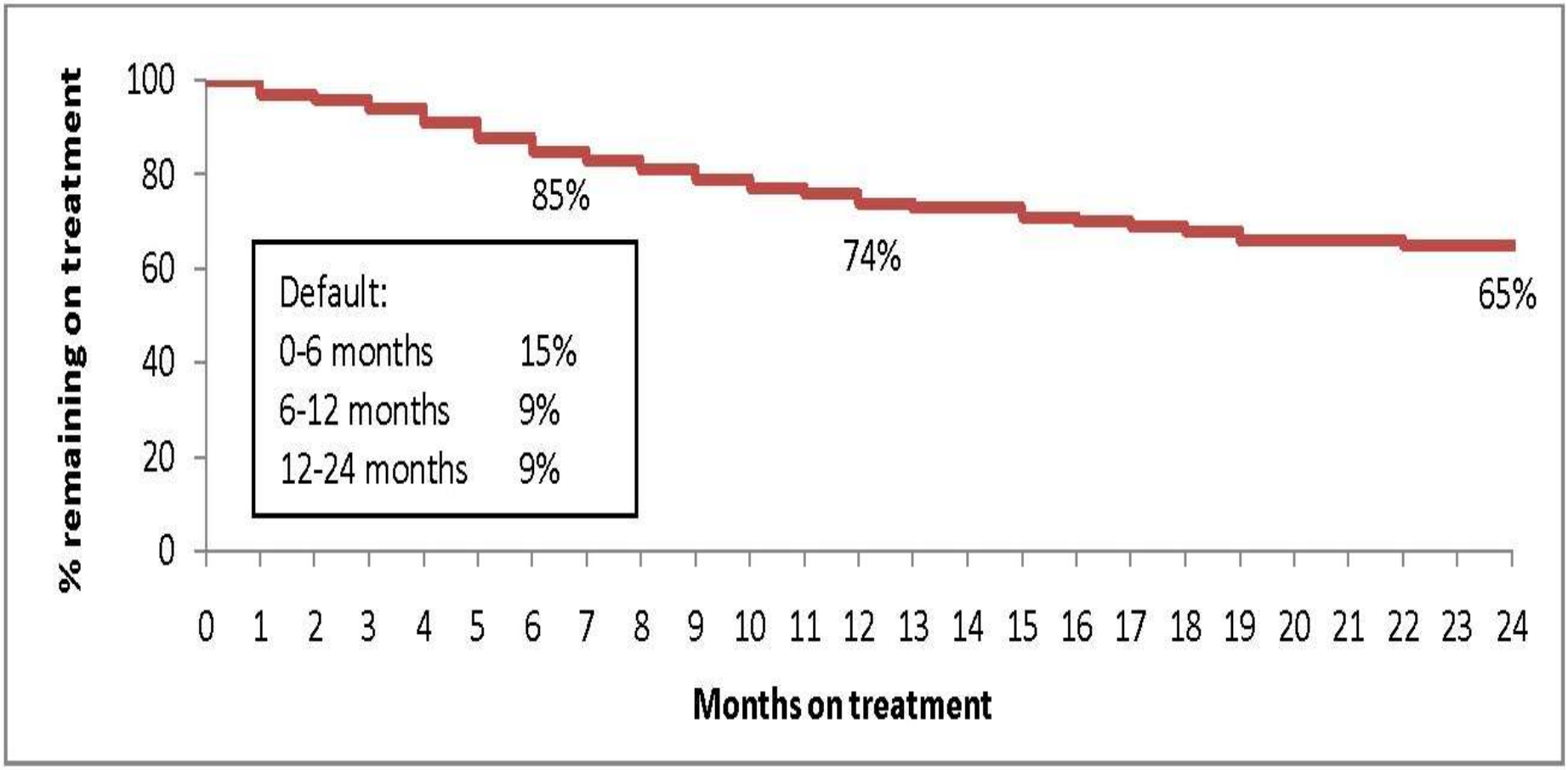
- 352 patients started DR-TB treatment in Khayelitsha throughout 2009 and 2010
- 96 patients defaulted at any point in their treatment (27%)



- 60% of the 96 pts had culture converted before default

Proportion DR-TB Patients Remaining on Treatment

2008 – 2010 (n=455)



Default from treatment: risk factors?

