

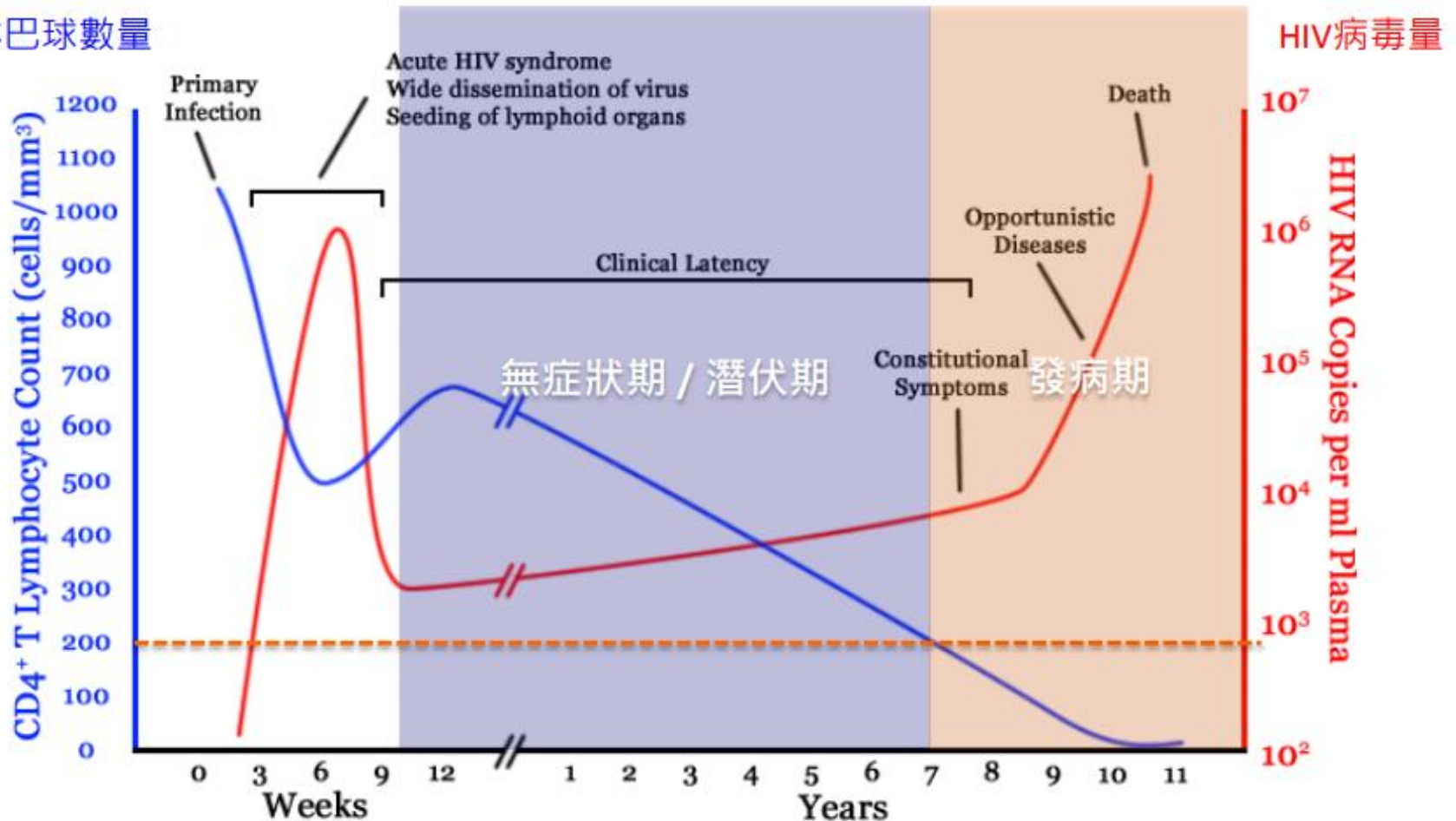
抗愛滋病毒藥物簡介暨 藥師的協助角色

洪增陽藥師

2019-4-21

HIV感染 自然病程

CD4淋巴球數量



1987年單一療法(AZT)問世

1986, Phase II Trial of AZT stopped by DSMB because of patients treated with AZT had a significant survival than the placebo ($p < .001$)

The New England Journal of Medicine

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Volume 317

JULY 23, 1987

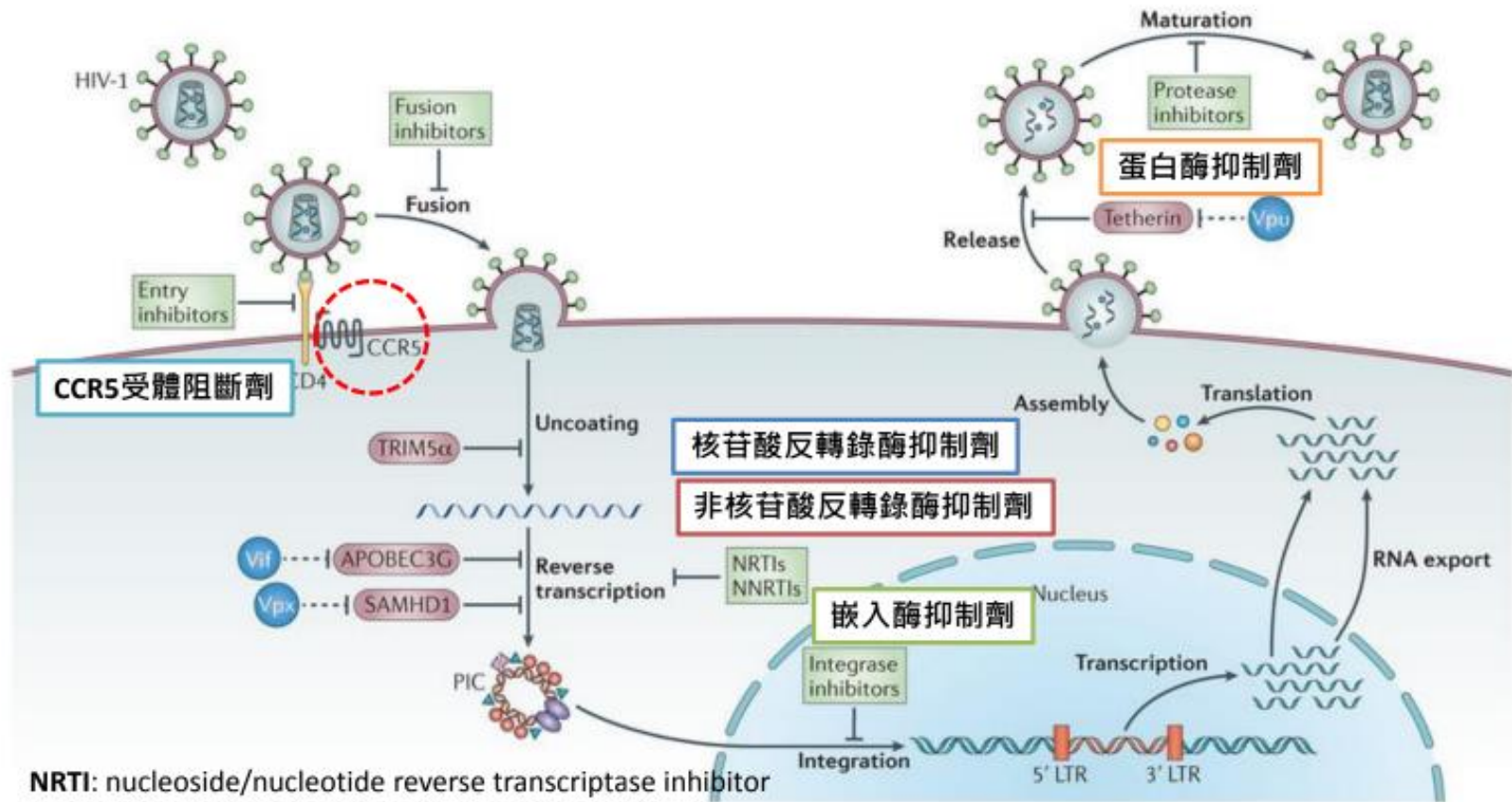
Number 4

THE EFFICACY OF AZIDOTHYIMIDINE (AZT) IN THE TREATMENT OF PATIENTS WITH AIDS AND AIDS-RELATED COMPLEX

A Double-Blind, Placebo-Controlled Trial

MARGARET A. FISCHL, M.D., DOUGLAS D. RICHMAN, M.D., MICHAEL H. GRIECO, M.D., J.D.,
MICHAEL S. GOTTLIEB, M.D., PAUL A. VOLBERDING, M.D., OSCAR L. LASKIN, M.D., JOHN M. LEEDOM, M.D.,
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GEORGE G. JACKSON, M.D., DAVID T. DURACK, M.B., D.PHIL., DANNIE KING, PH.D.,
AND THE AZT COLLABORATIVE WORKING GROUP

HIV複製機轉與藥物作用目標



NRTI: nucleoside/nucleotide reverse transcriptase inhibitor
NNRTI: non-nucleoside reverse transcriptase inhibitor
InSTI: integrase strand transfer inhibitor

