

## When to Switch GRADE tables

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**Question:** Should Clinical Monitoring vs Immunologic and Clinical Monitoring be used in guiding when to switch first-line antiretroviral therapy in adults in low-resource settings?

**Settings:** Low-resource settings

**Bibliography:** H.B.A.C. 2008; D.A.R.T. 2009

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Clinical Monitoring	Immunologic and Clinical Monitoring	Relative (95% CI)	Absolute		
<b>Mortality (follow-up median 3-5 years)</b>												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness <sup>2</sup>	serious <sup>3</sup>	none <sup>4</sup>	?/2037 <sup>5</sup>	?/2027 <sup>5</sup>	HR 1.35 (1.12 to	-	⊕⊕○○ LOW	CRITICAL
<b>AIDS-defining illness - not reported</b>												
0	-	-	-	-	-	-	-	-	-	-		CRITICAL
<b>AIDS-defining illness or Mortality (follow-up median 3-5 years)</b>												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness <sup>2</sup>	no serious imprecision	none <sup>4</sup>	547/2037 (26.9%) <sup>6</sup>	414/2027 (20.4%) <sup>6</sup>	HR 1.33 (1.16 to 1.51)	58 more per 1000 (from 29 more to 88 more)	⊕⊕⊕○ MODERATE	CRITICAL
<b>Serious Adverse Event (follow-up median 5 years)</b>												
1 <sup>7</sup>	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness <sup>2</sup>	serious <sup>3</sup>	none <sup>4</sup>	?/1660 <sup>8</sup>	?/1656 <sup>8</sup>	HR 1.12 (0.94 to	-	⊕⊕○○ LOW	CRITICAL
<b>Unnecessary Switch (Switch to Second-line with Undetectable Viral Load) (follow-up median 3 years)</b>												
1 <sup>7</sup>	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness <sup>2</sup>	serious <sup>3</sup>	none <sup>4</sup>	15/377 (4%)	0/371 (0%)	RR 30.5 (1.83 to 508)	-	⊕⊕○○ LOW	CRITICAL
<b>Switch to Second-Line (follow-up median 3-5 years)</b>												
2	randomised trials	serious <sup>1</sup>	serious <sup>9</sup>	no serious indirectness <sup>2</sup>	no serious imprecision	none <sup>4</sup>	331/2037 (16.2%)	365/2027 (18%)	RR 1.73 (0.37 to 8.06)	13 more per 100 (from 11 fewer to 127 more)	⊕⊕○○ LOW	

<sup>1</sup> Unclear sequence generation and allocation concealment and blinding was not possible for both studies; lost-to follow-up analyses not extensively presented for either trial but absolute numbers were relatively small.

<sup>2</sup> Patient populations pre-selected and within relatively well-resourced ART delivery programs; however, as setting(s) was low-resource, no downgrading occurred.

<sup>3</sup> Total number of events is small.

<sup>4</sup> Abstract(s) only, no peer-reviewed print publication(s) of these data are available; however, as a significant amount of data was available from abstracts/conference presentations no downgrading occurred.

<sup>5</sup> Number with event not reported in either study. DART mortality in clinical arm 2.94/100 P-Y, in immunologic + clinical arm 2.18/100 P-Y.

<sup>6</sup> In DART in clinical arm 6.94 events/100 P-Y, in immunologic + clinical arm, 5.24 events/100 P-Y. In HBAC in clinical arm 7.57 events/100 P-Y, in immunologic + clinical arm 5.97 events/100 P-Y.

<sup>7</sup> DART study only.

<sup>8</sup> Number with event not reported.

<sup>9</sup> Number of events and point estimate varied widely between the two studies.