Same-day ART initiation on care retention among people living with HIV

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Takeshi Miwa (D1)

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Original article

Impact of same-day ART initiation on medical care and medication discontinuation among patients with incident HIV infection or AIDS in Taiwan: A population-based cohort study



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Changes in ART initiation timing

• Modern antiretroviral therapy (ART) can effectively suppress HIV replication, reducing disease progression and mortality (Holkmann Olsen et al., 2007).



Impact of same-day ART

- While randomised controlled trials initially supported <u>same-day</u> <u>ART initiation</u>, real-world observational studies have yielded inconsistent results.
- Taiwan implemented same-week ART initiation in 2018, advancing to same-day initiation in 2021 (Taiwan AIDS Society 2020). However, population-based evidence on its impact on care and medication discontinuation remains limited.
- The study aims to <u>assess whether same-day ART initiation</u> <u>affect the risk of care and medication discontinuation</u> compared to starting ART 1-7 days after diagnosis (rapid ART).

Results

Study Design

- Population-based cohort study to <u>investigate the effect of</u> <u>ART initiation timing on care/medication discontinuation</u>
- Study population: Patients diagnosed with HIV/AIDS



Data source

• Taiwan National Health Insurance (NHI) claims database.

- 1. Ambulatory care expenditures by visitors
- 2. Details of ambulatory care orders
- 3. Inpatient expenditures by admission
- 4. Details of inpatient orders
- 5. Expenditures for prescriptions dispensed at contracted pharmacies
- 6. Details of prescriptions dispensed at contracted pharmacies
- Cause of Death Data managed by the Health and Welfare Data Science Center under the Ministry of Health and Welfare in Taiwan.

Study population

Inclusion criteria

- First medical visit related to HIV/AIDS occurred between January 1, 2017, and December 31, 2021.
- Adult patients with HIV/AIDS who initiated ART within 7 days of the initial visit.
- HIV and AIDS patients identified using ICD-10-CM code (Z21/B20 as the primary diagnostic codes).

Exclusion criteria

 Diagnosed with tuberculosis or cryptococcal meningitis within 60 days preceding their initial HIV/AIDS visits Results

Did not show up

Outcome definition

 <u>Care discontinuation</u>: Having no clinical visits for over 90 days since the last clinical visit, with the discontinuation date set as the last outpatient visit.



Outcome definition

 Medication discontinuation: Failing to claim ART prescriptions within 30 days after the expected pick-up date, with the discontinuation date set as the last pick-up date plus the days of drug supply.



Statistical analysis

• **Doubly robust estimation method** to estimate the effect of the timing of ART initiation on care and medication discontinuation.

Step 1: Adjust for Selection Bias using Propensity Scores

- Estimated each patient's propensity score using logistic regression the probability that they would start ART on the same day based on their background characteristics (e.g., age, comorbidities, location).
- Create <u>stabilized inverse propensity score weights</u>. This reweights the data so that the characteristics of the two groups (same-day ART vs. rapid ART) are balanced.

Stabilized inverse propensity weight

ID	Same-day ART	Sex	Propensity score	Inverse probability of treatment weighting (IPTW)	Stabilized IPTW
1	1	Male	0.80	1/0.80 = 1.25	$1.25^*0.6 = 0.75$
2	1	Female	0.60	1/0.60 = 1.67	$1.67^*0.6 = 1.00$
3	0	Male	0.40	1/(1-0.40) = 1.67	$1.67^{*}(1-0.6) = 0.67$
4	0	Female	0.20	1/(1-0.20) = 1.25	1.25*(1-0.6) = 0.50

Proportion of exposed (same-day ART) group = 60% Stabilized IPTW (exposed) = IPTW*0.6 Stabilized IPTW (unexposed) = IPTW*(1-0.6)

(Pezzi et al. 2016)

Statistical analysis

Step 2: Outcome analysis using Weighted Cox Regression

- Using the weighted data ("pseudo sample"), the authors ran a weighted Cox regression model to estimate the average hazard ratio (AHR) for same-day ART initiation compared with rapid ART initiation.
- A <u>cause-specific hazard model</u> was employed instead of a subdistribution hazard model because competing risk events could be disregarded (i.e., death very rare).

