

# **Finding and holding the line on quality: building an operational research agenda**

## **Mind the Gaps**

**Médecins Sans Frontières Satellite Meeting  
XVII International AIDS Conference**

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# Background

- Scale-up of antiretroviral therapy (ART) in resource-limited countries has given 3 million people access to treatment by the end of 2007<sup>1</sup>. “Universal Access” calls for 80% coverage by 2010, or an estimated 10 million people receiving ART.
- Success in reaching this goal will be enhanced if ART programs are effective in starting and retaining people on therapy.
- Currently, indications of ART scale-up progress has focused almost exclusively on numbers of people started on treatment.
- Treatment outcomes, such as patient retention and loss to care (or “attrition”) must also be measured to promote strategies that insure quality of ART programs

<sup>1</sup>*Towards universal access: Scaling up priority HIV/AIDS interventions in the health sector. Progress report, June '08. WHO*

## Background (II)

- Treatment outcomes are good in resource-limited settings if patients and care providers are supported properly.
  - Sufficient staff for the anticipated case load, often distributed among an array of cadres.
  - Treatment sites equitably located geographically.
  - Attention to treatment literacy and adherence counseling for patients.
  - Elimination of service fees
  - Uninterrupted supplies of ARVs and key OI drugs, such as cotrimoxazole and anti-TB medication



**Outcome indicators for innovation in  
implementation:  
operational research**



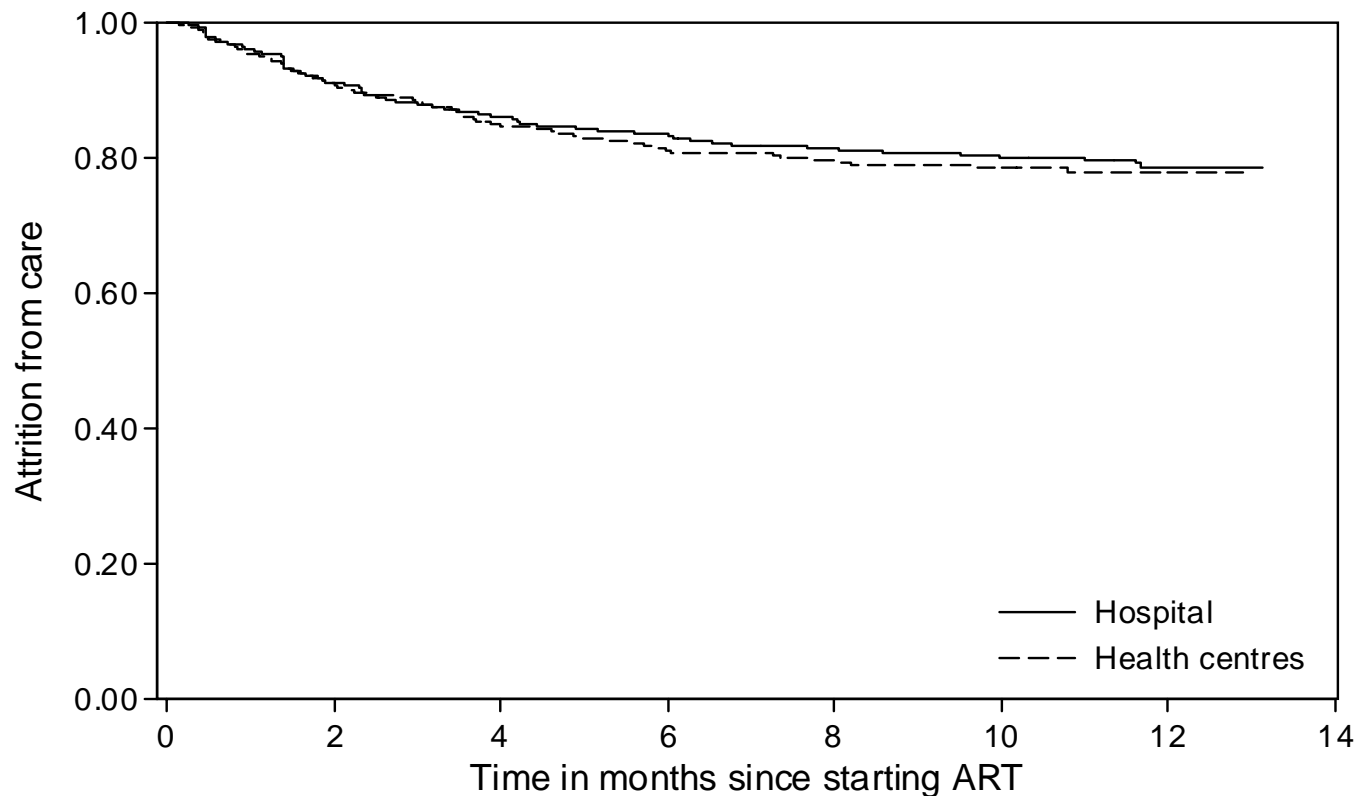
# What are some options for implementation?

