

“Linkage Case Management and Post-hospitalization Outcomes in People with HIV”

(The Daraja Randomized Clinical Trial)

Lessons learned from a randomized, multicenter clinical trial in hospitalized people with HIV in Northwestern Tanzania.

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Original Investigation

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Linkage Case Management and Posthospitalization Outcomes in People With HIV The Daraja Randomized Clinical Trial

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THANK YOU!

To all our CM teams and Social workers out there.



Presentation Objectives:

- Review clinical trial results/discuss how case management interventions impact PWH.
 - Discuss importance of an interdisciplinary approach in HIV care.
 - Interventions that can be generalized to positively impact patient care.
-

No Disclosures to report

Study Objective:

To determine whether a linkage case management intervention (named “Daraja”/ “bridge” in Kiswahili) designed to address barriers to HIV care engagement could improve posthospital outcomes.

Background/Significance:

2022: ~630,000 death from AIDS-related causes worldwide (2/3 occurred in sub-Saharan Africa.)

Systematic review pooled data from 29 cohorts,. 92,781 all-cause hospitalizations of PWH worldwide-→ 21% died in the 1st year post hospital discharge. 30% occurred in Sub-Saharan Africa.

Factors associated with post hospital mortality:

- Degree of immunosuppression*
 - Less than Primary level education*
 - Longer hospitalization*
 - Delayed linkage to HIV clinic care.*
-

Methods:

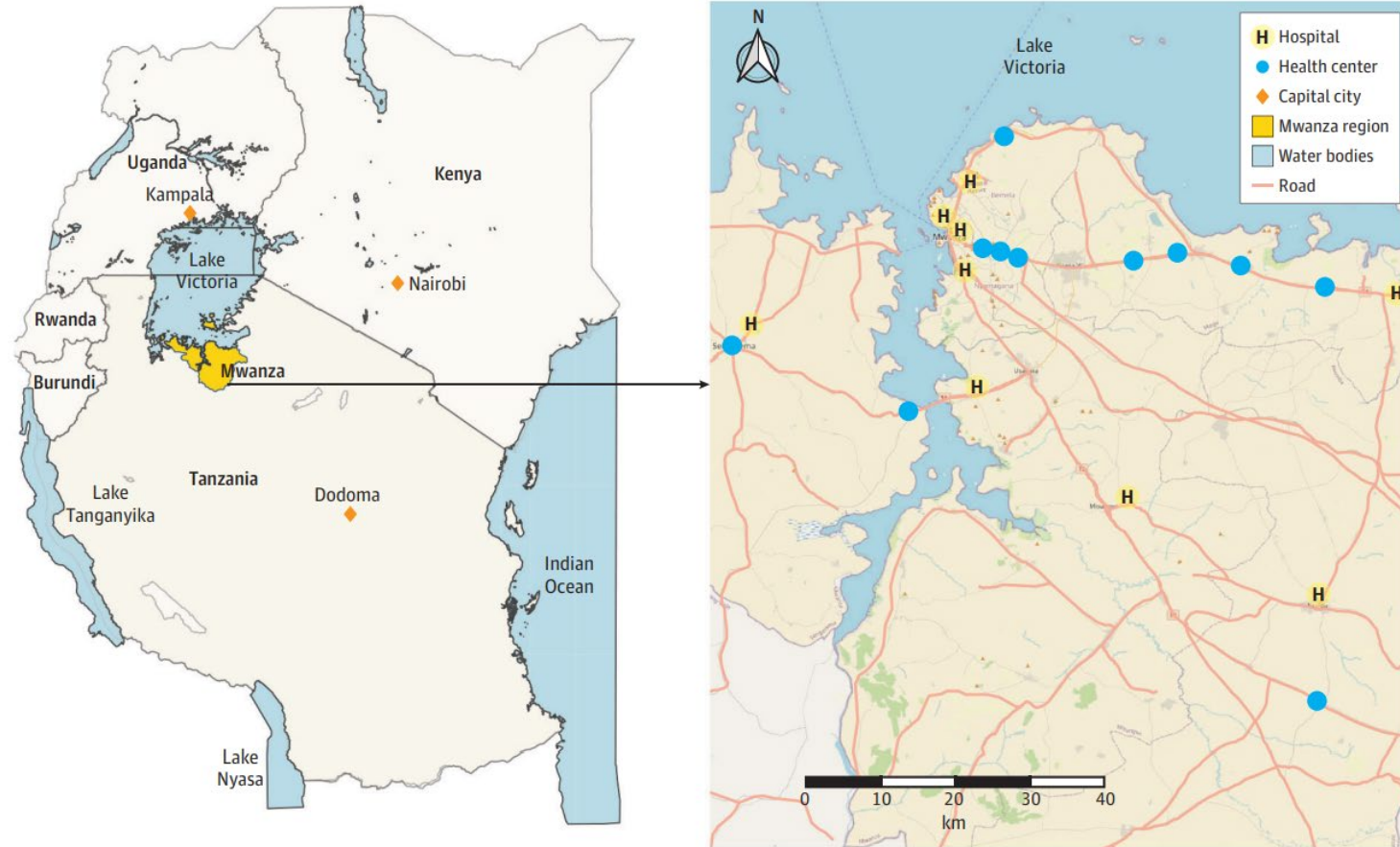
Study design:

