EUCAST EUROPEAN COMMITTEE ON ANTIMICROBIAL SUSCEPTIBILITY TESTING

European Society of Clinical Microbiology and Infectious Diseases

EUCAST clinical breakpoints for *Helicobacter pylori*

Over the past few months EUCAST have been in consultation with the European *Helicobacter* study group (EHSG) regarding clinical antimicrobial breakpoints for *Helicobacter pylori*. The following proposals are agreed between EUCAST and EHSG.

Comments should be sent before 30th April 2011to the EUCAST Scientific Secretary (derek.brown222@btinternet.com). Any proposal for alternative breakpoints should be supported by publications or other evidence.

Note the following:

1. Different test methods may give different results. There are no standard methods. Collated MIC distributions from the EUCAST database are as follows. Any additional MIC distributions would be appreciated (please give method details and the source of isolates).

Agent	MIC (mg/L)															
	0.008	0.016	0.03	0.06	0.12	0.25	0.5	1	2	4	8	16	32	64	128	256
Amoxicillin	5	7002	1804	1055	364	79	32	10	5	0	0	0	0	0	0	0
Clarithromycin	0	1752	1808	1740	587	142	81	104	117	211	487	841	910	595	290	1143
Levofloxacin	4	28	107	303	788	539	162	64	57	134	101	68	246			
Metronidazole	0	93	136	218	500	597	1089	1786	1781	336	133	224	324	421	384	3024
Rifampicin	0	0	4	5	9	23	14	15	11	0	0	0	0	0	0	0
Tetracycline	0	533	1583	2603	1804	387	136	53	13	7	3	7	11	79		

2. There is a shortage of clinical data linking in vitro susceptibility to outcome.

3. All agents are used in combination therapy so outcome data for individual agents are often difficult to assess.

Proposed breakpoints:

Agent	Susceptible (mg/L)	Resistant (mg/L)	Comment
Amoxicillin	≤0.12	>0.12	The breakpoints are based on the epidemiological cut-off value (ECOFF). Isolates with higher MICs are uncommon and there is no evidence to indicate whether treatment is successful for infections caused by isolates with MICs >0.12 mg/L.
Clarithromycin	≤0.25	>0.5	These breakpoints have been clinically validated and isolates with MIC above 0.5 mg/L have a resistance mechanism (23S RNA mutation). The ECOFF is 0.25 mg/L.
Levofloxacin	≤1	>1	These breakpoints largely correlate with *gyrA* mutations (although there are no outcome data). The ECOFF is 0.5 mg/L. While ciprofloxacin test results are indicative of levofloxacin susceptibility, ciprofloxacin susceptibility should not be reported as ciprofloxacin is not effective in vivo and may mislead clinicians.
Tetracycline	≤1	>1	These breakpoints correspond to mutation in 16S RNA. Resistance is rare and there is no clinical validation. The ECOFF is 0.25 mg/L. Tetracycline susceptibility should not be used as an indicator of susceptibility to other tetracyclines as other tetracyclines are not effective in vivo.
Rifampicin	≤1	>1	Few MIC data are available. The breakpoints correspond with *rpoB* mutation. Resistance is rare and there is no clinical validation. Rifabutin is used rather than rifampicin.
Metronidazole	≤8	>8	This is the current, widely accepted breakpoint, but there is no clinical validation. The ECOFF is 4 mg/L. It is possible that different breakpoints might be appropriate for different treatment regimens.