2009 Multivariate Analysis

Factor	OR (95% CI)
Male	2.1 (0.99-4.2)
HIV -	1.5 (0.65-3.4)
No prev TB Tx	ref
Prev 1st line Tx	1.5 (0.63-3.5)
Prev 2nd line Tx	20.0 (2.1-189)
Age 1-12	0.74 (0.14-3.9)
Age 13-25	3.0 (1.1-8.1)
Age 26-35	1.0 (0.45-2.4)
Age 36+	ref
Tx initiation Hospital	ref
Tx initiation Community	1.5 (0.52-4.1)

Reasons for default?

- A small retrospective review to assess reasons for default among DR-TB patients diagnosed and starting on treatment in Khayelitsha in 2008
- Concluded that factors associated with default are often complex and multi-factorial

	Male	Female
Youth, age 13-25	• Felt better • Treatment too long • Need to work/ go back to school • Initiation in /moved to Eastern Cape	• Felt better • Treatment too long • Move in with boyfriends, have babies (scared of losing boyfriend) • Side effects (injections) • Alcohol
Young adults, age 26-35	• Felt better • Treatment too long • Need to work • Moved to Eastern Cape • Pill burden	• Felt better • Treatment too long • Side effects • Alcohol • Need to work
Older adults, age 36+	• Felt better • Treatment too long • Need to work • Alcohol • No stable home	• Felt better • Treatment too long • Alcohol • Need to work • Want to go to Eastern Cape (to die at home)

How to address default?

- Difficult to predict default
- Rate of return to treatment after default is low despite specific defaulter identification and tracing
- Patients who do restart treatment are at significant risk of defaulting again
- A variety of different adherence support strategies are needed to prevent default in the first place

Adherence Strategies elsewhere and in HIV

- Supervision vs Support

- PIH – Peru, Nepal, Lesotho
  - daily DOT supporters in community
  - food packages (incentive and nutritional support)
  - reimbursement for travel expenses (enabler)
  - temporary accommodation
- Thailand – daily phone call reminders
- USA – Electronic medication monitors

Adherence Strategies elsewhere and in HIV

- Co-infection – can we learn from HIV?

- HIV systematic review: 26 studies 2003-2010: **Rx supporters, DOT, sms reminders, diary cards and food rations** can effectively increase adherence in SSA. Other interventions are unlikely to have long and lasting effects, others only effective in specific settings.
  - Barnighausen et al, Lancet Infect Dis 2011

Possible interventions in peri-urban settings like CT

TREATMENT REGIMENS AND SIDE EFFECTS

- Better regimens – ideally short, oral, effective, tolerable
- Access to XDR medications in local clinic if appropriate
- IV ports
  - manageable in well supported environment
- Addressing hearing impairment
  - prevention, adequate management, counselling and education, linkage with support services

Possible interventions in peri-urban settings like CT

PATIENT EDUCATIONAL, MOTIVATIONAL AND SOCIAL SUPPORT

- Focused counselling (training for staff to provide structured education sessions and adherence strategies) – *HIV?*
- Integration into TB/HIV Adherence Framework – supporting SAT in community through CCWs and treatment supporters
- Involvement of employers during continuation phase
- Mental health screening
- Incentives and enablers...

Conclusions

- Default is major contributor to poor outcomes
- Preventing vs managing default
- Default is difficult to predict; reasons multifactorial
- Variety of approaches needed to <u>enable</u> patients to adhere to treatment
- Clear need for better treatment regimens!!

DEBATE