-Multisite Randomized clinical trial in Northwestern Tanzania.

-Participants were enrolled from 20 inpatient health facilities in Mwanza region.

(31% mortality 3 months post-discharge, low rates of HIV clinic linkage in first month, strong association between HIV clinic non-linkage and mortality.

Figure 1. Map of the 20 Enrollment Sites for the Daraja Trial in Tanzania



Study population

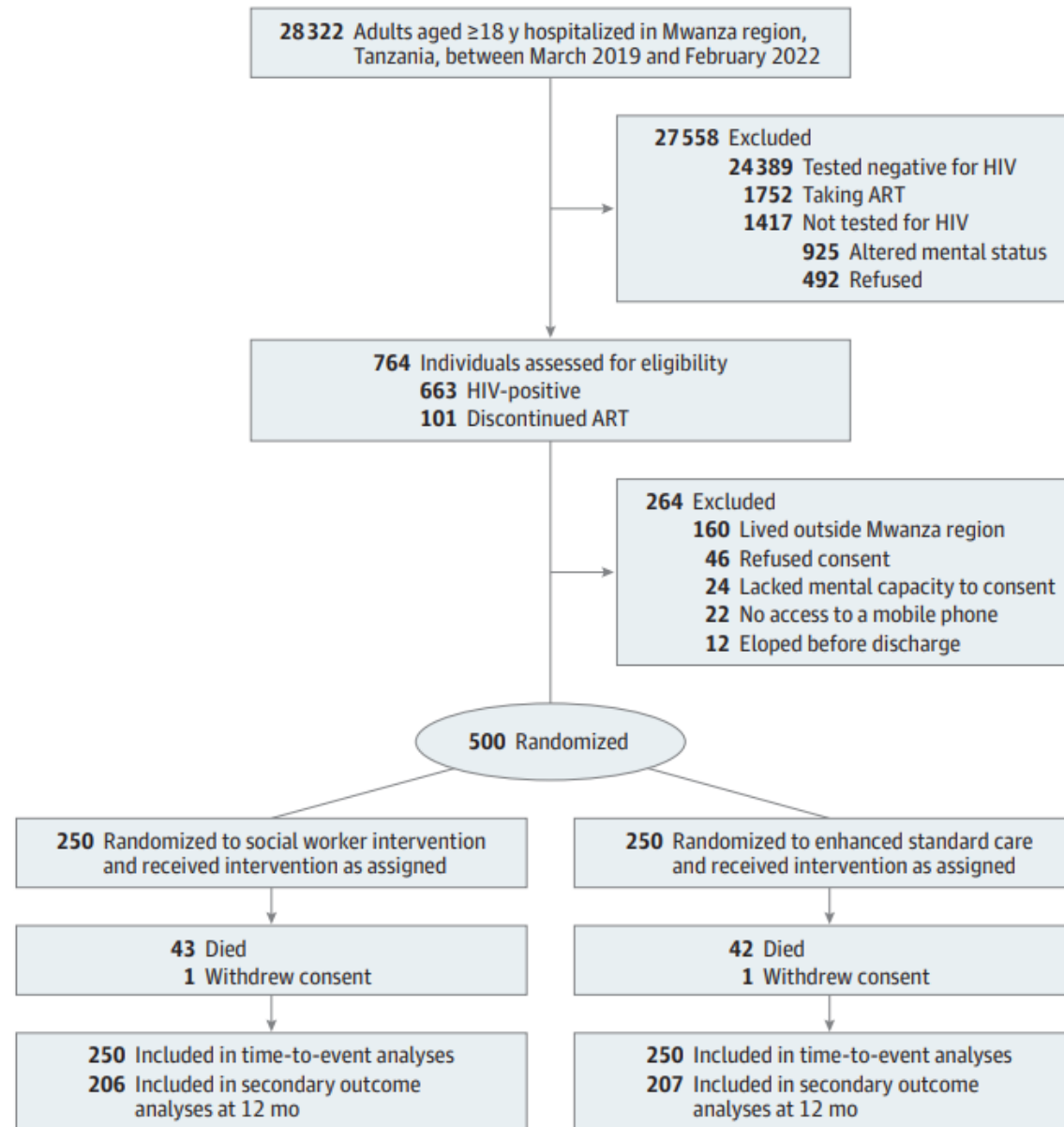
People with HIV hospitalized for any reason at the participating facilities if they met the following:

- 18 years or older
- ART- naïve or discontinued for >7 days
- Living in Mwanza region
- Mental capacity to consent
- Access to mobile phone.

Randomization

- Participants were randomized 1:1 ratio the day before discharge, unsealed enveloped by research coordinator at time of discharge.

Figure 2. Flow of Patients Through the Daraja Trial



Intervention

Participant in the intervention arm received 5 (45min) sessions delivered by a SW over a 3 month period.

1st session → Hospital (Building rapport, Identifying participants strengths)

2nd session → At participant Home (Developing plans to achieve participants goals)

3-5th session → At HIV clinic or participants location of choice. (transitioning case management to participants HIV primary care team.)

Primary Outcome:

1) All cause mortality at 12 months.

Secondary Outcomes:

1) Time to HIV clinic linkage after discharge.

2) Time to ART initiation after discharge

3) retention in care at 12 months

4) ART adherence at 12 months.

5) Achieving Viral load suppression at 12 months (defined by HIV RNA levels of <1000 copies.)

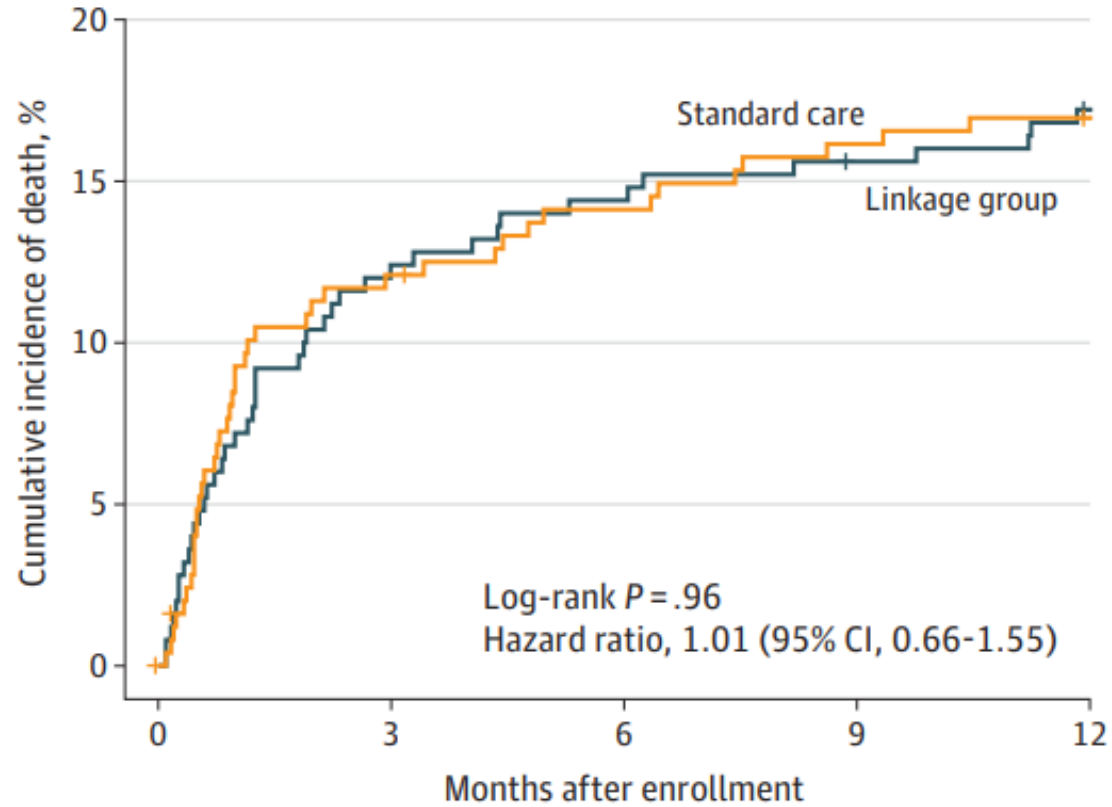
Results

Table 1. Baseline Characteristics of Participants

Characteristics	Linkage intervention (n = 250)	Standard care (n = 250)
Sex, No. (%)		
Women	190 (76)	194 (78)
Men	60 (24)	56 (22)
Age, mean (SD), y	38 (12)	36 (11)
Married or cohabitating, No. (%)	131 (52)	117 (47)
Head of household, No. (%)	133 (53)	126 (50)
Education level, No. (%) ^a		
Less than primary	85 (34)	81 (32)
Completed primary	158 (63)	163 (65)
Complete secondary	7 (3)	6 (2)
Source of income, No. (%)		
Small trade or unskilled labor	156 (62)	148 (59)