- Hospital- vs. health center-based
  - District hospital, regional referral center
  - Peripheral health center and health post
- Different Cadres
  - Physicians
  - Non-physician medical officers
  - Nurses
  - Community health workers
  - Lay providers, PLWA

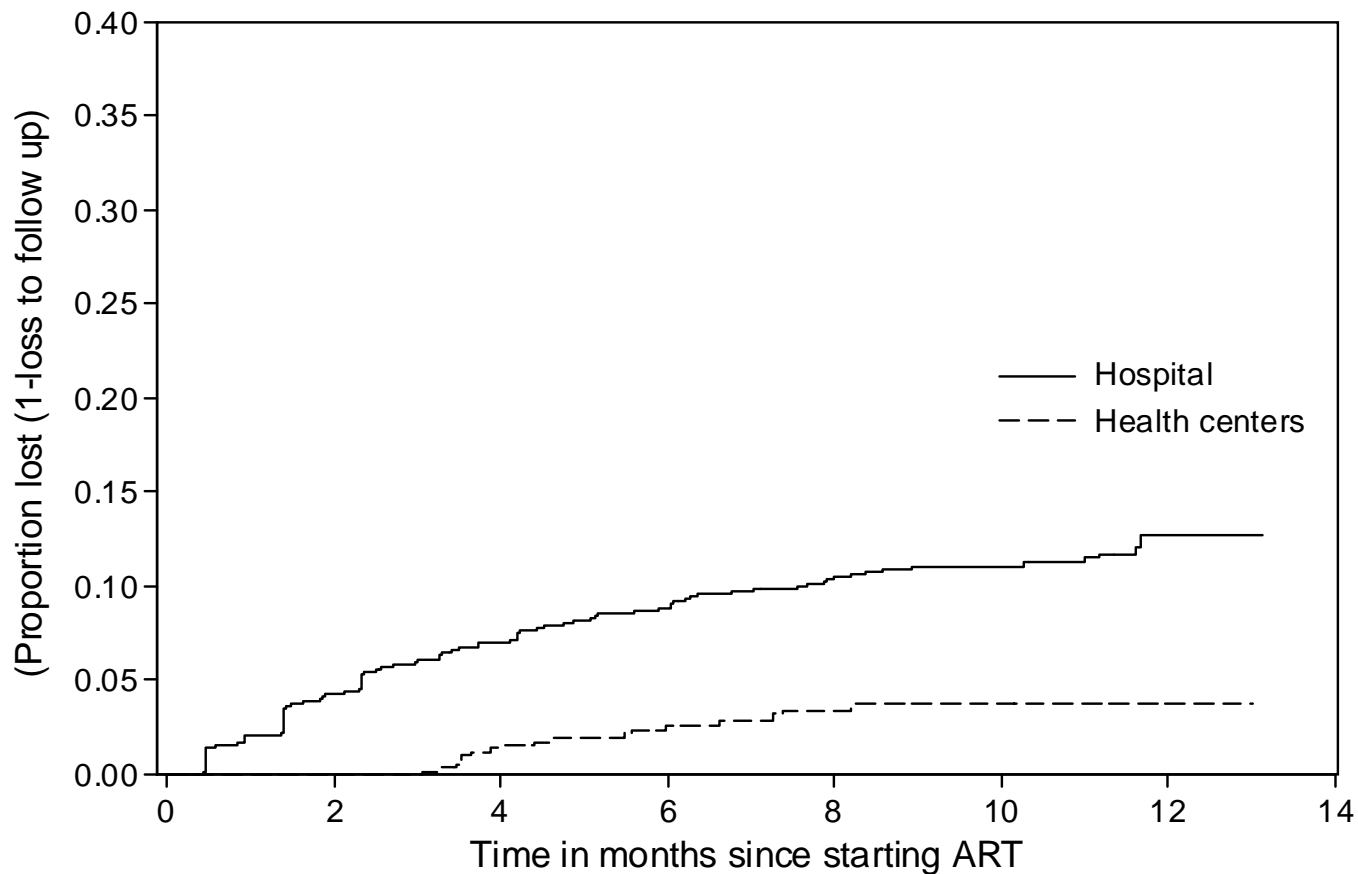
# Hospital vs. Primary Health Center: Thyolo, Malawi

- Setting: Thyolo District, rural Malawi
- Standardized ART outcomes:
  - 4,074 patients enrolled June 1, '06-June 30, '07
    - 2,904 followed at district hospital
      - 1 clinical officer, 2 medical assistants, 2 nurses, 3 nurse counselors
    - 1,170 followed in 4 health centers:
      - 1 medical assistant, 1 nurse, clerk/receptionist
  - Mobile district support/monitoring team
  - Volunteer home-care providers and community-based nurses
  - Treatment free for patients