Analytical samples

2,204 newly diagnosed with HIV

- 1,365 same-day ART
- 235 rapid ART
- 581 ART after one week
- 23 never initiated ART

Excluded

- Started ART after one week
- Never initiated ART
- Missing information

1,523 individuals with HIV

8,411 newly diagnosed with AIDS

- 5,688 same-day ART
- 908 rapid ART
- 1,678 ART after one week
- 137 never initiated ART



5,373 individuals with AIDS

Baseline characteristics (HIV)

	Weighted cohort (Weighted cohort (N = 1530.90)				
	Same-day ART initiation (N = 1336.62)		Rapid ART initiation (N= 194.29)		94.29)	
	N	%	Ν	%	SMD [#]	
Demographic Characteristics						
Men	1294.89	96.88	189.23	97.40	0.03	
Age (mean ± SD), year	31.78 ± 9.57		30.70 ± 8.81		0.12	
18-29	670.04	50.13	105.75	54.43	0.13	
30–39	425.51	31.83	63.96	32.92		
40-49	158.34	11.85	15.07	7.76		
≥ 50	82.73	6.19	9.51	4.90		
NHI enrollment salary (mean ± SD), NT\$	28,642.30 ± 24,07	5.70	29,240.10 ± 2	27,430.90	0.02	
≤ 30,000	798.16	59.71	129.12	66.46	0.13	
30,001-50,000	362.31	27.11	45.27	23.30		
50,001-70,000	108.08	8.09	11.95	6.15		
≥ 70,000	68.07	5.09	7.96	4.10		
Residence area						
Northern	1061.23	79.40	149.46	76.93	0.07	
Central	49.41	3.70	4.20	2.16	Standardized mean difference	
Southern	159.44	11.93	30.72	15.81	(SMD) of smaller than 0.1	
Eastern and outlying islands	66.53	4.98	9.91	5.10	indicates negligible differences	

Baseline characteristics (HIV)

	Weighted cohort (N = 1530.90)					
	Same-day ART initiation (N = 1336.62)		Rapid ART initiation (N = 194.29)			
	N	%	Ν	%	SMD [#]	
Medical History						
Depression	68.19	5.10	7.81	4.02	0.05	
Substance use	36.64	2.74	4.30	2.21	0.03	
Hepatitis	40.85	3.06	4.19	2.16	0.06	
Other sexually transmitted infections	389.89	29.17	59.39	30.57	0.03	
Medication Attributes						
Hospital ownership						
Public	720.24	53.89	111.69	57.49	0.07	
Non-public	616.38	46.11	82.60	42.51		
ART Initiation Policy						
Before 2018	232.43	17.39	37.96	19.54	0.03	
Between 2018 and 2020	885.80	66.27	116.67	60.05		
After 2020	218.38	16.34	39.66	20.41		

After stabilized weighting, baseline characteristics between the two groups were generally similar, except for age and NHI enrolment salary

Baseline characteristics (AIDS)

	Weighted cohort (N = 5383.44)				
	Same-day ART initiation (N = 4491.63)		Rapid ART in	itiation (N = 8	91.81)
	N	%	N	%	SMD [#]
Demographic Characteristics					
Men	4358.40	97.03	873.22	97.92	0.06
Age (mean ± SD), year	32.88 ± 10.10		33.03 ± 9.84		0.02
18-29	2020.13	44.98	385.65	43.24	0.04
30-39	1493.45	33.25	297.75	33.39	
40-49	631.33	14.06	138.11	15.49	
≥ 50	346.72	7.72	70.31	7.88	
NHI enrollment salary (mean ± SD), NT\$	25,615.50 ± 22,103	3.80	24,247.00 ± 1	9,855.60	0.07
≤ 30,000	2957.80	65.85	604.75	67.81	0.06
30,001-50,000	1096.15	24.40	218.02	24.45	
50,001-70,000	293.90	6.54	45.73	5.13	
≥ 70,000	143.78	3.20	23.30	2.61	
Residence area					
Northern	2084.72	46.41	395.37	44.33	0.01
Central	1010.40	22.50	224.19	25.14	
Southern	1304.90	29.05	257.09	28.83	Slight differences in residence
Eastern and outlying islands	91.61	2.04	15.16	1.70	compared to HIV group

Baseline characteristics (AIDS)

	Weighted cohort (N = 5383.44)					
	Same-day ART initiation (N = 4491.63)		Rapid ART initiation (N = 891.81)			
	N	%	Ν	%	SMD [#]	
Medical History						
Depression	206.27	4.59	37.09	4.16	0.02	
Substance use	151.15	3.37	20.18	2.26	0.07	
Hepatitis	174.93	3.89	25.88	2.90	0.06	
Other sexually transmitted infections	1189.62	26.49	238.70	26.77	0.01	
Opportunistic infections	926.02	20.62	188.40	21.13	0.01	
Medication Attributes						
Hospital ownership						
Public	2125.98	47.33	423.61	47.50	< 0.01	
Non-public	2365.65	52.67	468.20	52.50		
ART Initiation Policy						
Before 2018	871.14	19.39	165.18	18.52	0.02	
Between 2018 and 2020	2856.59	63.60	572.72	64.22		
After 2020	763.91	17.01	153.91	17.26		

Results

Care discontinuation (HIV/AIDS)



After 150 days, <u>rapid ART initiation showed a higher rate of care</u> <u>discontinuation</u> compared to same-day ART initiation in both HIV and AIDS groups.