Skilled labor worker or professional	35 (14)	46 (18)
Farmer	34 (14)	30 (12)
Unemployed	25 (10)	26 (10)
Income <5000 Tanzanian shillings (US \$2.15) per d, No. (%) ^b	143 (57)	156 (62)
Health insurance, No. (%)	22 (9)	18 (7)
Alcohol use category by AUDIT score, No. (%) ^c		
Abstainee (score 0)	201 (80)	190 (76)
Low risk (score 1-7)	27 (11)	33 (13)
Hazardous use/dependence (score >7)	22 (9)	27 (11)
Depression category by PHQ-9 score, No. (%) ^d		
None (score 0-4)	95 (38)	100 (40)
Mild (score 5-9)	103 (41)	84 (34)
Moderate or severe (score >9)	52 (21)	66 (26)
HIV-related stigma score (self-reported), mean (SD) ^e	2.3 (0.9)	2.3 (0.9)
Social support by Social Provisions Scale score, mean (SD) ^f	34.8 (4.7)	34.7 (4.3)
Health-related quality of life by SF-12 score, mean (SD) ^g		
Physical component score	38 (9)	37 (9)
Mental component score	45 (12)	45 (12)

HIV/ART status, No. (%)		
Newly diagnosed HIV	211 (84)	191 (76)
Discontinued ART (≥ 7 d)	39 (16)	59 (24)
CD4 cell count, / μ L, No. (%)		
0-100	86 (34)	89 (36)
101-200	35 (14)	31 (12)
>200	128 (51)	128 (51)
Enrollment hospital, No. (%)		
Sekou Toure Regional Hospital	90 (36)	85 (34)
Nyamagana District Hospital	32 (13)	39 (16)
Igoma Health Center	36 (14)	30 (12)
Bugando Referral Hospital	16 (6)	23 (9)
Buzuruga Health Center	16 (6)	21 (8)
Other hospital or health center	60 (24)	52 (21)
Hospital stay, median (IQR), d	4 (2-6)	4 (2-7)
Enrollment before onset of COVID-19 in Tanzania, No. (%) ^h	105 (42)	104 (42)
Reason for hospital admission, No. (%) ⁱ		
Medical, infectious	153 (61)	156 (62)
Medical, noncommunicable	33 (13)	41 (16)
Obstetric or gynecological	48 (19)	39 (16)
Surgical	16 (6)	14 (6)

