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Evaluating indicators of standard of ART care

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BACKGROUND

- A WHO recommended indicator of standard of care for antiretroviral treatment (ART) is the proportion of individuals fully virologically suppressed 48 weeks after ART-initiation (FDA snapshot)[1,2]
- Other standard of care indicators exist, that seek to predict short- and long-term outcome for HIV-positive individuals on ART.
- These standard of care indicators have not previously been compared to the FDA snapshot, and it is not known which indicator may perform best at monitoring the quality of ART programs

AIMS

- To evaluate and compare the performance of the following standard of care indicators for ART:
  - Viral Copy Years[3]
  - Consecutive months with VL ≥50copies/mL
  - Percentage of time being fully suppressed (%FS)

  for four ART-related outcomes: resistance development, triple class failure (TCF), all-cause mortality, and fatal/non-fatal AIDS/non-AIDS events.
- To compare the performance of these indicators with the FDA snapshot[2] from 48 weeks onwards.

METHODS

- We evaluated follow-up time for patients on ART followed in the EuroSIDA study from the latest of January 1st 2001 or entry into EuroSIDA, and with ≥3 viral load (VL) measurements after baseline. The first 4 months after treatment initiation or change due to treatment failure or with HIV VL ≥50copies/mL were censored to allow full suppression to occur. VL measurements were censored if the assay-sensitivity was >50 copies/mL. Follow-up was until death or last follow-up, and multiple events were allowed (not for TCF or all-cause mortality).
- Generalised estimating equation for Poisson regression adjusted for demographics, HIV- and non-HIV-related factors was used to model association between the evaluated indicators and incidence rates (IR) of our endpoints: i) TCF: Failed 2 NRTIs, 1 NNRTI or 1PI(/r) where failure was defined as 4 consecutive months of use with VL-measurements >500copies/mL ii) resistance: first NRTI, NNRTI or major PI-mutation, iii) fatal/non-fatal AIDS/non-AIDS events, iv) all-cause mortality.

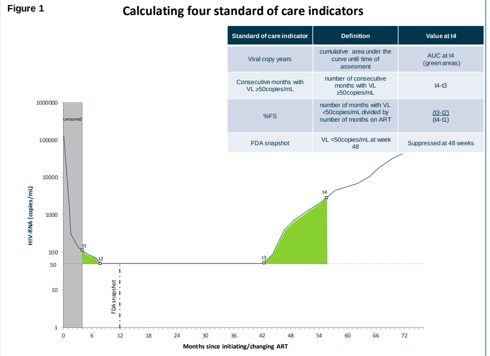
Calculating and comparing the four standard of care indicators (figure 1)

- The four standard of care indicators were calculated as illustrated in **FIGURE 1**
- For comparison of the 4 indicators, we calculated the QIC and the change in QIC (ΔQIC). QIC is a measure analogous to the AIC for comparing the fit of generalised estimating equations, and compares the models containing each specific indicator to the best fitting model. For comparisons after week 48, TCF was excluded as an endpoint due to too few events (n=19).
- The area under the ROC curve (AUROC) was used to assess the ability of the individual indicators to identify those at risk of developing each of the endpoints within 5 years after the 48 week point.

References:
1. http://www.euro.who.int/__data/assets/pdf_file/0012/152013/e95794.pdf
2. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm355239.htm
3. S Cole, S Napravnik, M Mugavero et al., Am J Epidemiol. 2010 Jan 15; 171(2):198-205.

Figure 1

Calculating four standard of care indicators



Standard of care indicator	Definition	Value at t4
Viral copy years	cumulative area under the curve until time of assesment	AUC at t4 (green areas)
Consecutive months with VL ≥50copies/mL	number of consecutive months with VL ≥50copies/mL	t4-t3
%FS	number of months with VL <50copies/mL divided by number of months on ART	(t3-t2)/(t4-t1)
FDA snapshot	VL <50copies/mL at week 48	Suppressed at 48 weeks