Critical Appraisal

Medication discontinuation (HIV/AIDS)

HIV







Both same-day ART and rapid ART initiation had similar patterns of medication retention over time in both HIV and AIDS groups.

Table 3

Weighted Cox model for one-year care and medication discontinuation among patients with HIV infection who initiated ART within 7 days of their medical visit.

Same-day ART had no significant impact	Care discontinuation		Medication discontinuation		
on care/medication discontinuation	cAHR (95 % CI)	aAHR (95 % CI)	cAHR (95 % CI)	aAHR (95 % CI)	
Same-day ART initiation (REF. = Rapid ART initiation)	0.93 (0.68, 1.27)	0.93 (0.69, 1.25)	0.99 (0.43, 2.26)	1.07 (0.51, 2.20)	
Demographic Characteristics					
Women (REF. = Men)	1.15 (0.72, 1.83)	1.18 (0.73, 1.92)	1.39 (0.65, 2.97)	1.16 (0.52, 2.62)	
Age (REF. = 18–29), year					
30–39	0.87 (0.72, 1.06)	0.89 (0.73, 1.08)	0.64 (0.44, 0.93)	0.75 (0.51, 1.09)	
40-49	0.74 (0.55, 0.98)	0.72 (0.54, 0.97)	0.75 (0.45, 1.23)	0.82 (0.49, 1.37)	
≥ 50	0.76 (0.48, 1.21)	0.69 (0.43, 1.09)	0.65 (0.26, 1.62)	0.45 (0.17, 1.14)	
NHI enrollment salary (REF. = ≤30,000), NT\$					
30,001-50,000	0.82 (0.66, 1.00)	0.77 (0.63, 0.94)	0.56 (0.38, 0.82)	0.56 (0.39, 0.81)	
50,001-70,000	0.87 (0.62, 1.22)	0.86 (0.61, 1.21)	0.20 (0.07, 0.56)	0.22 (0.08, 0.61)	
≥70,000	1.04 (0.74, 1.47)	1.09 (0.76, 1.56)	0.13 (0.03, 0.52)	0.15 (0.04, 0.63)	
Residence area (REF. = Northern)					
Central	1.21 (0.78, 1.87)	1.19 (0.76, 1.87)	1.16 (0.56, 2.40)	1.11 (0.52, 2.37)	
Southern	0.56 (0.40, 0.80)	0.55 (0.39, 0.77)	0.90 (0.53, 1.52)	0.82 (0.48, 1.39)	
Eastern and outlying islands	0.42 (0.23, 0.80)	0.40 (0.21, 0.74)	1.50 (0.74, 3.07)	1.13 (0.56, 2.29)	
Medical History					
Depression (REF. = No history)	1.06 (0.69, 1.63)	0.97 (0.63, 1.51)	1.58 (0.83, 3.00)	1.16 (0.63, 2.14)	
Substance use (REF. = No history)	1.63 (1.00, 2.64)	1.81 (1.09, 2.98)	3.22 (1.82, 5.70)	3.81 (2.18, 6.68)	
Hepatitis (REF. = No history)	0.84 (0.49, 1.41)	0.88 (0.51, 1.51)	1.13 (0.49, 2.62)	1.37 (0.62, 3.02)	
Other sexually transmitted diseases (REF. = No history)	1.06 (0.87, 1.29)	1.07 (0.89, 1.30)	0.98 (0.69, 1.40)	0.94 (0.67, 1.31)	
Medication Attributes					
Hospital ownership (REF. = Public)	0.96 (0.80, 1.14)	1.06 (0.89, 1.27)	1.45 (1.03, 2.04)	1.43 (1.01, 2.02)	
ART Initiation Policy (REF. = Before 2018)					
Between 2018 and 2020	0.97 (0.75, 1.24)	0.98 (0.76, 1.25)	0.67 (0.45, 0.99)	0.64 (0.43, 0.96)	
After 2020	1.12 (0.81, 1.54)	1.14 (0.84, 1.55)	0.86 (0.45, 1.66)	0.83 (0.46, 1.50)	

cAHR, crude average hazard ratio; aAHR, adjusted average hazard ratio; CI, Confidence interval; NHI, National Health Insurance; ART, Antiretroviral therapy

Table 4

Weighted Cox model for one-year care and medication discontinuation among patients with AIDS who initiated ART within 7 days of their medical visit.