1997年三合一療法確立

The New England Journal of Medicine

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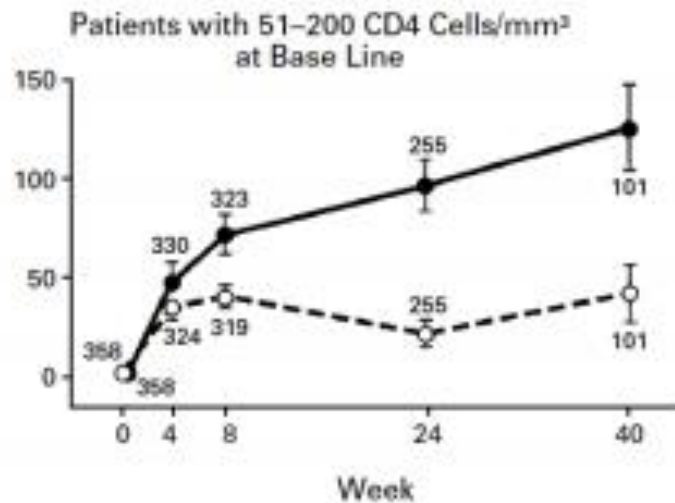
VOLUME 337

SEPTEMBER 11, 1997

NUMBER 11



A CONTROLLED TRIAL OF TWO NUCLEOSIDE ANALOGUES PLUS INDINAVIR
IN PERSONS WITH HUMAN IMMUNODEFICIENCY VIRUS INFECTION
AND CD4 CELL COUNTS OF 200 PER CUBIC MILLIMETER OR LESS



*Robust
immune recovery*

三合一抗HIV藥物組合原則

核苷酸反轉錄酶抑制劑骨架 (NRTI Backbone)

TDF/FTC (Truvada)
舒發泰

ABC/3TC (Kivexa)
克維滋

AZT/3TC (Combivir)
卡貝滋

ddI
惠妥滋

+

3TC
速汰滋

d4T
滋利特

+

3TC
速汰滋

+

非核苷酸反轉錄酶抑制劑 (NNRTI)
衛滋、希寧、恩臨

蛋白酶抑制劑 (PI)
快利佳、瑞塔滋、普利他



嵌入酶抑制劑 (InSTI)
宜昇瑞、汰威凱

CCR5受體阻斷劑 (CCR5 Antagonist)
新特滋

以機率說明雞尾酒療法使用概念

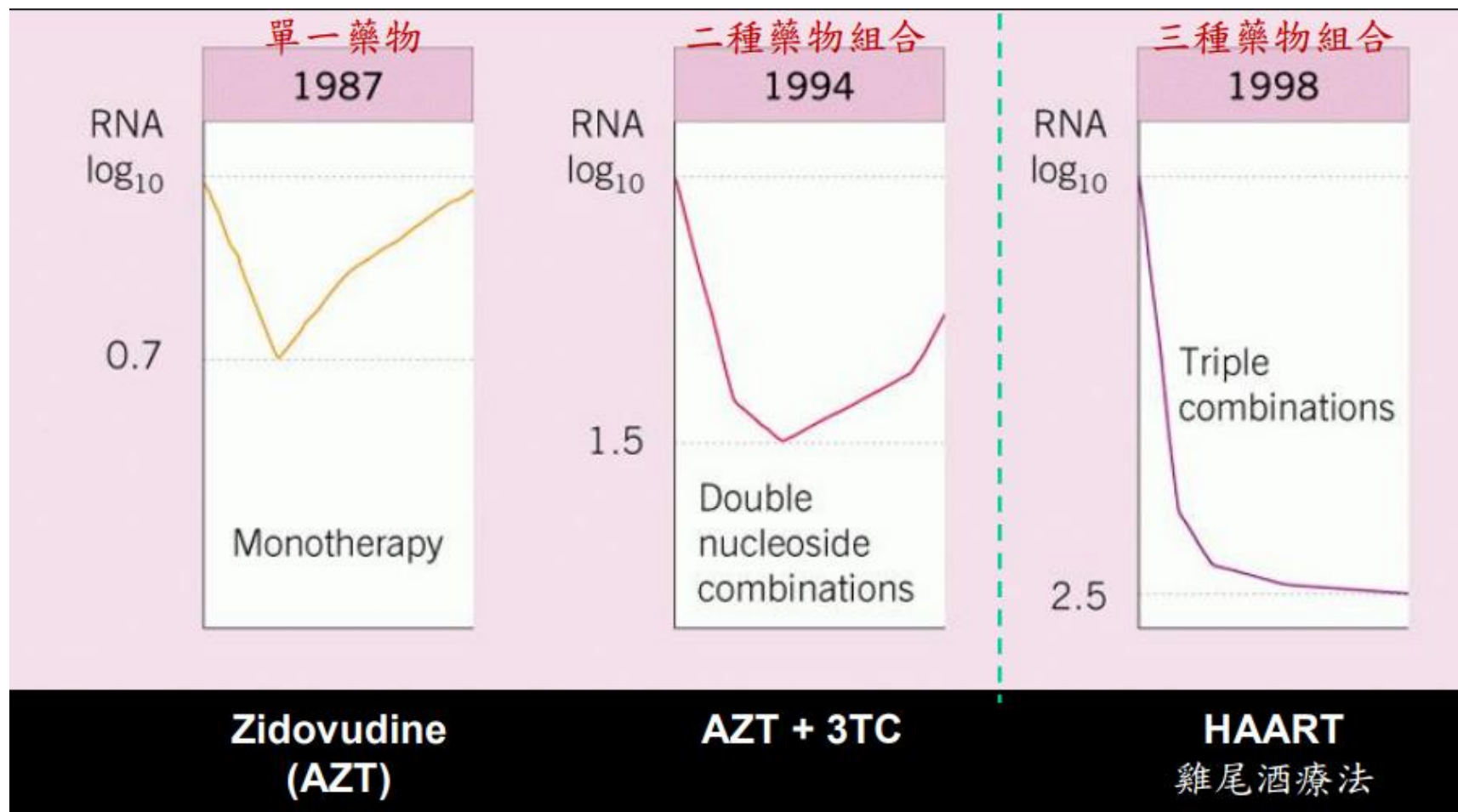
每天體內平均有
 10^{10} 個HIV病毒產生

使用三種藥物組合發生
抗藥性突變的機率就小於1

$$10^{10} \times \left[\frac{5}{10^5} \times \frac{5}{10^5} \times \frac{5}{10^5} \right] \approx 10^{-3}$$

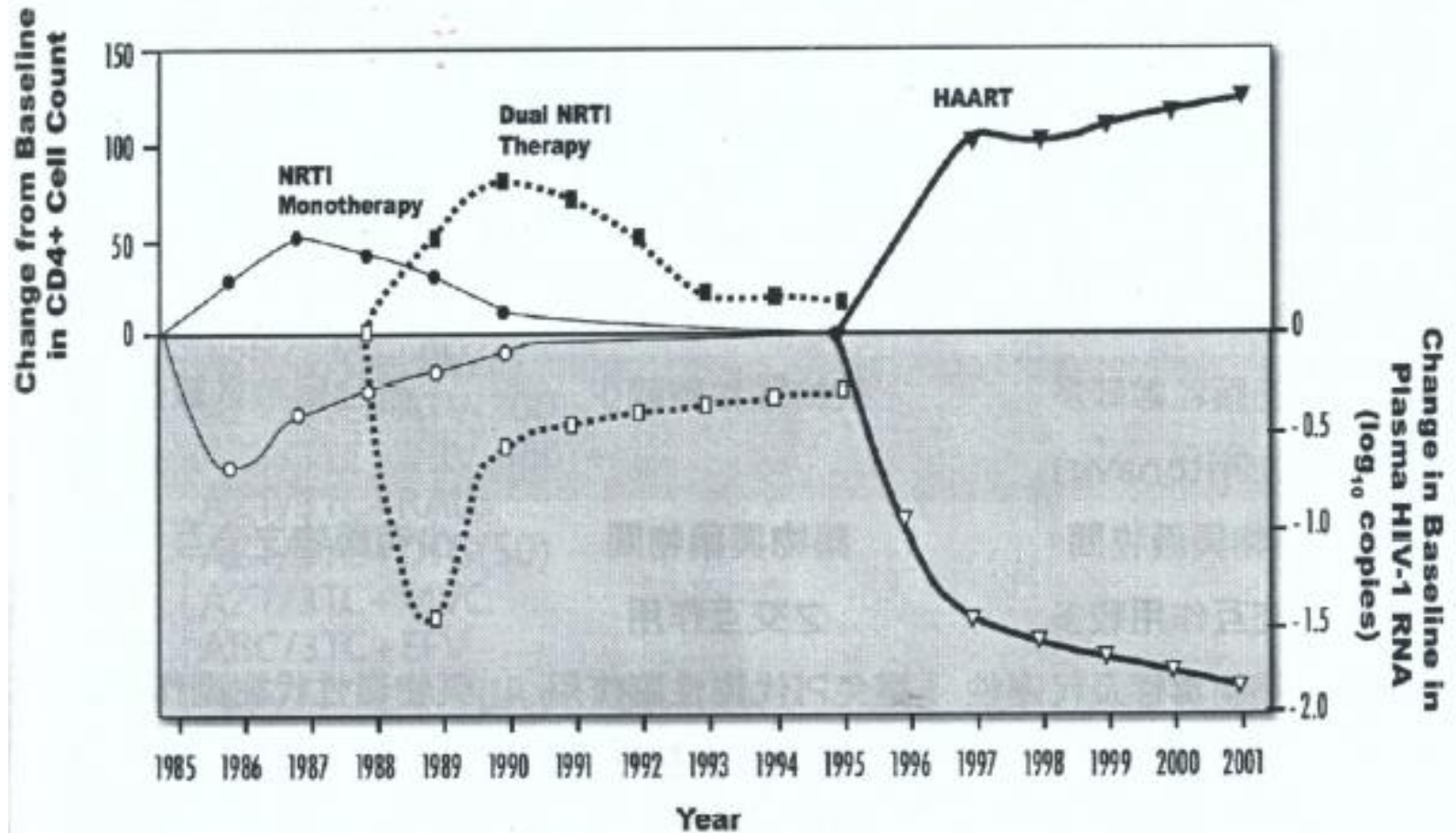
每10,000個HIV病毒中有5個病毒
(也就是 5×10^{-5} 的機率) 會發生抗藥性的突變