Table 1

Baseline characteristics of included patients

Factor	Total	TCF	Resistance	All-cause mortality	Fatal/non-fatal clinical events
Total n (%)	11855 (100)	80 (100)	552 (100)	526 (100)	1612 (100)
Median age, (years (IQR))	41.0 (35.4;48.2)	38.0 (33.3;44.1)	42.0 (37.0;48.7)	47.4 (40.2;56.9)	44.8 (38.7;53.3)
Median CD4 cell count (cells/mm³ (IQR))	430 (284;608)	344 (230;517)	375 (232;524)	342 (207;520)	369 (232;555)
HIV VL < 400 copies/mL (n (%))	10025 (84.6)	41 (51.3)	149 (27.0)	383 (72.8)	1254 (77.8)
Median HIV VL (copies/mL (IQR))	49 (39;75)	354 (49;16,919)	2150 (305;11,000)	49 (49;640)	49.0 (40;220)
Risk group n (%)					
Homosexual	5228 (44.1)	28 (35.0)	247 (44.7)	232 (44.1)	769 (47.7)
Injecting drug user	2,151 (18.1)	15 (18.8)	121 (21.9)	147 (27.9)	334 (20.7)
Heterosexual	3,613 (30.5)	31 (38.8)	151 (27.4)	116 (22.1)	388 (24.1)
Other/missing	863 (7.3)	6 (7.5)	33 (6.0)	31 (5.9)	121 (7.5)
Ethnicity white n (%)	10292 (86.8)	77 (96.3)	474 (85.9)	469 (89.2)	1423 (88.3)
Prior AIDS event n (%)	3605 (30.4)	33 (41.3)	200 (36.2)	217 (41.3)	648 (40.2)
Prior non-AIDS event n (%)	593 (5.0)	4 (5.0)	25 (4.5)	77 (14.6)	133 (8.3)
Median baseline date (IQR)	May 2004 (Mar 2001; Oct 2008)	Jul 2002 (Feb 2001; Jul 2004)	Apr 2003 (Apr 2001; Jul 2005)	Jul 2001 (Feb 2001; Mar 2004)	Dec 2001 (Feb 2001; Jan 2005)
Year of first cART	1999 (1997;2005)	1999 (1997;2001)	1997 (1996;1999)	1997 (1996;1999)	1997 (1996;2000)

Baseline was defined as latest of January 1st 2001 or entry into EuroSIDA

Table 2

Incidence rates (IR) per 1000 person years follow-up (PYFU)

