### **Accepted Manuscript**

Wide variation in activity of antibiotic disks from nine manufacturers

Gunnar Kahlmeter

PII: S1198-743X(15)00990-8

DOI: 10.1016/j.cmi.2015.11.008

Reference: CMI 446

To appear in: Clinical Microbiology and Infection

Received Date: 9 November 2015

Accepted Date: 20 November 2015

Please cite this article as: Kahlmeter G, Wide variation in activity of antibiotic disks from nine manufacturers, *Clinical Microbiology and Infection* (2015), doi: 10.1016/j.cmi.2015.11.008.

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#### ACCEPTED MANUSCRIPT

### **Editorial, CMI**

# Wide variation in activity of antibiotic disks from nine manufacturers.

**Gunnar Kahlmeter** 

EUCAST compared 16 strategically chosen antibiotic disks, available on the international market, produced by 9 manufacturers. The disks were chosen to represent different antibiotic classes or because they were important for screening for specific resistance mechanisms. The study was performed during 2014 and 2015 and in part presented at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) 2015 in Copenhagen<sup>1</sup>. The results, some good and some appalling, were recently released on the EUCAST website<sup>2</sup>. Similar studies encompassing four manufacturers have been previously performed<sup>3</sup>

The final report, unlike the interim report at ECCMID, openly names the manufacturers and lists all disk lot numbers, which means that laboratories around the world can obtain important information on whether or not the disks they have purchased and are using in everyday routine susceptibility testing can be expected to perform well or poorly. It highlights the need for manufacturers to take production quality control (QC) seriously and the need for diagnostic laboratories to QC their everyday susceptibility testing results.

EUCAST and CLSI do not **dis**agree on any QC target or range as long as the technical specifications agree (the same QC strain, disk potency, medium). This means that companies can manufacture disks (and media) to exactly match the targets and ranges listed in the QC tables. It is a common misconception that as long as the mean value (of repeated testing, of inhibition zones over time, of many disks from the same lot, of the agar depth of Mueller Hinton plates) is within the listed range (which for a specific disk is typically 6 mm; which for the depth of a MH agar plate is 4 mm +/-0.5 mm), the QC is within spec. However, this is not the case. The range represents the acceptable **random** variation between tests (or depth of agar plates), which means that if at least 95% of all measurements shall be kept within the recommended range, then the mean needs to be close to the middle of the range (within 1 mm from target values listed in the EUCAST QC tables).

All phenotypic antimicrobial susceptibility testing (AST) systems, whether or not they are based on the MIC or on the inhibition zone diameter, are relative and it is not important whether or not a 1, 5, 10 or 30 µg disk contains exactly 1, 5, 10 or 30 µg. What is important is that the system is calibrated to perform according to an agreed standard in a fully reproducible way. The EUCAST AST system was developed using disks and media from several manufacturers. This was to respect unavoidable random variation in and between laboratories and to make sure that the EUCAST recommended

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