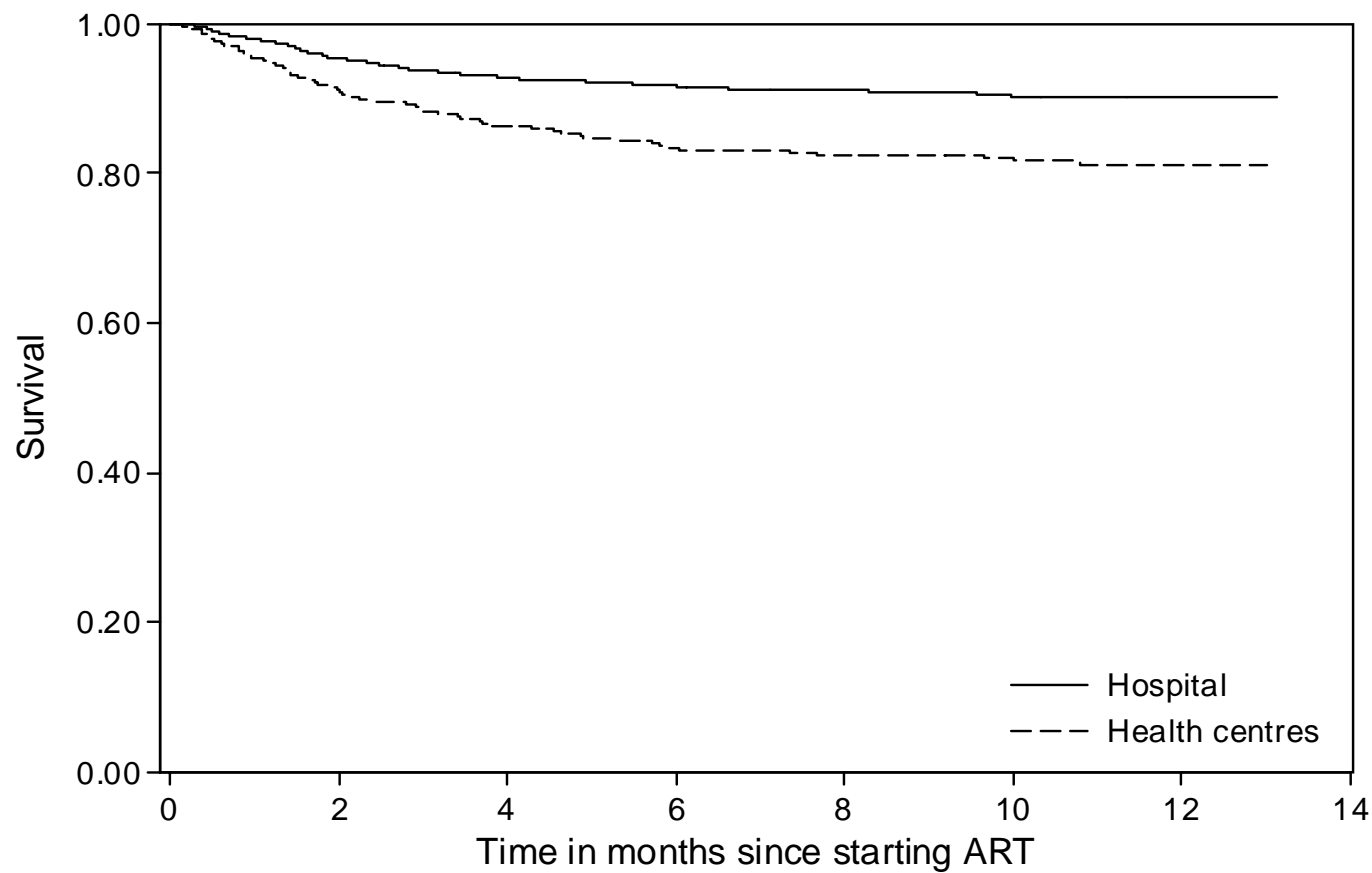
# Probability of attrition from care, all causes, over time since ART initiation by care site: Thyolo, Malawi



# Probability of loss to follow up over time since ART initiation by care site: Thyolo, Malawi



# Probability of survival over time since ART initiation by care site: Thylo, Malawi



## Decentralization and Task-shifting: Lusikisiki, S. Africa

- Severe shortages in physicians and nurses
  - Physician-population ratio 14 times below country average
  - 50% of all nursing posts unfilled
- High HIV prevalence (31% in antenatal clinic)
- 1 hospital, 12 health centers
- Doubling of clinical case-load with no increase in staff
- Decentralization of enrollment from hospital to peripheral health centers

# Decentralization and Task-shifting: Lusikisiki, S. Africa

- Physicians:
  - sees only problem patients,
  - Supervises, via mobile team, clinics and mentors nurses/counselors
- Nurses
  - Manages OIs, performs clinical staging and initiates and manages ART
  - Supervises clinic staff and manages drug supply
- Adherence counselors
  - Readies patients for ART, provides treatment literacy
  - Collects data and traces defaulters
- Community caregivers: run HIV support groups
- Support groups, PLWA
  - Adherence monitoring, default tracing, advocacy

## Decentralization and Task-shifting: effect on outcomes Lusikisiki, S. Africa

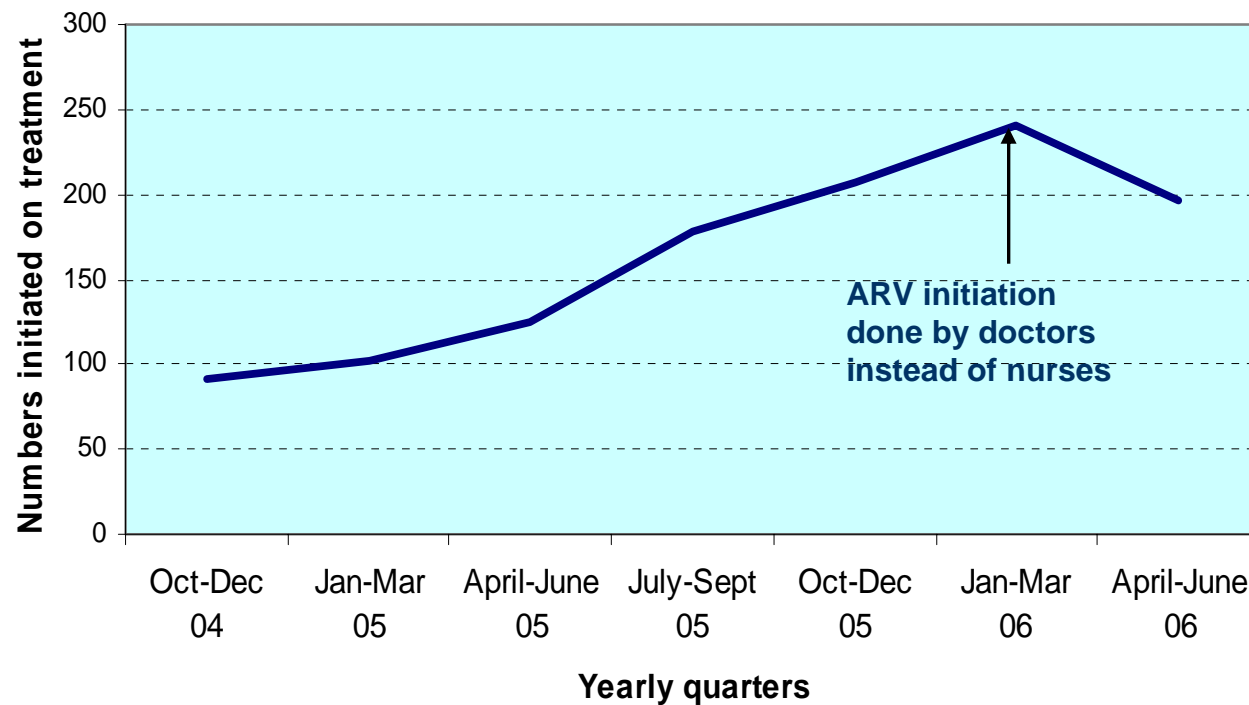
Outcome	Patients at clinics		Patients at the hospital		<i>P</i>
	No.	Percentage (95% CI)	No.	Percentage (95% CI)	
Started ART	595	100.0	430	100.0	...
Continued to receive ART *	482	81.0 (77.6–84.1)	289	67.2 (62.5–71.6)	<.001
Died	100	16.8 (13.9–20.1)	58	13.5 (10.4–17.1)	.147
Lost to follow-up *	13	2.2 (1.2–3.7)	83	19.3 (15.7–23.4)	<.001
CD4 cell count at 12 months					
Determined	348	58.5 (54.4–62.5)	81	18.8 (15.3–22.9)	<.001
≥200 cells/mm <sup>3</sup>	303	87.1 (83.1–90.4)	61	14.2 (64.5–84.2)	.008
Viral load at 12 months					
Determined	296	49.7 (45.7–53.8)	41	9.5 (6.9–12.7)	<.001
<400 copies/mL	265	89.5 (85.5–92.8)	32	78.0 (62.4–89.4)	.033