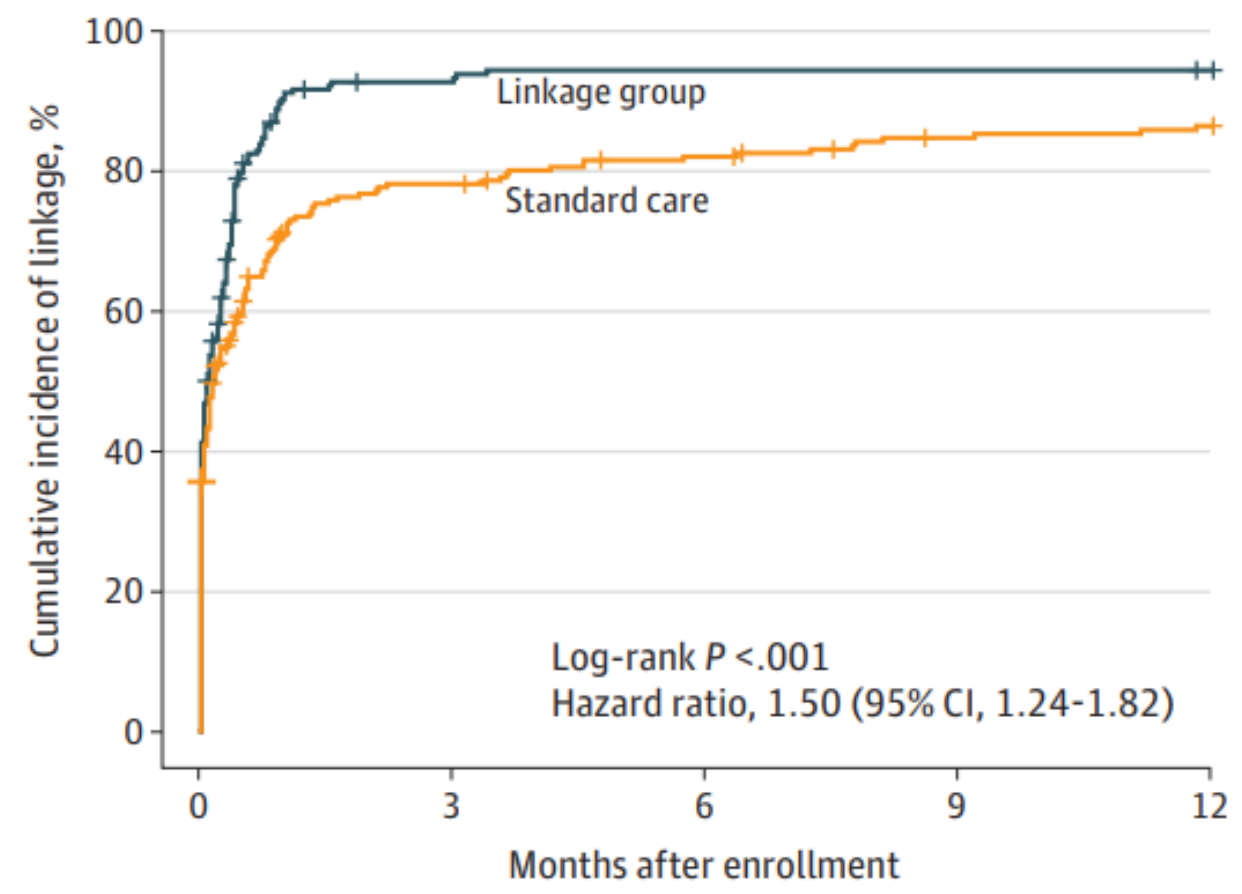
A All-cause death (primary)



No. at risk		0	3	6	9	12
Linkage group	250	219	214	210	206	
Standard care	250	218	212	207	205	