Indicator	Triple class failure			Resistance			All-cause mortality			Fatal/non-fatal AIDS/non-AIDS events		
	Events	PYFU	IR per 1000 PYFU (95%CI)	Events	PYFU	IR per 1000 PYFU (95%CI)	Events	PYFU	IR per 1000 PYFU (95%CI)	Events	PYFU	IR per 1000 PYFU (95%CI)
Viral copy years												
0	3	24814	0.1 (0.0;0.4)	96	5738	16.7 (13.7;20.4)	154	25253	6.1 (5.2;7.1)	666	25253	26.4 (24.4;28.5)
1-58	2	12380	0.2 (0.0;0.7)	68	3588	19.0 (14.9;24.0)	95	12689	7.5 (6.1;9.2)	393	12689	31.0 (28.1;34.2)
59 - 140	4	3515	1.1 (0.4;3.0)	47	1018	46.2 (34.7;61.4)	33	3623	9.1 (6.5;12.8)	108	3623	29.8 (24.7;36.0)
141 - 271	2	1937	1.0 (0.3;4.1)	67	746	89.8 (70.7;114.1)	20	2028	9.9 (6.4;15.3)	85	2028	41.9 (33.9;51.9)
272 - 1127	8	3693	2.2 (1.1;4.3)	169	1710	98.9 (85.0;114.9)	37	4013	9.2 (6.7;12.7)	139	4013	34.6 (29.3;40.9)
1127 +	61	9153	6.7 (5.2;8.6)	524	4264	122.9 (112.8;133.9)	187	10955	17.1 (14.8;19.7)	625	10955	57.1 (52.8;61.7)
Consecutive months with VL≥ 50copies/mL												
0 Months	33	48184	0.7 (0.5;1.0)	137	1437	9.5 (8.1;11.3)	396	50166	7.9 (7.2;8.7)	1571	50166	31.3 (29.8;32.9)
1-2 Month	4	2015	2.0 (0.8;5.3)	148	700	211.5 (180.1;248.5)	23	2194	10.5 (7.0;15.8)	85	2194	38.7 (31.3;47.9)
3-4 Months	7	1412	5.0 (2.4;10.4)	132	489	270.2 (227.9;320.5)	14	1554	9.0 (5.3;15.2)	61	1554	39.3 (30.5;50.5)
5-7 months	5	1148	4.4 (1.8;10.5)	106	413	256.7 (212.2;310.5)	20	1294	15.5 (10.0;24.0)	70	1294	54.1 (42.8;68.4)
8-17 Months	25	1496	16.7 (11.3;24.7)	252	594	424.0 (374.7;479.7)	36	1784	20.2 (14.6;28.0)	125	1784	70.1 (58.8;83.5)
18+ Months	6	1238	4.9 (2.2;10.8)	196	493	397.2 (345.3;456.9)	37	1569	23.6 (17.1;32.6)	104	1569	66.3 (54.7;80.3)
Percentage of time being fully suppressed (%FS)												
0-59	53	9271	5.7 (4.4;7.5)	735	3647	201.6 (187.5;216.7)	152	11020	13.8 (11.8;16.2)	567	11020	51.5 (47.4;55.9)
60-69	8	2795	2.9 (1.4;5.7)	50	1086	46.0 (34.9;60.7)	37	3010	12.3 (8.9;17.0)	123	3010	40.9 (34.2;48.8)
70-79	6	3922	1.5 (0.7;3.4)	55	1473	37.4 (28.7;48.6)	45	4136	10.9 (8.1;14.6)	156	4136	37.7 (32.2;44.1)
80-89	8	6961	1.2 (0.6;2.3)	43	2372	18.1 (13.4;24.4)	70	7198	9.7 (7.7;12.3)	251	7198	34.9 (30.8;39.5)
90-94	1	5171	0.2 (0.0;1.4)	23	1687	13.6 (9.1;20.5)	49	5331	9.2 (7.0;12.2)	181	5331	34.0 (29.4;39.3)
95-99	2	4388	0.5 (0.1;1.8)	10	1554	6.4 (3.5;12.0)	32	4502	7.1 (5.0;10.1)	132	4502	29.3 (24.7;34.8)
100	2	22984	0.1 (0.0;0.4)	55	5244	10.5 (8.1;13.7)	141	23363	6.0 (5.1;7.1)	606	23363	25.9 (24.0;28.1)
Total	78	55491	1.4 (1.2;1.8)	971	17063	56.9 (53.4;60.6)	526	58561	9.0 (8.3; 9.8)	2016	58561	34.4 (32.3;36.0)

For definition of the standard of care indicators, see figure 1.

RESULTS: baseline characteristics, IRs and aIRRs (tables 1, 2 and figure 2)

- 11,855 patients contributed with a median of 4.42 PYFU [IQR 1.91-7.58] and a median of 14 [IQR 6-24] VL-measurements. Baseline characteristics are shown in **TABLE 1**
- Incidence rates (IR) for each of the 4 outcomes are shown by standard of care indicator in **TABLE 2**
- Adjusted incidence rate ratios (aIRR) tended to increase above one with increasing viral copy years **(FIGURE 2a)**, with higher number of consecutive months with VL ≥50copies/mL **(FIGURE 2b)**, and with lower %FS **(FIGURE 2c).**
- Each indicator was significantly associated with TCF and resistance. Both viral copy years and consecutive months with VL≥50copies/mL were associated with clinical events, whereas %FS was not. The gradient of the associations were most pronounced for TCF and resistance and less so for the clinical events. The threshold for significantly elevated risk differed, however, depending on the endpoint evaluated **(FIGURE 2)**.