藥物組合抗HIV比較



抗HIV藥物組合進程

Highly Active Anti-Retroviral Therapy



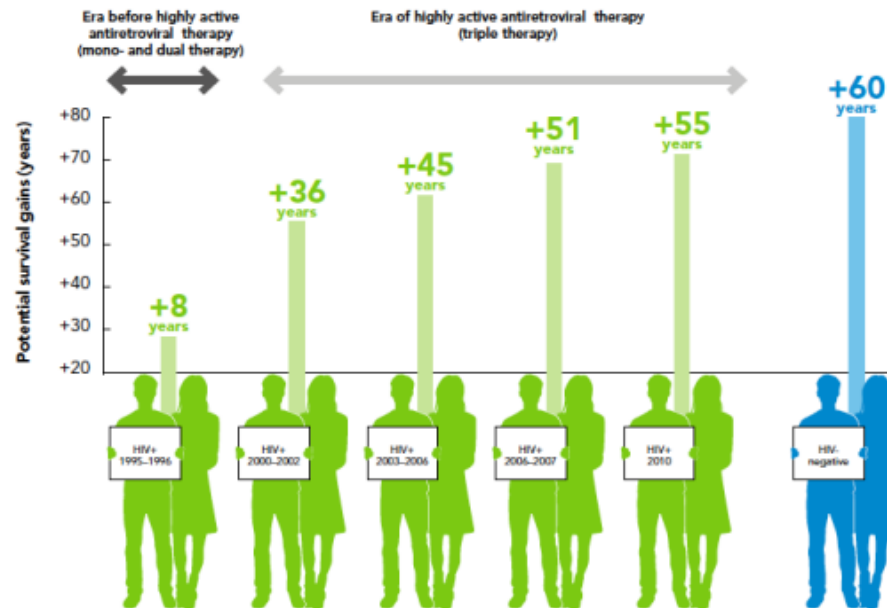
除了治療，尚有預防



振奮的訊息

U=U UNDETECTABLE
EQUALS
UNTRANSMITTABLE

Projected impact of highly active antiretroviral therapy on expected survival of a 20-year-old person living with HIV in a high-income country



Source: Adapted from Lohse et al, 2007; Hoog et al, 2008; May et al, 2011 & Hogg et al, 2013.

FDA Approval of HIV Medicines

1981: First AIDS cases are reported in the United States.				
'85-'89	1987 Zidovudine (NRTI)			
'90-'94	1991 Didanosine (NRTI)	1992 Zalcitabine (NRTI)	1994 Stavudine (NRTI)	
'95-'99	1995 Lamivudine (NRTI) Saquinavir (PI)	1996 Indinavir (PI) Nevirapine (NNRTI) Ritonavir (PI)	1997 Combivir (FDC) Delavirdine (NNRTI) Nelfinavir (PI)	1998 Abacavir (NRTI) Efavirenz (NNRTI)
'00-'04	2000 Didanosine EC (NRTI) Kaletra (FDC) Trizivir (FDC)	2001 Tenofovir DF (NRTI)	2003 Atazanavir (PI) Emtricitabine (NRTI) Enfuvirtide (FI) Fosamprenavir (PI)	2004 Epzicom (FDC) Truvada (FDC)
'05-'09	2005 Tipranavir (PI)	2006 Atripla (FDC) Darunavir (PI)	2007 Maraviroc (CA) Raltegravir (INSTI)	2008 Etravirine (NNRTI)
'10-'14	2011 Complera (FDC) Nevirapine XR (NNRTI) Rilpivirine (NNRTI)	2012 Stribild (FDC)	2013 Dolutegravir (INSTI)	2014 Cobicistat (PE) Elvitegravir (INSTI) Triumeq (FDC)
'15-'18	2015 Evotaz (FDC) Genvoya (FDC) Prezcobix (FDC)	2016 Descovy (FDC) Odefsey (FDC)	2017 Juluca (FDC)	2018 Biktarvy (FDC) Cimduo (FDC) Delstrigo (FDC) Doravirine (NNRTI) Ibalizumab-uiyk (PAI) Symfi (FDC) Symfi Lo (FDC) Symtuza (FDC) Temixys (FDC)

Drug Class Abbreviations:

CA: CCR5 Antagonist; **FDC:** Fixed-Dose Combination; **FI:** Fusion Inhibitor; **INSTI:** Integrase Inhibitor; **NNRTI:** Non-Nucleoside Reverse Transcriptase Inhibitor; **NRTI:** Nucleoside Reverse Transcriptase Inhibitor; **PE:** Pharmacokinetic Enhancer; **PI:** Protease Inhibitor; **PAI:** Post-Attachment Inhibitor

Note: Drugs in gray are no longer available and/or are no longer recommended for use in the United States by the HHS HIV/AIDS medical practice guidelines. These drugs may still be used in fixed-dose combination formulations.

一張表格了解STR (Single Tablet Regimen)

(資料來源：藥師張小風網站)

	Genvoya	Triumeq	Atripla	Complera
成份 機轉	E/C/F/TAF Boosted INSTI / 2NRTI	ABC/3TC/DTG 2NRTI / INSTI	TDF/FTC/EFV 2NRTI / NNRTI	TDF/FTC/RPV 2NRTI / NNRTI
外觀				
適應症 歐美推薦首選	HIV首選 (CDC) DHHS / EACS	HIV首選 (CDC) DHHS / EACS	HIV首選 (CDC) alternative	HIV首選* (CDC) EACS *
安全性	佳	佳；心毒性疑慮	影響腎、骨、中樞	佳；影響腎、骨
劑量	1# QD 隨餐	1# QD 空腹/隨餐	1# QD 空腹 (睡前)	1# QD 隨餐 禁PPI
服用注意事項	勿磨粉 錯開金屬制酸劑	可磨粉 錯開金屬制酸劑	勿磨粉	勿磨粉 錯開制酸劑
腎功能限制	CrCl < 30 勿用	CrCl < 50 勿用	CrCl < 50 勿用	CrCl < 50 勿用
肝功能限制 (Child A/B/C)	C: 不建議使用	A: 不建議使用 B/C: 禁用	B/C: 不建議使用	C: 無資料
HIV/HBV	推薦	不建議單用	推薦	推薦
HIV/TB (RIF)	不可用	需再加 DTG 1#	可用	不可用
懷孕婦女	替代治療 (無視病毒量， 不建議用在妊娠第3期)	推薦 (無視病毒量)	不建議	推薦 *
臨床療效優勢	最快、基因屏障低	最快、基因屏障高	基因屏障低	基因屏障低
交互作用	最多 SSRI/SNRI/azole/statin	較少	多	較少

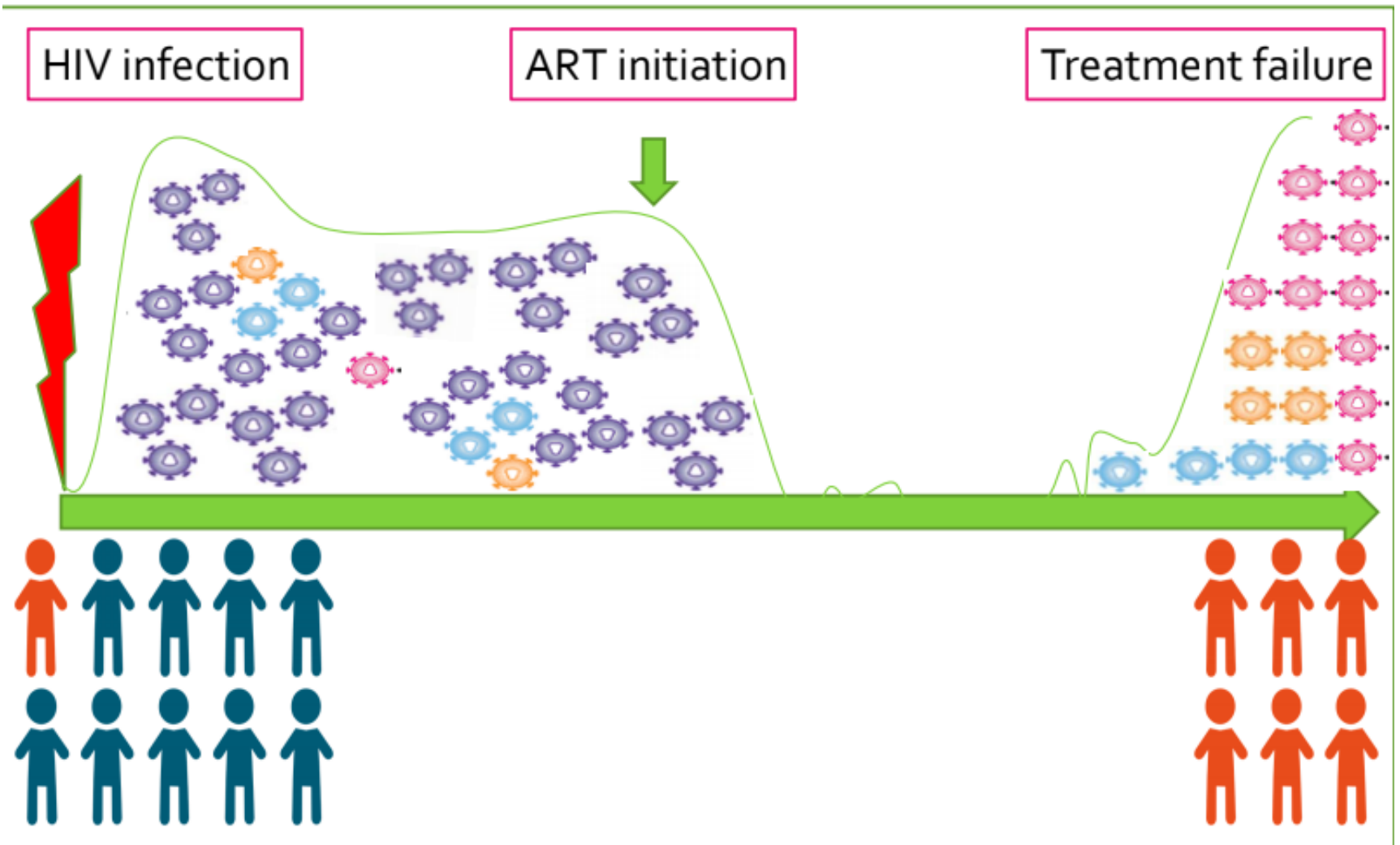
* Complera 不建議用於 HIV viral load > 10萬 cp/mL 或 CD4 < 200 CFU/mm³