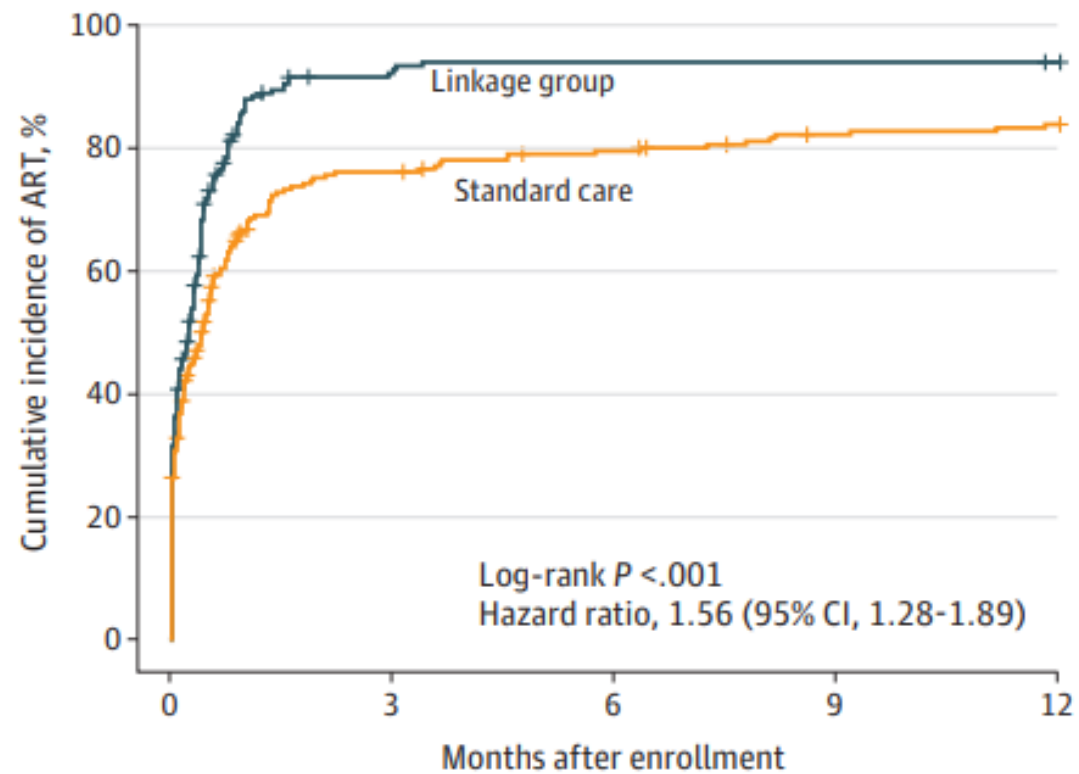
- All-cause mortality at 12-month **did not differ by group.**
- Death occurred in 17.0% (85/500) of participants, did not differ by trial group (17.2% vs 16.8% with standard care)

B HIV clinic linkage (secondary)



No. at risk	0	3	6	9	12
Linkage group	250	13	10	10	9
Standard care	250	47	36	27	24

C ART initiation (secondary)



No. at risk	0	3	6	9	12
Linkage group	250	13	10	10	9
Standard care	250	51	41	32	29

- 1 month after enrollment, 87.6% of intervention participants had attended the HIV clinic vs 69.6% of control participants
- 3 months, 87.6% had started ART vs 72.8% of control participants.

Table 2. Secondary Outcomes

12-mo Outcomes ^a	Linkage intervention (n = 206) ^b	Standard care (n = 207) ^b	Difference (95% CI)	Rate ratio (95% CI) ^c	P value ^d
Retention in HIV care	180 (87.4)	158 (76.3)	11.1 (3.7-18.4)	1.14 (1.04-1.25)	.005
ART adherence	167 (81.1)	140 (67.6)	13.4 (5.1-21.8)	1.20 (1.07-1.34)	.002
Viral load suppression (<1000 copies/ μ L)	162 (78.6)	139 (67.1)	11.5 (3.0-20.0)	1.18 (1.04-1.32)	.01

Discussion

This low-cost intervention failed to reduce 12-month posthospital mortality (primary outcome).

However:

- **Improved continuity of care** after hospital discharge among newly diagnosed people with HIV and those who discontinued ART.
- **Reduced time to HIV clinic linkage and ART initiation** after hospital discharge.
- Intervention recipients who survived to 12 months had higher rates of HIV clinic retention, ART adherence, and viral load suppression
- These findings are **similar to the first trial of the ARTAS** linkage case management intervention, which demonstrated a 15% increase in HIV clinic linkage within 6 months

- In the current trial, the **benefits of case management persisted to 12 months.**
- The intervention was associated **with >10% absolute increase in continued engagement in HIV care and viral load suppression.**
- Long-term viral load suppression may represent **public health benefits (reduced HIV transmission)**
- These findings support the hypothesis that hospitalization is “an opportunity to engage patients when they are particularly apt to consider behavior change, given their acute illness.”

Possible explanations for the failure of the intervention to reduce posthospital mortality:

- Hospitalized people with HIV often present with **multiple OI's and advanced illness**.
(Reducing posthospital mortality will likely require earlier Dx and improved management of OIs)
- Rapid VL assessment with **drug resistance testing may be necessary** due high incidence of HIV drug resistance. *(Of 786 hospitalized people with HIV taking stable ART who were enrolled in 1 recent trial in Malawi and South Africa, 32% had virologic failure.)* Resistance to at least 2 ART drugs was common and was associated with increased mortality.
- In some hospitalized people with HIV with terminal disease, the only way to prevent death might be through interventions addressing stigma and targeting early diagnosis.