**NOTE.** Sample includes all patients who enrolled between January 2004 and June 2005 to receive antiretroviral therapy (ART) and who had completed at least 12 months of treatment by July 2006.

<sup>1</sup> Bedelo M, Ford N, et al, Implementing antiretroviral therapy in rural communities: The Lusikisiki model of decentralized HIV/AIDS care. *Journal of Infectious Diseases*, 2007;196:S464-S468

# Task Shifting: ART initiation Lusikisiki, S. Africa

Quarterly initiation of antiretroviral treatment at clinics in Lusikisiki,  
South Africa.  
(October 2004-June 2006)



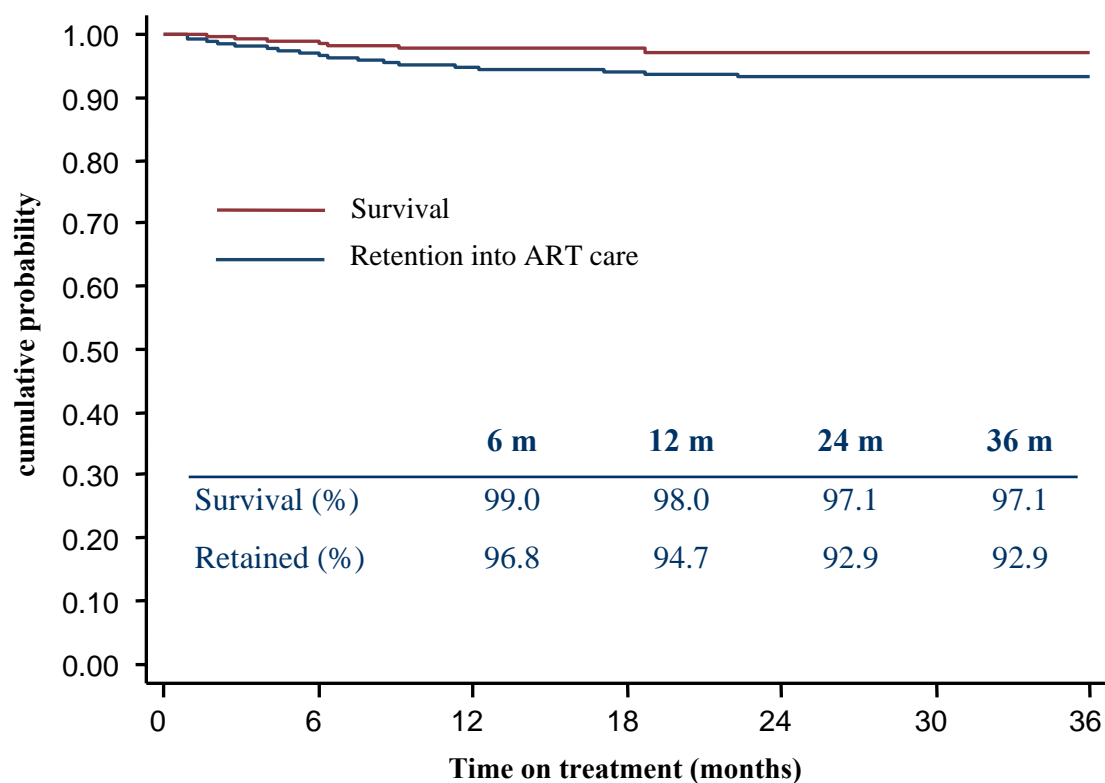
# Decentralization and Task Shifting: Nurse-based pediatric care Kigali, Rwanda

- Setting:
  - 2 health centers, urban and semi-rural
  - General health care + HIV care/ART
- Nurse-based care
  - Didactic and bed-side training by HIV doctor
  - Full ART management
    - Simplified protocols
    - 1 FTE physician present daily, than 3 times weekly
  - Dedicated pediatric consultation day
    - Minimize out-of-school time
    - Create child-friendly environment
    - Focus on disclosure and psychosocial support