RPh. RxWind

健保價、類別 與廠牌

類別	藥物	中文	健保價	廠牌
三合一	Triumeq	三恩美	466	gsk
三合一	Atripla	亞翠佩	430	GILEAD
三合一	Genvoya	捷扶康	466	GILEAD
三合一	Complera	康普萊	451	J & J
NRTI	Kivexa	克為滋	375	gsk
NRTI	Truvada	舒發泰	345	GILEAD
NRTI	Viread	惠立妥	163	GILEAD
NRTI	3TC	速汰滋	90	gsk
NRTI	Combivir	卡貝茲	37.9	gsk
NNRTI	Edurant	恩麟	276	J & J
NNRTI	Stocrit	希寧	107(200mg) 93(600mg)	MSD
NNRTI	Viramune	衛滋	83(200mg) 171(400mg)	Boehringer
PI	Kaletra	快利佳	85	ABBVIE
PI	Norvir	諾億亞	31.3	ABBVIE
PI	Prezista	普利他	156(400mg) 392(600mg)	J & J
PI	Reyataz	瑞塔滋	156(150mg) 171(200mg)	BMS
II	Tivicay	汰威凱	355	gsk
II	Isentress	宜昇瑞	175	MSD
CCR6	Celsentri	新特滋	163(150mg) 163(300mg)	gsk

When does resistant viruses appear?

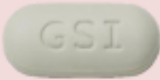


重要：HAART服藥順從性

- 研究顯示必須服用療程的95%以上才能避免抗藥性，換算起來，即每個月最多miss兩次以上則藥物容易失效。
- 服藥順從性若不到70%者 (即每月miss九次以上)，只有7%的人病毒量測不到。
- 順從性目標：100%

Q：藥師(醫院/社區藥局)可以做點什麼？

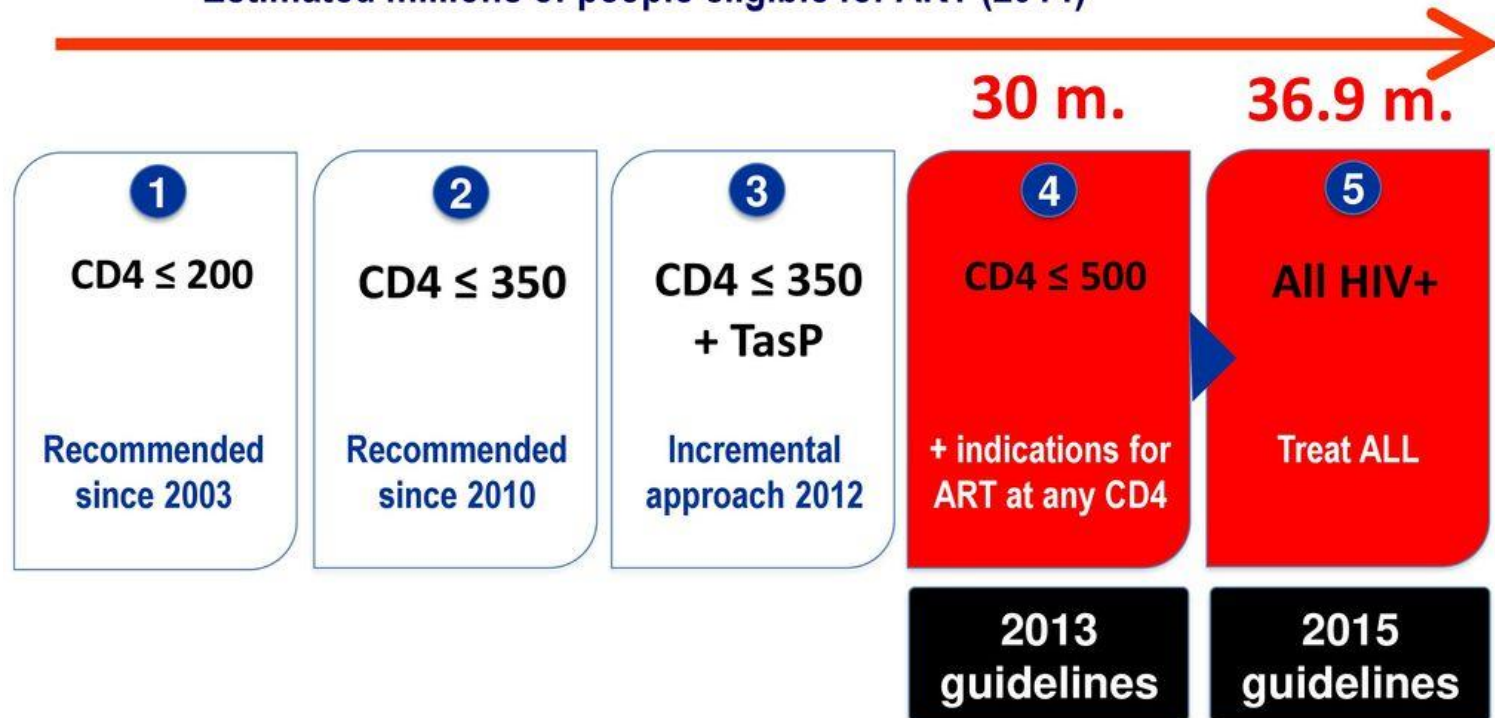
常用STR的副作用

TDF/FTC/EFV 	Atripla 亞翠佩 (300/200/600)	1# QN	頭痛、腹瀉、無力、腎功能受損、骨質流失、皮疹、肝功能異常、中樞神經系統症狀 (頭暈、嗜睡、作夢、注意力不集中、幻想、失憶等)
TDF/FTC/RPV 	Complera 康普萊 (300/200/25)	1# QD with meal	頭痛、腹瀉、無力、腎功能受損、骨質流失、不適宜VL >100,000 copies/ml，尤其是CD4 <200的病患，需與食物並用、避免和制酸劑並用
ABC/3TC/DTG 	Triumeq 三恩美 (600/300/50)	1# QD	不適宜HBV帶原者，須注意過敏反應 (可能致命)：發燒、皮疹、嘔吐、疲憊、咽喉痛、喘等 (HLA B*5701)、要避免與含有Mg²⁺或Al³⁺的胃藥同時服用、惡化憂鬱症狀 (少見)
EVG/c/FTC/TAF 	Genvoya 捷扶康 (150/150/200/10)	1# QD with meal	噁心、腹瀉、頭痛、要避免與含有Mg²⁺或Al³⁺的胃藥同時服用惡化憂鬱症狀 (少見)、需與食物並用
AZT/3TC/NVP 	Duovir-N, Trezav 倍歐滅-N (300/150/200)	1# BID <i>Lead-in:</i> AZT/3TC/NVP 1# QD + AZT/3TC 1# QD	貧血、白血球降低、腸胃不適、乳酸代謝性酸中毒、不適宜HBV帶原者、初次治療開始需分開lead-in，初次治療不適宜治療前男性CD4 >400、女性CD4 >250