- One major strength of this trial was the high rate of HIV testing, with more than 28 000 adults undergoing testing during the study period.
- Another strength was the low rate of study withdrawal, and the intervention team also achieved a high rate of treatment exposure.

Limitations

- The **generalizability** of these findings is unknown but posthospital mortality rate observed in the trial is consistent with rates reported in studies in both Africa and the US.
- Enhanced standard care in the control group may have reduced mortality in the control group, leading to an **underestimation of the intervention effect**.
- For patients who are highly amenable to starting or restarting ART, enhanced nurse counseling and accompaniment to the clinic may be sufficient to promote posthospital HIV clinic linkage and use of ART
- Besides mortality, perhaps HIV clinic linkage and ART initiation may be more reasonable targets for case management interventions after hospitalization.
- Intervention **social workers were employed by the research study rather than by health care facilities.**

Metsch LR, Feaster DJ, Gooden L, et al. Effect of patient navigation with or without financial incentives on viral suppression among hospitalized patients with HIV infection and substance use: a randomized clinical trial. *JAMA*. 2016;316(2):156-170

Ford N, Patten G, Rangaraj A, Davies MA, Meintjes G, Ellman T. Outcomes of people living with HIV after hospital discharge: a systematic review and meta-analysis. *Lancet HIV*. 2022;9(3): e150-e159



Mt. Kilimanjaro

Efficacy of a brief case management intervention to link recently diagnosed HIV-infected persons to care

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AIDS 19(4):p 423-431, March 4, 2005. | DOI: 10.1097/01.aids.0000161772.51900.eb

Objectives	Assess a CM intervention to improve linkage to care for persons recently receiving an HIV diagnosis
Method	<p>Recently diagnosed HIV-infected patients were randomized to either (SOC) passive referral or case management (CM) for linkage to nearby HIV clinics.</p> <ul style="list-style-type: none"> ➤ SOC arm received information about HIV and local care resources. ➤ CM intervention arm included <u>up to five contacts with a case manager over a 90-day period.</u>
Results	<ul style="list-style-type: none"> ▪ 136 case-managed participants ▪ 137 SOC participants <p>78% (CM) vs 60% (SOC) visited an HIV clinician at least once within 6 months and at least twice within 12 months (64% vs 49%)</p> <p>>40 years, Hispanic, individuals enrolled within 6 months of an HIV-seropositive test result and participants without recent Substance use <u>were all significantly more likely to have made two visits to an HIV care provider</u></p>
Conclusion	<p>A brief <u>intervention by a CM was associated with a significantly higher rate of successful linkage to HIV care.</u></p> <p>Brief case management is an affordable and effective resource that can be offered to HIV-infected clients soon after their HIV diagnosis</p>



HIV

HIV > Effective Interventions > Treat

Effective Interventions

Diagnose +

Treat -

ARTAS

Data to Care

Fundamentals of Motivational Interviewing for HIV

HIV Navigation Services

Partnership for Health – Medication Adherence

PROMISE for HIP

Stay Connected for Your Health

ARTAS

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Anti-Retroviral Treatment and Access to Services (ARTAS) is an intervention designed to link individuals with diagnosed HIV to medical care.

About ARTAS

Anti-Retroviral Treatment and Access to Services (ARTAS) is an individual-level, multi-session, time-limited intervention designed to link individuals with recently diagnosed HIV to medical care. ARTAS supports early access to HIV medical care and helps clients to address barriers by emphasizing the client's *abilities* rather than *inabilities* through use of the strengths-based approach. The setting of objectives and goals is driven by the client who must implement these changes. Finally, the mutually respectful and cooperative relationship between the client and linkage coordinator supports the client in their efforts to implement changes and overcome barriers.



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ARTAS

Linkage to Care

Antiretroviral Treatment and Access to Services (ARTAS)

An individual-level, multi-session intervention for persons who are recently diagnosed with HIV

Implementation Manual

July 2022

Important Information for Users

This strategy is intended to be used with persons who were recently diagnosed with HIV and who are voluntarily participating in this strategy, or who are attempting to re-enter care. The materials in this package are not intended for general audiences.

The package includes an implementation manual, training and technical assistance materials, and other items used in intervention delivery. You can find supplemental HIV training materials on the [Effective Interventions website](#).

Before conducting ARTAS in your community, all materials must be approved by your community HIV review panel for acceptability in your project area. Once approved for implementation, the materials are to be used by trained facilitators.

Conclusions

Thoughts, institutional experiences?