# Nurse-based pediatric care Kigali, Rwanda

Patient Characteristics	
Age at start	7.2 (4.5 – 10.4)
< 3 years	38 (12%)
Sex (male/female)	157/158 (50/50%)
WHO stage I	145 (46.0%)
WHO stage II	115 (36.5%)
WHO stage III	12 (3.8%)
Weight for age (z-score) (n=293)	-1.9 (-3.0;-0.9)
Baseline CD4 count % (n=282)	14% (9-18)
< 15 %	158 (56.0%)
15-25 %	118 (42%)
> 25 %	6 (2.1%)
Time on ART (years)	2.0 (1.2-2.6)
< 1 year vs. ≥ 1 year	59 (19 %) vs 256 (81 %)

# Nurse-based pediatric care Kigali, Rwanda



<b>Viral load</b>	<b><u>Months on ART</u></b>	<b><u>&lt; 40 c/ml</u></b>	<b><u>&lt; 400 c/ml</u></b>
<b>(N=174)</b>	<b>18 (15-23)</b>	<b>127 (73.0%)</b>	<b>144 (82.8%)</b>



# **Indicators for monitoring national programs**



# Simple system of indicators for measuring program effectiveness: The Malawi example

ARV Registration Number	Year	Quarter	Date of registration	Name	Sex	Age	Address	Date first started ARV drugs	Reason for starting ARV drugs	Name / address of Guardian	ARV Treatment Unit

*Reason for starting ARV Drugs: Stage III, Stage IV, CD4 count < 200/mm<sup>3</sup>, Stage II with TLC < 1200/mm<sup>3</sup>*

*Also indicate under Reasons for ART – PTB, EPTB, KS and Transfer In (TI)*

*Quarters: 1 = January to March: 2 = April to June: 3 = July to September: 4 = October - December*

## The Malawi example, cont.

Outcome (provide date when change from alive)					Of those alive (provide date when change from start)			Ambulant		At work or (in children) at school		Remarks (including occupation, BMI, ITN)
Alive	Dead	Default	Stop	Transfer	Start	Substitute	Switch	Yes	No	Yes	No	

**Alive** - alive and on ARV drugs: **Dead** - whatever the cause: **Default** - not seen in three months: **Stop** - stopped treatment due to side effects/other:

**Transfer** - transfer-out to another ARV treatment unit

**Start** - on first line regimen: **Substitute** - changed to alternative first line regimen: **Switch** - changed to second line regimen

**Ambulant** - yes/no: **At work or school** - at previous or new employment for adults

# Indicators proposed by the Global Fund, UNAIDS, WHO

- **Number of people with advanced HIV infection currently receiving ART.\*°^**
- **Percent of adults and children with HIV still alive 12 months after initiation of ART.\*°^**
- **Percent of patients still on therapy and receiving a standard first-line regimen after 12 months from treatment initiation.°**
- **PLWHA receiving diagnosis and treatment for opportunistic infections\***
- **Health facilities dispensing ARVs that experienced stock-outs of ARV in the last 12 months\*°**
- **Facilities providing ART using CD4 monitoring in line with national guidelines/policies, on site or through referral\*°**
- **Facilities offering ART that meet national targets for ART patient on-time drug pick-up\***
- **Number of FTE health care providers trained in and providing HIV care, treatment and prevention per 1000 clients on ART°**

\* Global Fund *M&E Toolkit (2006, 2008 addendum)*

° WHO *Framework for Global Monitoring and Reporting, 2007*

^ UNGASS *Guidelines on Construction of Core Indicators, 2008 reporting*

# Priorities for operational research

- **Quality and Safety:** cohort and biologic outcomes
  - Task shifting effects on quality of care
    - Identifying patients' medical and support needs
    - Efficiency of ART initiation
    - Treatment outcomes over time
- **Acceptability:** qualitative surveys
  - Societal and cultural values and preferences
    - Hospital vs. health care roles in care
    - Acceptance of lay workers in clinical tasks
    - Doctor and nurse accepting shifting roles/responsibilities

# Priorities for operational research, cont.

- Health system impact: cost analyses, qualitative surveys
  - Cost effectiveness
  - Assessment of payment/incentives for long-term care giver retention and sustainability
  - Vertical vs. integrated approaches
- Public health impact: evolution of program data over time
  - Impact on task shifting, decentralization in improving efficiency and effectiveness of ART access and outcome at a population level
  - Shifts in clinical and biologic status at enrollment
  - ART coverage