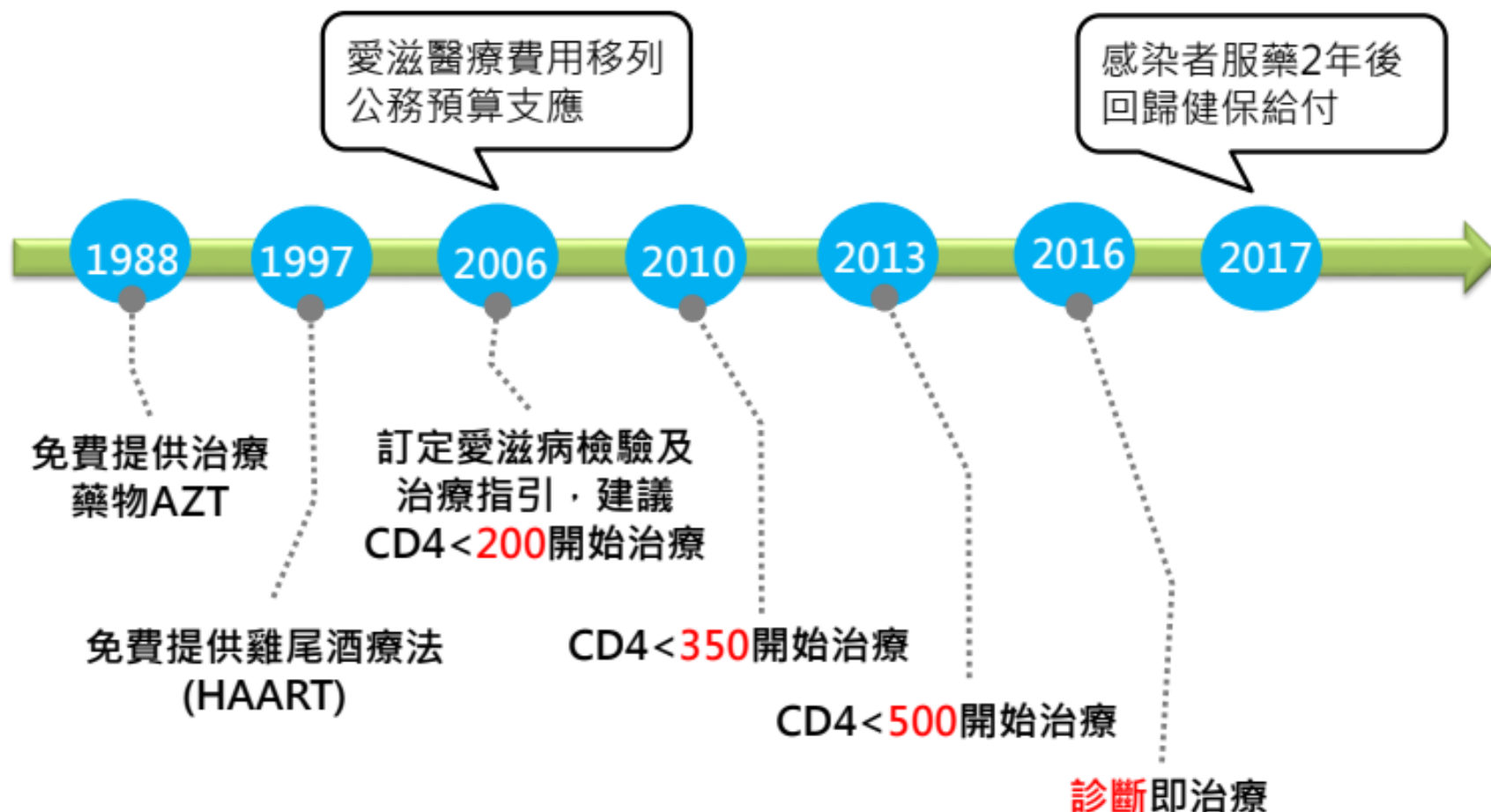
趨勢：提早用藥

ART eligibility: 5 potential policy scenarios

Estimated millions of people eligible for ART (2014)



台灣抗愛滋藥物治療政策



知道自己感染嗎？

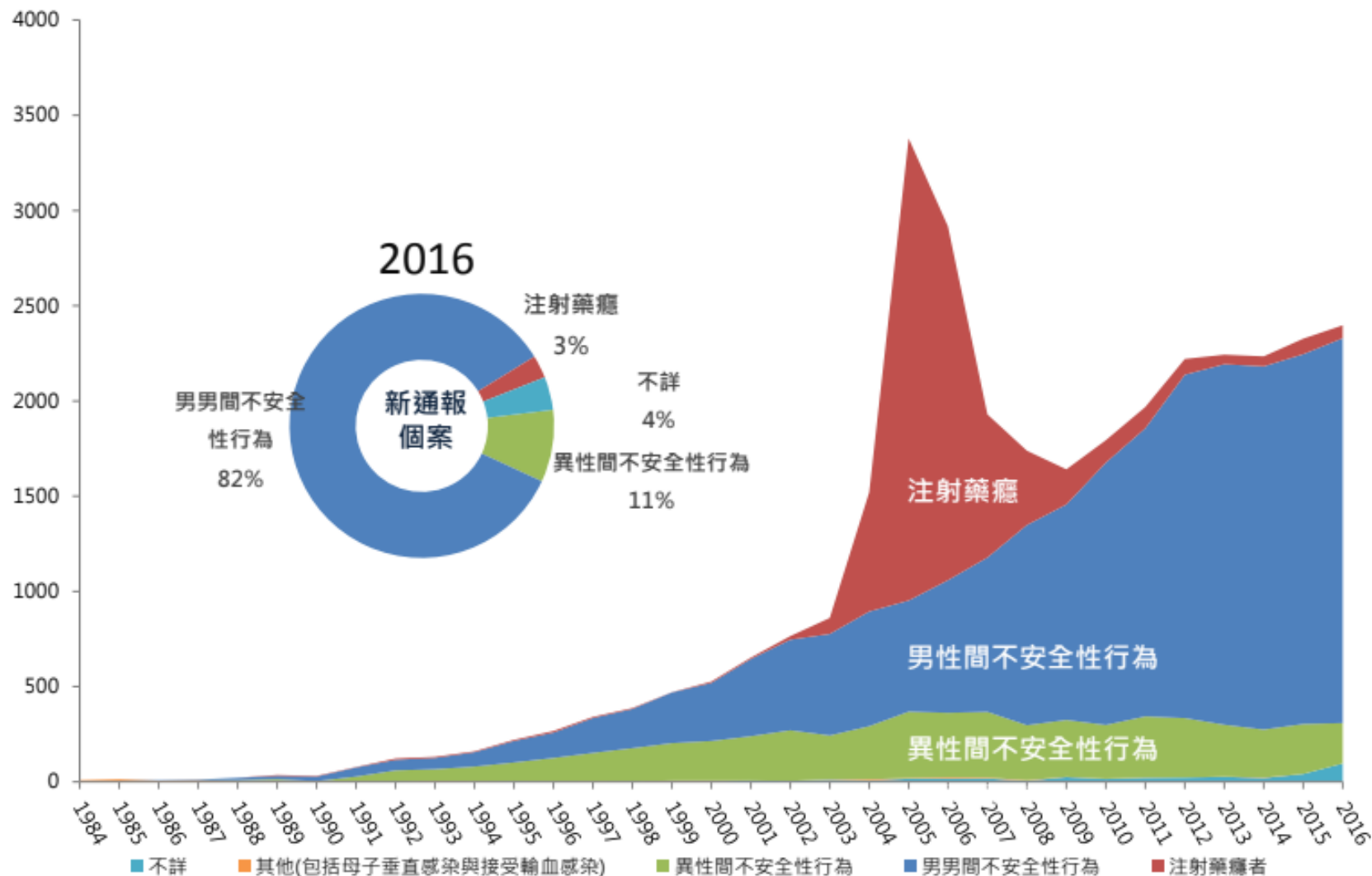
1 in **7** people with **HIV**
don't **know** they have it.

Get the facts. Get Tested. Get involved.

Find out more about HIV, including where to get tested, at gettested.cdc.gov



主要傳染途徑



常見HIV篩檢方式

檢驗標的	檢驗方式	快速篩檢	空窗期
Anti-HIV抗體	第三代酵素免疫分析法 ELISA 靜脈抽血		3-12週
	Alere Determine™ HIV-1/2 靜脈抽血或指頭採血	V	3-12週
	OraQuick Advance™ HIV-1/2 口腔滲出液	V	3-12週
Anti-HIV抗體 + HIV p24 抗原	第四代酵素免疫分析法 Ag/Ab Combo Test 靜脈抽血		2-6週
	Alere Determine™ HIV-1/2 Combo 靜脈抽血或指頭採血 (目前尚未上市)	V	2-6週
HIV病毒核酸	HIV RT-PCR / 核酸增幅法 靜脈抽血		7-28天

空窗期資料來源：美國CDC網站

AIDS 檢驗方法空窗期一覽表

檢測方式	準確度	空窗期
唾液篩檢	很高	3 個月
血液篩檢	高	2 個月
PCR	中	10 天
病毒抗原 - EIA	高	10 天
病毒抗原 - NAT	很高	10 天

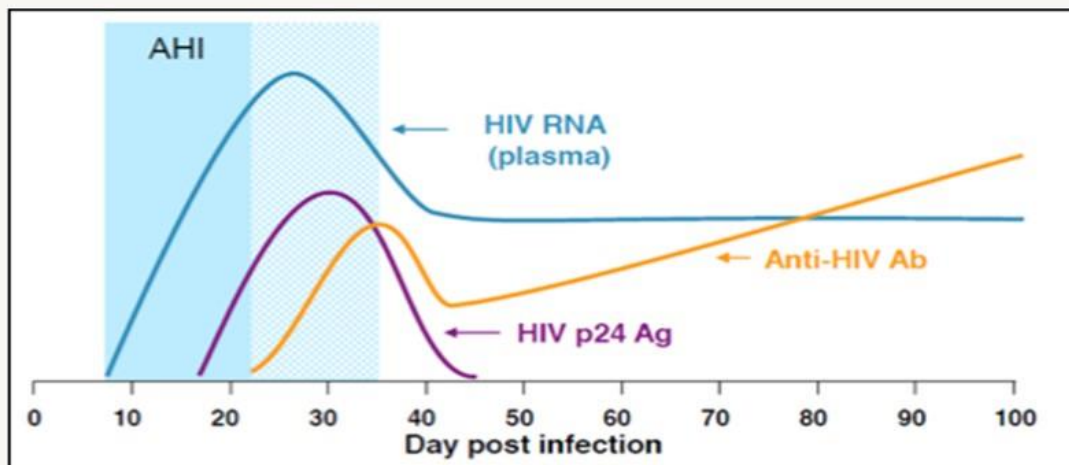
新的檢測技術大幅縮短空窗期

HIV檢測工具 vs. HIV空窗期



排除HIV
感染

- 抗體檢測 vs. 病毒核苷酸檢測(PCR)