Same-day ART reduced the hazard of care discontinuation	Care discontinuation		Medication discontinuation	
but increased medication discontinuation	cAHR (95 % CI)	aAHR (95 % CI)	cAHR (95 % CI)	aAHR (95% CI)
Same-day ART initiation (REF. = Rapid ART initiation)	0.88 (0.74, 1.04)	0.86 (0.74, 0.99)	1.12 (0.84, 1.50)	1.14 (0.86, 1.52)
Demographic Characteristics				
Women (REF. = Men)	1.35 (1.05, 1.73)	1.37 (1.06, 1.76)	1.73 (1.24, 2.41)	1.50 (1.07, 2.12)
Age (REF. = 18–29), year				
30-39	0.89 (0.80, 0.99)	0.94 (0.85, 1.04)	0.95 (0.80, 1.13)	0.95 (0.80, 1.13)
40-49	0.81 (0.69, 0.96)	0.90 (0.76, 1.06)	0.96 (0.76, 1.22)	0.91 (0.70, 1.17)
≥ 50	1.03 (0.87, 1.23)	1.09 (0.90, 1.32)	1.46 (1.11, 1.91)	1.31 (1.01, 1.70)
NHI enrollment salary (REF. = ≤30,000), NT\$				
<mark>30,001–50,000</mark>	0.94 (0.84, 1.05)	0.90 (0.80, 1.00)	0.54 (0.45, 0.66)	0.56 (0.46, 0.68)
50,001–70,000	0.95 (0.79, 1.13)	0.89 (0.74, 1.07)	0.51 (0.36, 0.72)	0.56 (0.40, 0.79)
≥ 70,000	0.62 (0.47, 0.82)	0.60 (0.45, 0.79)	0.32 (0.19, 0.56)	0.31 (0.18, 0.54)
Residence area (REF. = Northern)				
Central	0.94 (0.83, 1.05)	0.89 (0.79, 0.99)	0.85 (0.71, 1.02)	0.86 (0.71, 1.04)
Southern	0.64 (0.57, 0.72)	0.62 (0.55, 0.70)	1.19 (0.99, 1.42)	1.12 (0.94, 1.35)
Eastern and outlying islands	1.26 (0.95, 1.67)	1.26 (0.94, 1.67)	1.57 (1.06, 2.34)	1.59 (1.05, 2.39)
Medical History				
Depression (REF. = No history)	0.94 (0.77, 1.16)	0.98 (0.79, 1.22)	1.56 (1.11, 2.18)	1.33 (0.98, 1.80)
Substance use (REF. = No history)	0.98 (0.76, 1.27)	1.01 (0.77, 1.32)	1.48 (1.06, 2.05)	1.30 (0.91, 1.86)
Hepatitis (REF. = No history)	0.90 (0.70, 1.15)	0.91 (0.70, 1.19)	1.04 (0.74, 1.46)	0.89 (0.62, 1.27)
Other sexually transmitted infections (REF. = No history)	1.07 (0.97, 1.19)	1.03 (0.93, 1.14)	1.08 (0.91, 1.27)	1.13 (0.96, 1.33)
Opportunistic infections (REF. = No history)	0.55 (0.47, 0.65)	0.56 (0.47, 0.67)	1.59 (1.30, 1.95)	1.61 (1.32, 1.96)
Medication Attributes				
Hospital ownership (REF. = Public)	0.90 (0.82, 0.99)	0.95 (0.87, 1.04)	0.92 (0.79, 1.07)	0.88 (0.75, 1.02)
ART Initiation Policy (REF. = Before 2018)				
Between 2018 and 2020	0.90 (0.80, 1.02)	0.93 (0.82, 1.05)	0.87 (0.72, 1.05)	0.92 (0.76, 1.12)
After 2020	1.17 (1.01, 1.37)	1.20 (1.03, 1.41)	1.07 (0.84, 1.35)	1.14 (0.90, 1.45)

cAHR, crude average hazard ratio; aAHR, adjusted average hazard ratio; CI, Confidence interval; NHI, National Health Insurance; ART, Antiretroviral therapy

Same-day ART and care discontinuation

Same-day ART reduced the hazard of care discontinuation among patients with AIDS.

 An observational study in Taiwan reported no significant impact of same-day ART on care retention (Huang et al. 2024). This is partly because of differences in the outcome definition (180-day vs. 90-day).