# Conclusions

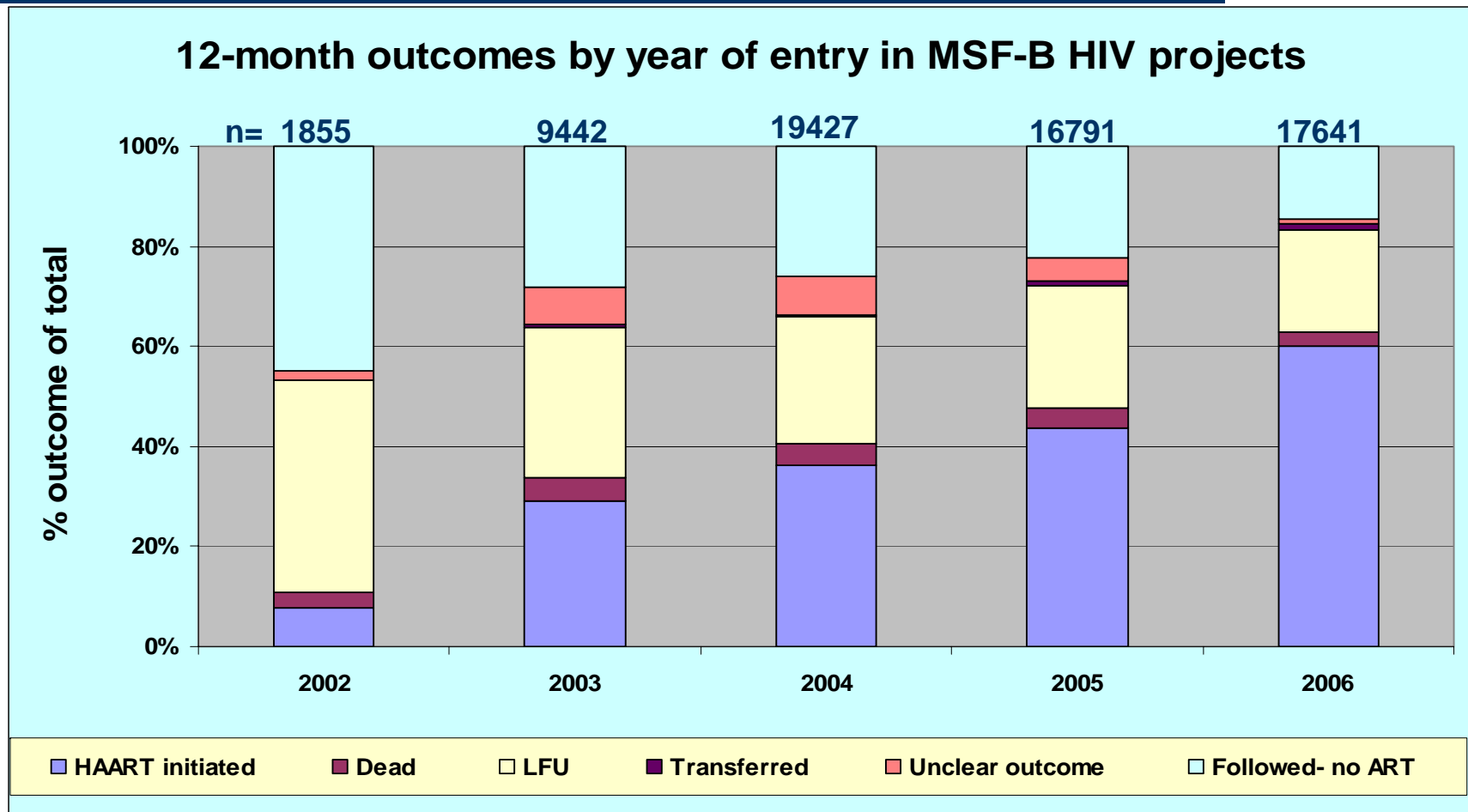
- The gains in treatment access to date and those expected under “Universal Access” can and should be consolidated by retaining people in care.
- Simple monitoring tools at the country level are needed now to ensure that scale-up is successful in terms of quantity *and* quality.
- Other program indicators have been and will be used by implementing partners to measure effectiveness of innovative approaches that can then be adopted more widely.