一次危險行為後，**病毒核苷酸約在7-10天可被檢測**
人體自行產生抗體且可被檢驗出來，需花6-12週（1-3個月）

所以關鍵是**何時發生危險行為，且隔多久來檢測！**
而決定使用何種檢測工具！

疾管署提供自我檢測試劑

“歐瑞克”愛滋病毒抗體自我檢測試劑 (OraQuick HIV Self-Test)

本產品為單片包裝的定性免疫分析檢測試劑，用於偵測第一型及第二型人類免疫缺乏病毒（又稱愛滋病毒HIV-1及HIV-2）抗體。

內容物：

1. 試劑外包裝



2. 內含



*為尊重您的隱私，內容物將以無印刷的咖啡色紙箱密封包裝，箱子上不會有任何關於試劑的標記和文字。

提醒

請於108年12月25日前，至本計畫網頁登錄檢驗結果(可匿名)即可領取 200 元退費

【步驟1】掃描QR code 或輸入試劑編號(試劑編號在試劑包上)。

【步驟2】點選篩檢結果及填選問卷。

【步驟3】試劑費用退款方式統一以轉帳匯款方式辦理，請拍攝可清楚顯示試劑編號之試劑包裝照片，並上傳照片、填妥轉帳金融機構代碼及帳號(不需戶名資料)，本署委辦辦理退款的單位將於45個日曆天內將款項匯到您的帳戶。

服務費：245 元

(含 200 元試劑服務費用及便利商店取貨運費 45 元)

數量

1

設定取貨超商

網路購物 到店取貨



便利達康超商取貨服務

服務代號查詢(共五碼)

☒ 以街道查詢	以門市查詢
以地標查詢	以地址查詢

 建議以街道名稱方式搜尋

台北市 ▼

中正區 ▼

 請選擇街道

杭州南路一段
林森南路
信陽街
信義路一段
南昌路一段
南海路
南陽街

 請選擇一家門市



超商取貨付款



超商取貨付款



超商取貨付款



超商取貨付款



超商取貨付款



超商取貨付款



超商取貨付款



超商取貨付款



超商取



超商取



超商取



超商取

在家自我篩檢成果

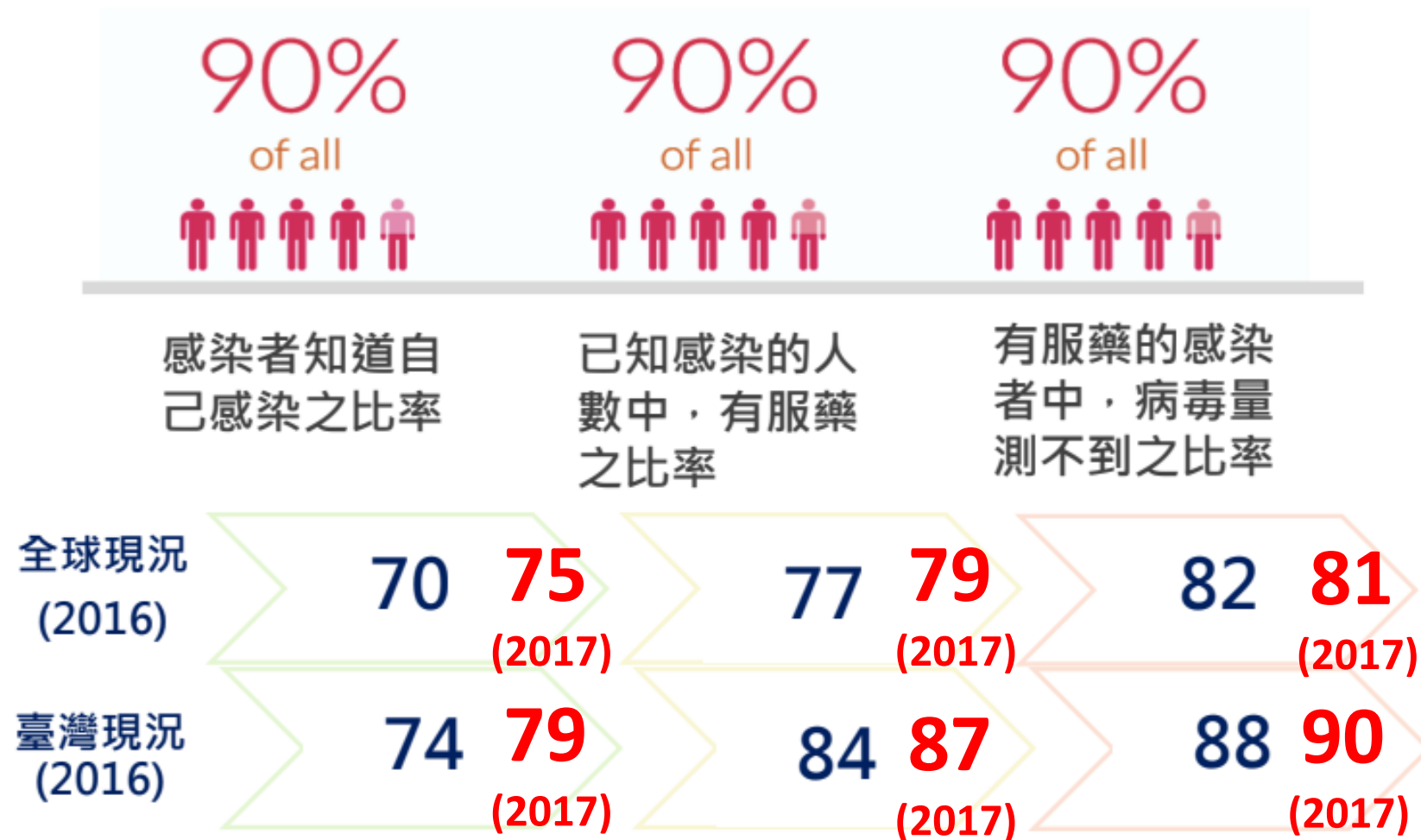
2016年

- 全國9縣市共設置81個執行點及23台
- 自動服務機提供愛滋自我唾液篩檢試劑
- 提供4,812人次篩檢服務
- 2,249人上網登錄結果
- 發現25名陽性個案
- 初篩陽性率:1.1%

2017年

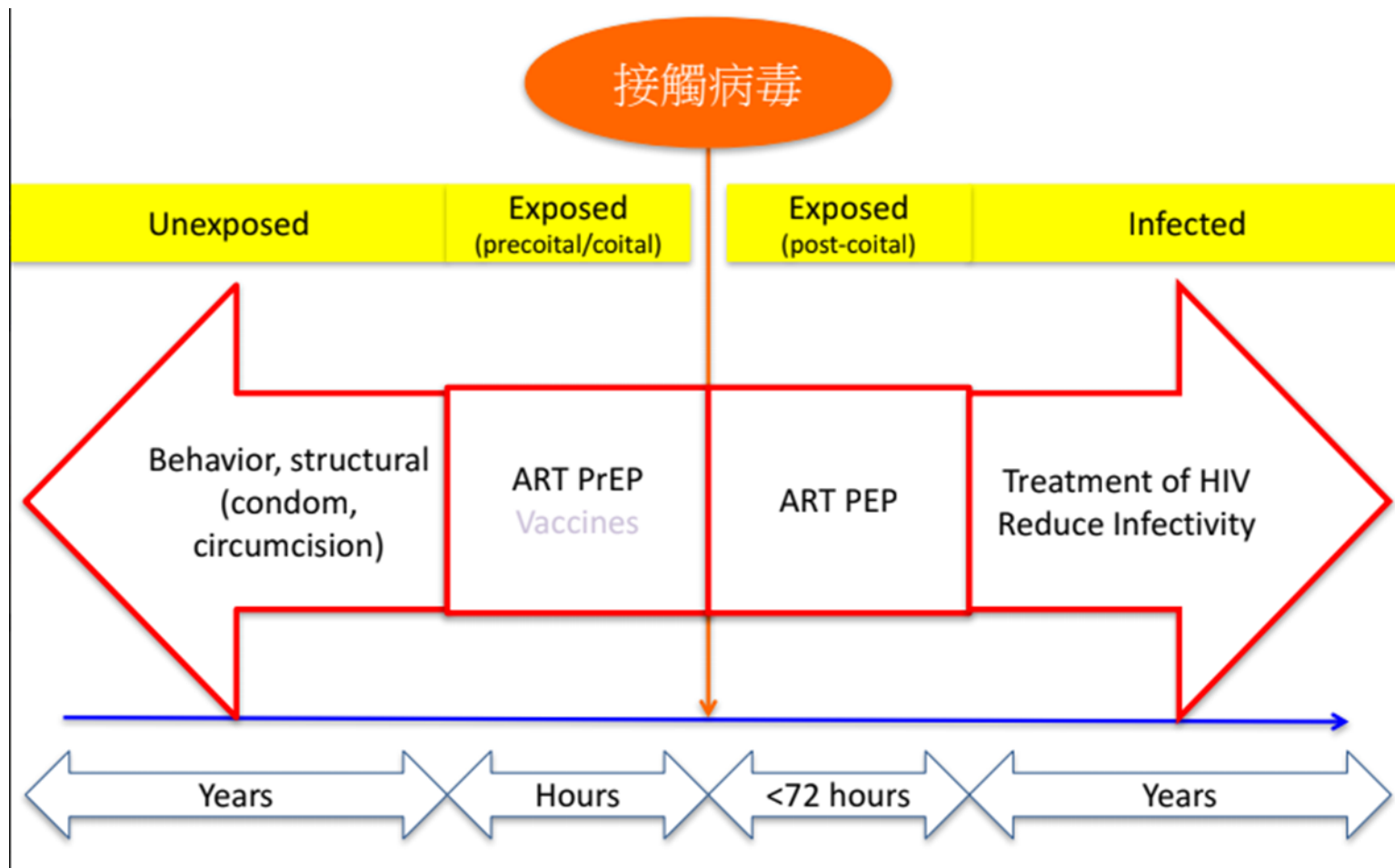
- 提供13,342人次篩檢服務 (截至2017.08.10)
- 5,069人上網登錄結果
- 發現66名陽性個案
- 初篩陽性率:1.3%