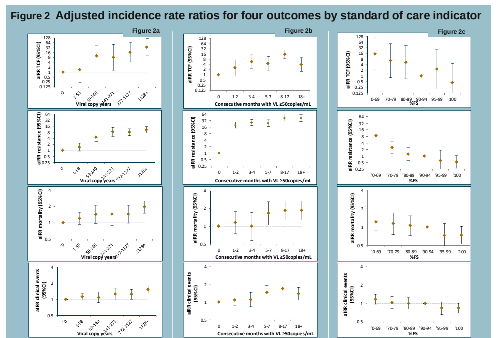
RESULTS: evaluating standard of care indicators (figure 3)

- Using QIC statistics to compare the longitudinal indicators prospectively from baseline, consecutive months with VL ≥50copies/mL was most informative for developing resistance and fatal/non-fatal AIDS/non-AIDS events. Viral copy years were more informative for risk of TCF and all-cause mortality, as indicated by a lower QIC and a ΔQIC = 0.
- Similarly, when comparing the four indicators prospectively from 48 weeks after treatment initiation/change, consecutive months with VL ≥50copies/mL was most informative for both fatal/non-fatal AIDS/non-AIDS events and resistance, and copy years more informative for all-cause mortality.
- With AUROC scores of 0.54-0.57, none of the indicators performed well in identifying those at risk of fatal/non-fatal AIDS/non-AIDS events or all-cause mortality. Overall the indicators performed better at identifying those at risk of short-term outcomes (TCF [AUROC 0.67-0.76]) and resistance [AUROC 0.64-0.79]) **(FIGURE 3)**
- Differences between the indicators were not great, as illustrated with quite similar AUROC scores. **(FIGURE 3)**

CONCLUSIONS

- Neither of the evaluated standard of care indicators were markedly better at predicting risk of fatal/non-fatal AIDS/non-AIDS events or all-cause mortality, but the indicators generally performed better at predicting short-term outcomes (TCF and resistance).
- A substantial time-delay between the FDA snapshot and developing clinical events or death may explain this indicator's poor predictive value for clinical events.
- More complicated longitudinal indicators did not predict short-term or long-term outcomes better than the FDA snapshot
- None of the standard of care indicators were sufficient in reliably evaluating the success or failure of treatment programs.
- An indicator that provides a more comprehensive picture of ART care is warranted in order to more reliably evaluate the success or failure of treatment programs. Such an indicator may in addition to VL assessment include CD4 cell counts and stability on ART.

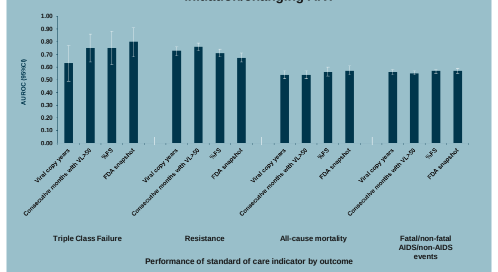
Figure 2 Adjusted incidence rate ratios for four outcomes by standard of care indicator



Figures are on different log2 scales. TCF = triple class failure. Mortality = all-cause mortality. Clinical events = fatal/non-fatal AIDS/non-AIDS events. For definition of the standard of care indicators, see figure 1. Adjusted incidence rate ratios (aIRRs) were adjusted for age (per 10 years older), gender, body mass index, smoking status, risk group, ethnicity, region of residence, current CD4 cell count, cumulative years on ART, current PI use, current NNRTI use, cumulative number of ARVs used historically, prior AIDS event, prior non-AIDS event (cardiovascular, end stage liver disease, non-AIDS defining malignancy, pancreatitis), prior HBV, prior HCV, diabetes, and hypertension. Resistance models were also adjusted for prior resistance.

Figure 3

Area under the ROC curve (AUROC); the predictive performance of four standard of care indicators after 48 weeks following initiation/changing ART



The ability of the individual standard of care indicators to identify those at risk of developing each of the endpoints within 5 years after the 48 week point. For definition of the standard of care indicators, see figure 1. Viral copy years and FDA snapshot were log10 transformed for this analysis.

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SEVENTH FRAMEWORK PROGRAMME

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