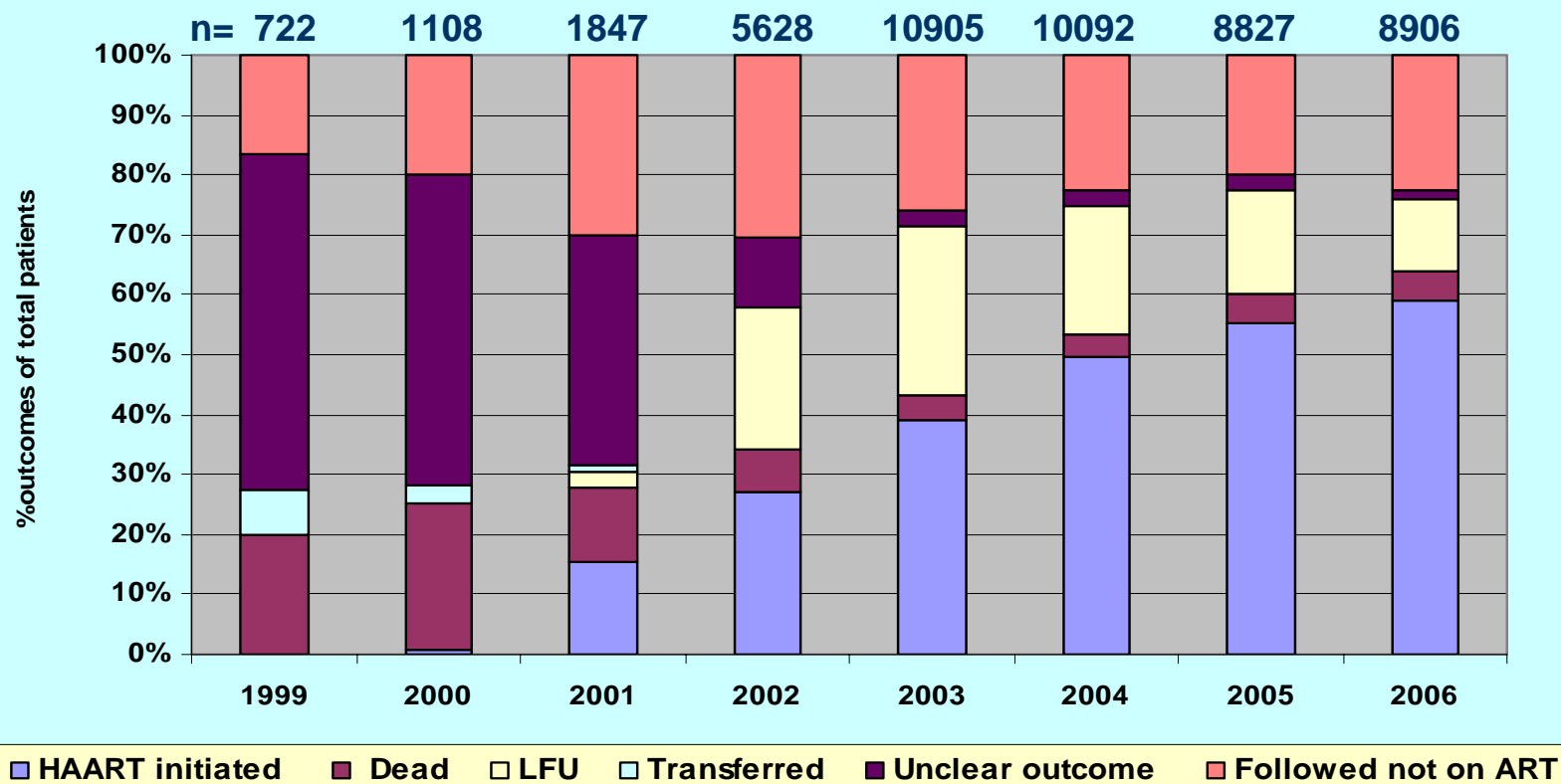
**Thank you!**



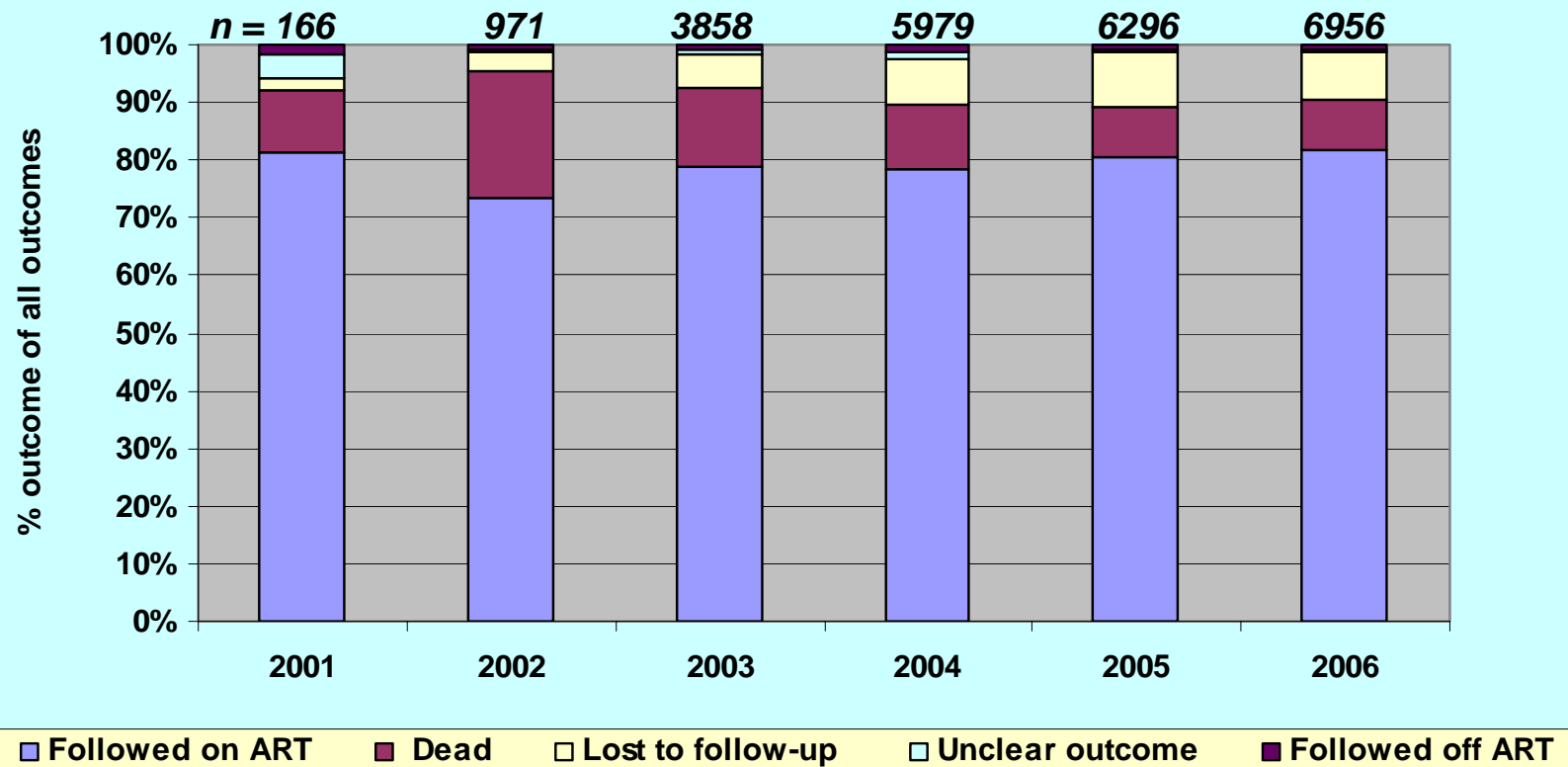
## 12-month outcomes by year of entry in MSF-B HIV projects