聯合國愛滋病規劃署(UNAIDS)目標



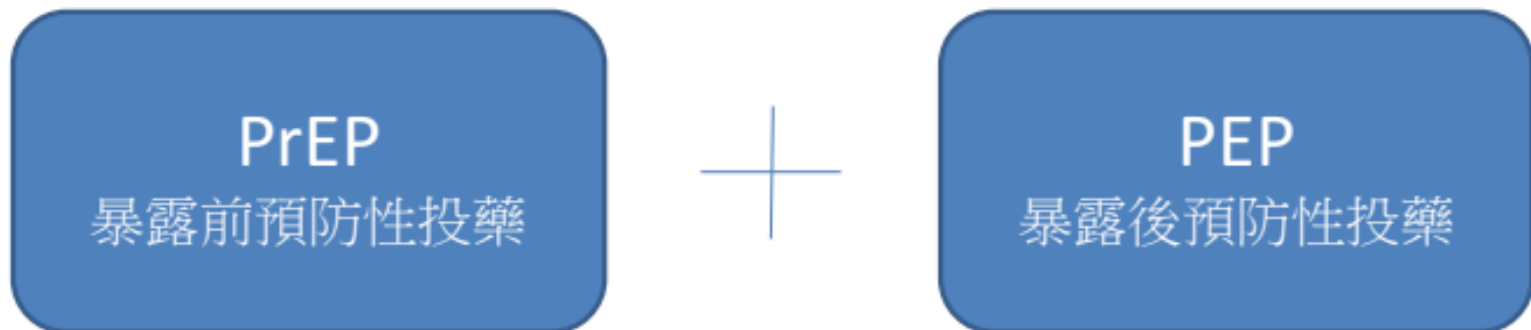
PrEP PEP

- 阻止HIV傳播的時機



減害計畫2.0 PrEP+PEP

- Pre-exposure prophylaxis (PrEP)(暴露前預防)
 - 包皮割除
 - 抗病毒凝膠 (1% tenofovir gel)
 - Vaginal ring (Dapivirine)
 - 口服抗病毒藥物
(tenofovir;tenofovir/emtricitabine)
 - 疫苗 (發展中)
- Post-exposure prophylaxis (PEP)(暴露後預防)



iPrEx study 的延伸試驗

- 藥物濃度和HIV感染的機率

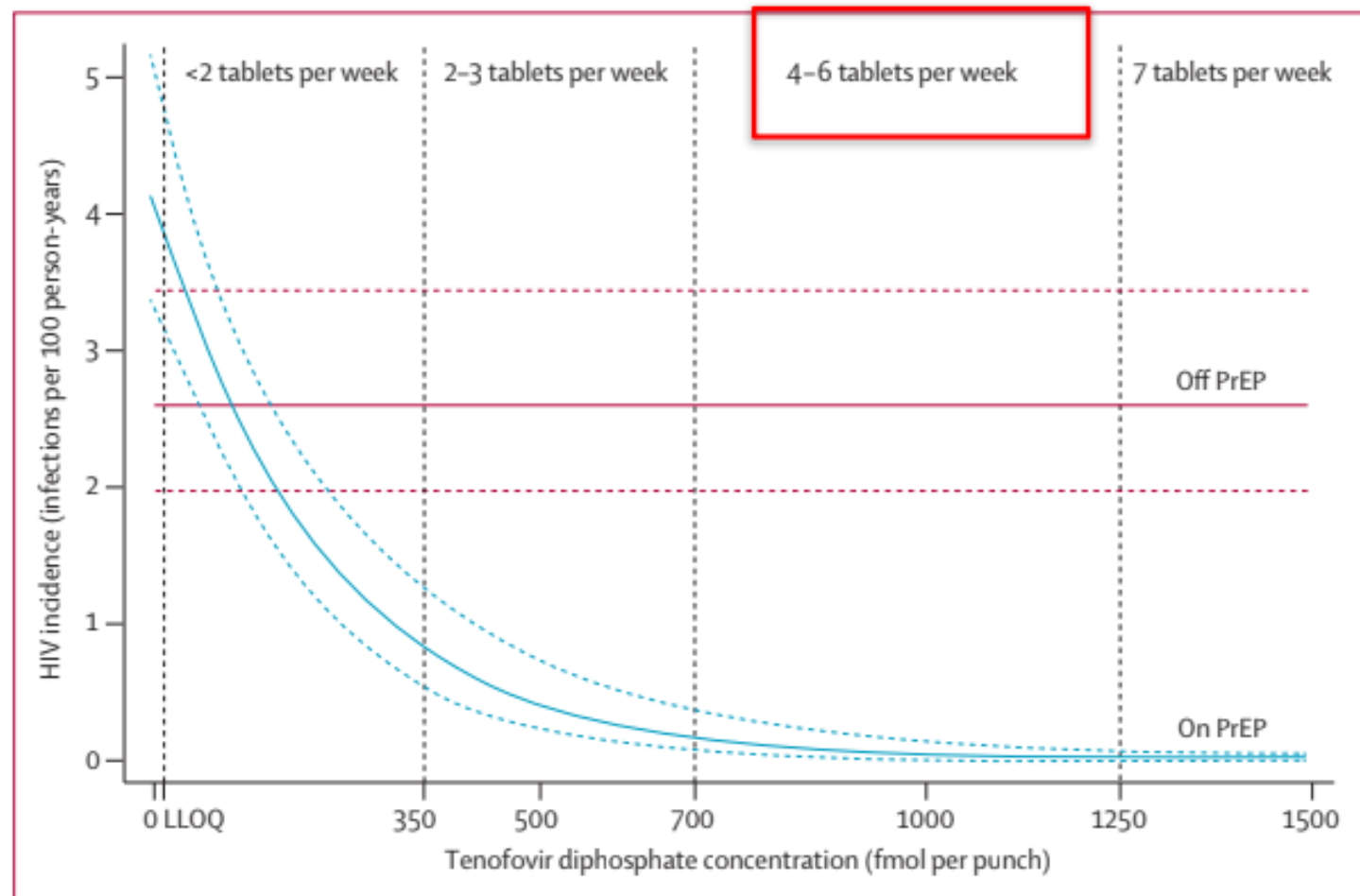


Figure 2: Pre-exposure prophylaxis and HIV incidence

美國疾管局Guidance on PrEP

- 事前評估
 - 需確定為HIV-negative (甚至排除急性感染)
 - 確定使用對象為高危險群
- 定期追蹤
 - 每2-3個月檢查一次並評估服藥順從性
 - 每6個月篩檢一次其他性病
 - 單次處方不超過90天(Truvada)
- 停藥
 - HIV確診

美國PEP建議藥物最新準則

- Preferred regimen:
 - TDF/FTC (Truvada) + RAL

- Alternative regimen:

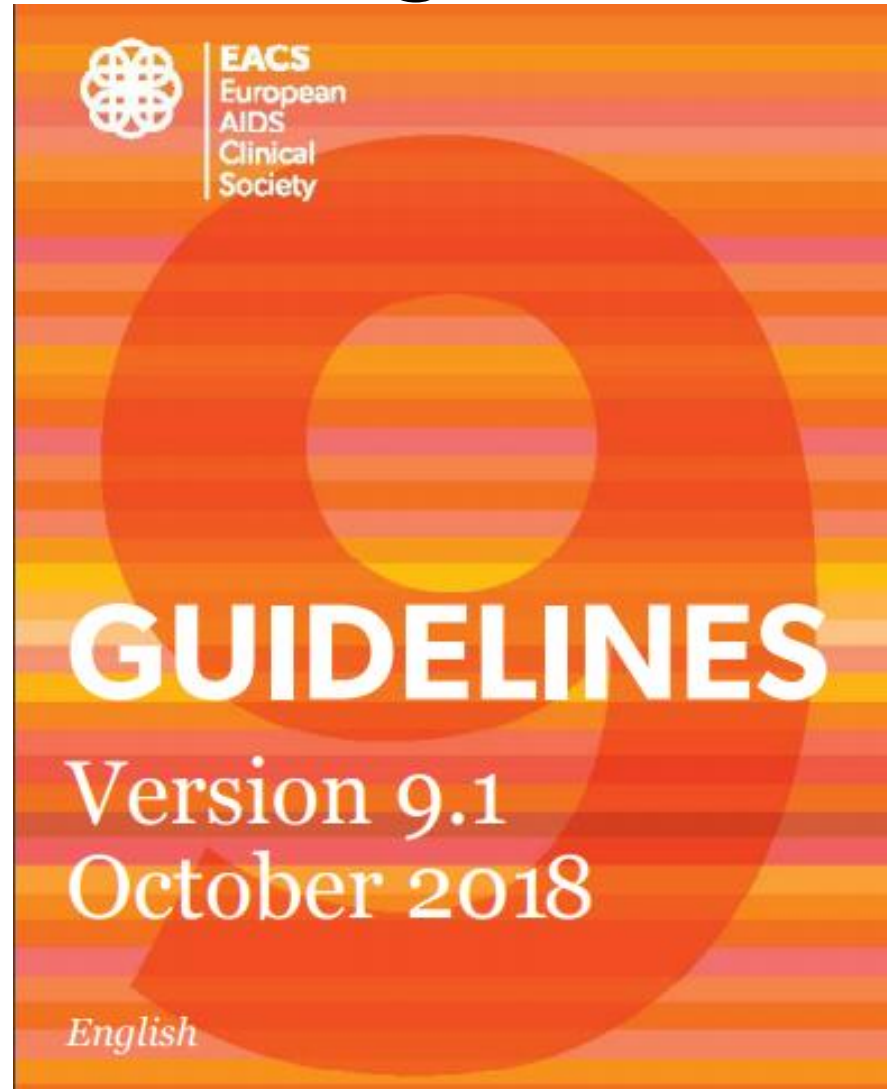
TDF/FTC Truvada)		RAL
TDF+3TC	Plus	DRV/r
AZT+FTC		ATV/r
AZT+3TC		LPV/r (Kaletra)
		ETR (etravirine)
		RPV (rilpivirine)

重大改變: 不再區分風險高低; 有風險即給藥!!!