Suggests that <u>same-day ART may reduce early</u> <u>care discontinuation</u> but has minimal impact on those unlikely to return. 2

Same-day ART and medication discontinuation

Same-day ART linked to <u>increased risk of medication discontinuation</u> among patients with AIDS (though not statistically significant).

 Starting treatment <u>without progressing beyond the contemplation</u> stage may lead to medication discontinuation.

Transtheoretical Behavioural Model (TBM)

Pre-contemplation	Contemplation	Preparation	Action	Maintenance
Unwilling to start lifelong ART or do not self- identify as an ART candidate	Willing to start lifelong ART and self- identify as in need of treatment	Have treatment supporters, Prepared for drug adherence	Consulting healthcare workers and has initiated ART	Adhere to ART and return for the next clinical visit

(Moges et al., 2020)

Strengths and Limitations

Strengths

- Use of a weighted Cox regression model to address sample selection bias.
- Population-based approach, overcoming limitations of previous single-site or multiple-site studies.

Limitations

- Potential misclassification of ART-initiation timing due to data limitations.
- Outcome definitions based on practical judgment using NHI claims data.
- Immortal time bias (though could be minimal).
- Exclusion of individuals opting for self-paid HIV testing or not seeking medical care.
- Absence of key variables such as clinical examination data (CD4+ cell count and viral load) and pre-exposure prophylaxis usage.

Conclusion

- Same-day ART initiation has diverse effects on the continuation of care and medication.
- While it enhances care retention in people with AIDS, it may also heighten the risk of medication discontinuation, although this was not statistically significant.
- Medical professionals and policymakers should note this issue to ensure effective HIV/AIDS care management.



Discrepancy with Taiwan CDC data

• This study reported 2,204 HIV cases and 8,411 AIDS cases (2017-2021).

*not diagnosed with tuberculosis or cryptococcal meningitis within 60 days before their initial HIV/AIDS visit



Clinical significance of the results

- While the author concluded that same-day ART enhances care retention in people with AIDS, <u>the difference seems marginal</u> (AHR: 0.86, 95% CI: 0.74-0.99). Survival analysis also reported non-significant result.
- Care/medication discontinuation seems to be more influenced by other factors such as income, substance use history, hospital ownership, etc.
 - More could have been discussed on these factors and what interventions may be effective in improving care/medication retention among people living with HIV/AIDS.

Why this paper was published

- Implications for HIV/AIDS care policies.
 - Suggests that <u>same-day ART should be implemented with caution</u> and appropriate support to prevent medication discontinuation.
- Interest of the research community.
 - Concerns towards higher attrition from care after same-day ART initiation (Maskew et al. 2021), with inconsistent results depending on context (Murenzi et al., 2023; Huang et al., 2019).



Comment on Impact of same-day ART initiation on medical care and medication discontinuation among patients with incident HIV infection or AIDS in Taiwan: A population-based cohort study

D2 Chih-Wei Tseng

Comment 1

- Previous literature has emphasized that continuity of care with the same physician is associated with better medication adherence and health outcomes across chronic diseases, including HIV care.
- I appreciate the robust design and important findings of the study, and I believe that adding provider-level continuity measures (i.e., discontinuity with the same provider) could further strengthen the understanding of care trajectories in people living with HIV/AIDS.

Comment 2 regarding the use of the doubly robust weighted Cox regression model

- (1) Could you kindly clarify what specific model assumptions are required for the validity of the doubly robust weighted Cox regression
- (2) Given that the cumulative incidence of medication discontinuation was around 15% (with approximately 85% of patients censored), would you consider this event-to-censor ratio sufficient for a stable hazard ratio estimation? Are there any potential limitations related to statistical power or model robustness that readers should be aware of?

Response to Question 1

- The doubly robust estimator assumes that <u>one of the</u> <u>two models below needs to be correctly specified</u> to obtain an unbiased effect estimator (Funk et al. 2011).
 - 1. Exposure model (Propensity score)
 - The model correctly captures the true probability of receiving same-day ART with no unmeasured confounding.
 - 2. Outcome model (Cox regression)
 - The model correctly captures the hazard ratio (i.e., care/medication discontinuation) with no unmeasured confounding.

Response to Question 2

- The low event rate (i.e., medication discontinuation) may pose several challenges such as reduced power and instability in estimates of hazard ratio.
- As an alternative, Han et al. (2022) recommends the use of <u>restricted</u> <u>mean survival time (RMST)</u> as an alternative measure in survival analysis to hazard ratio.

*RMST is defined as the area under the survival curve up to a specific time point



Source: Han et al. (2022)

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