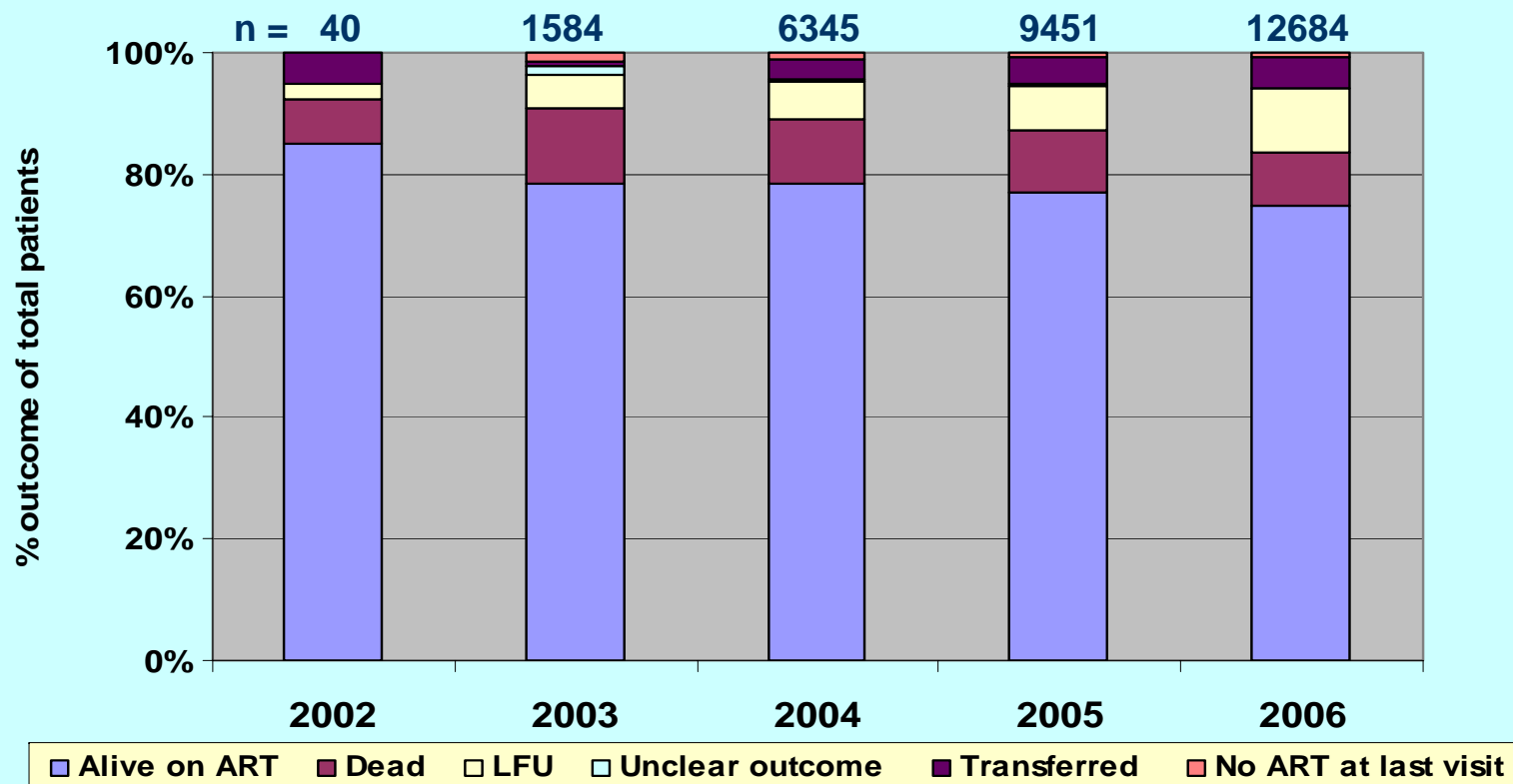
### 12-month outcomes by year of entry MSF-France HIV programs



12-month outcome on ART by year of initiation: MSF France programs  
(8 programs)



**12-month outcome by year of ART initiation: MSF-Belgium  
n = 20 programs**



## Volunteer home-care providers and community-based nurses: effect on outcomes

	Thyolo district, Malawi <sup>1</sup> April 2003-April 2005		
	With community involvement n (%)	Without community involvement n (%)	<i>P</i> *
Placed on ART	895	739	-
<i>Alive and on ART</i>	856 (95.6)	560 (76)	< 0.001
<i>Died</i>	31 (3.5)	115 (15.5)	< 0.001
<i>Loss to follow-up (defaulted)</i>	1 (0.1)	39 (5.2)	< 0.001
<i>Stopped</i>	7 (0.8)	25(3.3)	< 0.001

<sup>1</sup>Zachariah R, Teck R, et al, Community support is associated with better antiretroviral treatment outcomes in a resource-limited rural district in Malawi. *Trans R Soc Trop Med Hyg* 2007, **101**:79-84.

# Hospital vs. Primary Health Center Thyolo, Malawi

	Hospital		Health centre		Hazard Ratio (95% CI) <sup>b</sup>	P-value
	n (%)	Rate /100py	N (%)	Rate /100py		
<b>Started on ART</b>	2904	-	1170	-		
<b>Retained in care</b>	2463 (84.9)	185	999 (85.4)	211	1.14 (1.06-1.23)	< 0.001
<b><i>Alive and on ART</i></b>	2384 (82.1)	179.3	994 (85)	210	1.17 (1.09-1.26)	<0.001
<b>Attrition</b>	439 (15.1)	33.3	171 (14.6)	36.1	1.07 (0.89-1.27)	0.5
<b><i>Defaulted</i></b>	226 (7.8)	17	18 (1.5)	3.8	0.22 (0.13-0.35)	<0.001
<b><i>Dead</i></b>	202 (7.0)	15.2	150 (12.8)	31.7	2.02 (1.63-2.49)	<0.001
<b><i>Stopped</i></b>	11(0.4)	0.82	3 (0.3)	0.63	0.71 (0.19-2.57)	0.6