Timing: 最好<72小時內, 最久可放寬至1周

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(1) EACS guidelines



例：TB/HIV共同感染(書面)

ART in TB/HIV Co-infection

Principles

Persons with TB should be started on standard TB therapy with 2 months rifampicin/isoniazid/pyrazinamide/ethambutol followed by 4 months rifampicin/isoniazid (choice of drugs and length of treatment depends on drug susceptibility and site of disease), see [Diagnosis and Treatment of TB in HIV-positive Persons](#)

All persons with TB/HIV co-infection should start ART irrespective of CD4 count. Treatment supervision and adherence evaluation are very important.

Suggested timing of ART initiation in TB/HIV co-infection according to CD4 count

< 50 cells/ μ L^{**} : As soon as TB treatment is tolerated and wherever possible within 2 weeks

$\geq$ 50 cells/ μ L: Can be deferred until between 8 and 12 weeks of TB treatment, especially when there are difficulties with drug-drug interactions, adherence and toxicities

Although a RCT showed that early ART (within 2 weeks) did not reduce mortality in TB meningitis, recommendations on ART initiations should be based on the CD4 count in HIV-positive persons with TB co-infection.

- * Be aware of IRIS reaction in persons starting ART at low CD4 count levels and with early initiation of ART. Corticosteroids should be considered for treatment of symptomatic IRIS, with dosages and duration tailored according to response.
See online video lectures [HIV and IRIS-Part 1](#) and [HIV and IRIS-Part 2](#) from the EACS online course Clinical Management of HIV.
- ** Although the data suggest a cut-off of 50 cells/ μ L, because of the daily variability in CD4 count, a cut-off of 100 cells/ μ L may be more appropriate.

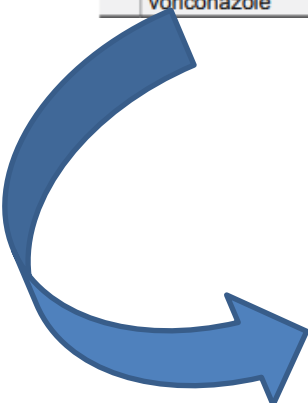
Important drug-drug interactions between ART and rifampicin / rifabutin

ARV drug class	Specific ARVs	Drug-drug interactions and recommended adjustment of dose of either or both drugs
NRTIs^(*)		rifampicin: standard dose of all drugs rifabutin: standard dose of all drugs
PI/r and PI/c		rifampicin: not recommended
PI/r	Monitor liver enzymes and, whenever possible, perform TDM for PI	rifabutin: dose as 150 mg qd ^(*) . PI/r at standard dose
PI/c		rifabutin: not recommended. If needed recommended dose of rifabutin: 150 mg qd ^(*)
NNRTIs	EFV	rifampicin: No dose change required. EFV: standard dose ARV TDM recommended after 2 weeks rifabutin: 450 mg qd. EFV: standard dose
	NVP	neither rifampicin nor rifabutin recommended
	RPV	rifampicin: not recommended rifabutin: standard dose. RPV dose should be increased (use with caution)
	ETV	rifampicin: not recommended rifabutin: standard dose of both drugs (few data – use with caution)
INSTI	EVG/c	rifampicin: not recommended rifabutin: 150 mg qd. EVG: standard dose. Use with caution.

例：TB/HIV共同感染(表格)

Drug-drug Interactions between ARVs and Non-ARVs⁽¹⁾

Non-ARV drugs		ATV/c	ATV/r	DRV/c	DRV/r	LPV/r	EFV	ETV	NVP	RPV	MVC	BIC	DTG	EVG/c	RAL	ABC	FTC	3TC	TAF	TDF
Anti-infectives	clarithromycin	↑E ⁱⁱ	↑ ⁱⁱ	↑	↑	↑ ⁱⁱ	↓	↓E	↓	E	E	E	↔	↑E	↔	↔	↔	↔	E	E
	fluconazole	↑?	↔	↑?	↔	↔	↔	E86%	E100%	E	↔	↔	↔	↑?	↔	↔	↔	↔	E?	↔
	itraconazole	↑E	↑E	↑E	↑E	↑E	↓	↓E	↓61%	E	E	E	↔	↑E	↔	↔	↔	↔	E	E
	rifabutin	↑D	↑	↑D	↑E50%	↑	↓38%	D37%	↑17%	D	*	D	↔	↑D	↔	↔	↔	↔	D ⁱⁱⁱ	↔
	rifampicin	D	D72%	D	D	D	D26%	D	D58%	D80%	D	D	D54% ^x	D	D40% ⁱⁱⁱ	D	↔	↔	D ⁱⁱⁱ	↔
	voriconazole	↑E	↓	↑E	↓	↓	↓E	↑E	↓E	E	E	E	↔	↑E	↔	↔	↔	↔	↔	↔



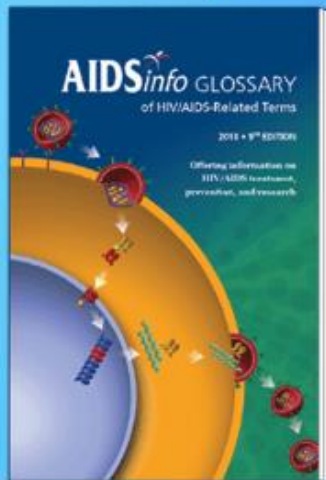
Anti-infectives	clarithromycin	↑E ⁱⁱⁱ	↑ ⁱⁱⁱ
	fluconazole	↑?	↔
	itraconazole	↑E	↑E
	rifabutin	↑D	↑
	rifampicin	D	D72%
	voriconazole	↑E	↓

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(2) AIDSinfo



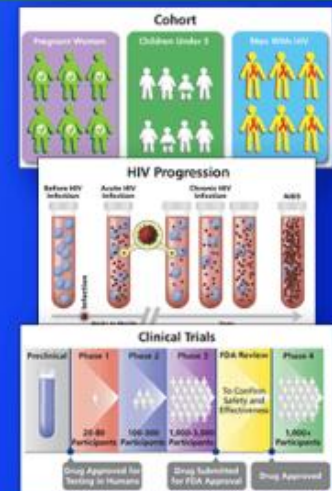
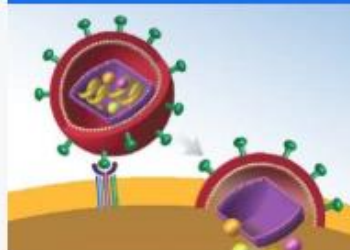
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例：NNRTI/Acid Reducers(表格)

Concomitant Drug Class/Name	NNRTI ^a	Effect on NNRTI and/or Concomitant Drug Concentrations	Dosing Recommendations and Clinical Comments
Acid Reducers			
Antacids	RPV	↓ RPV expected when given simultaneously	Give antacids at least 2 hours before or at least 4 hours after RPV.
H2 Receptor Antagonists	RPV	↓ RPV	Give H2 receptor antagonists at least 12 hours before or at least 4 hours after RPV.
PPIs	RPV	<u>With Omeprazole 20 mg Daily:</u> ● RPV AUC ↓ 40% and C _{min} ↓ 33%	Contraindicated. Do not coadminister.

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(3) Liverpool

 **HIV Drug Interactions**

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例：抗H藥/降糖藥(表格)

● Do Not Coadminister ■ Potential Interaction ▲ Potential Weak Interaction ◆ No Interaction Expected
◆ No Clear Data

○ Do Not Coadminister ■ Potential Interaction ▲ Potential Weak Interaction ◆ No Interaction Expected
◆ No Clear Data

Results Key

	ABC	ATV	ATV/c
Acarbose	◆	◆	◆
Glimepiride	◆	◆	◆
Metformin	◆	◆	■
Sitagliptin	◆	◆	◆

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例：Efavirenz/Ginkgo(表格)

● Do Not Coadminister ⬮ No Clear Data ■ Potential Interaction ▲ Potential Weak Interaction ◆ No Interaction Expected		● Do Not Coadminister ⬮ No Clear Data ■ Potential Interaction ▲ Potential Weak Interaction ◆ No Interaction Expected
--	--	--

- Ginkgo biloba會增加CYP450 enzyme表現誘導CYP3A4，當Efavirenz與銀杏併服時易造成血中濃度降低，導致病毒量失控，產生抗藥性。(AIDS 2009;23:1184-85)

謝謝!

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line :



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◎感謝台灣愛滋病學會資料提供