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PK/PD of antifungals and miscellaneous antibacterials

TWO YEARS EXPERIENCE AND CLINICAL PERFORMANCE IN RUNNING AN ANTI-FUNGAL THERAPEUTIC DRUG MONITORING EXTERNAL QUALITY ASSURANCE SCHEME

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Objectives

In recent years, the increasing use of the azole antifungals and clearer therapeutic drug monitoring (TDM) objectives has lead to an increase in laboratories offering assay services for these agents. To support these laboratories, the UK National External Quality Assurance Scheme for Antibiotic Assays launched an antifungal panel in April 2012, having piloted it over the preceding 18 months. Here we report the main methods used in the TDM of antifungal agents and the relative performance of the methods by individual laboratories across Europe and the rest of the world.

Methods

EQA samples are distributed monthly to participating laboratories. The full panel is comprised of 4 samples spiked with a) itraconazole and hydroxyitraconazole, b) posaconazole, c) voriconazole and d) flucytosine. Laboratories have 21 days to return results by web entry, while further data are obtained from the distribution schedules and from the EQA software used by the scheme. Statistical calculations are carried out by the EQA software or by Excel. Performance is assessed both by the magnitude of error for individual results and by the consistency of results over the previous six month period. Laboratories are rated as good performers if their mean+2SD error score over the 6 months is below 30%, borderline performers if their score is 30-50% and poor performers if their score is >50%.

Results

Twenty-six laboratories participate in the scheme; 17 are located in Europe, 3 in North America and 6 in Australia. Nineteen laboratories return results for itraconazole, 24 for posaconazole, 24 for voriconazole and 11 for flucytosine. The methods used for the assay of each analyte are shown in the Table. Laboratories with good performance were for itraconazole 44.4%, posaconazole 60.9%, voriconazole 54.6% and flucytosine 87.5%, with poor performance of 11.2%, 17.4%, 22.7% and 12.5%, respectively. Although 66.7% of laboratories performing bioassay were rated as poor, there were no significant differences in performance between laboratories using LC and LCMS.

Conclusion

Overall most laboratories offering TDM services for the antifungal agents use either HPLC or LCMS techniques and achieve broadly equivalent performance. In contrast, 66% of laboratories using bioassay have performance at such a level as it would be likely to have clinical impact and were rated as poor. Although 42% of laboratories are currently rated as poor performers for at least one analyte, compared with 37% at the start of the panel, only 3 were so rated on both occasions. This observation both suggests that improvements in performance are possible and highlights the importance of continued participation in EQA.

Analyte	N	HPLC Assay	LCMS Assay	Bioassay
Itraconazole	19	53%	47%	0%
Posaconazole	24	50%	42%	8%
Voriconazole	24	46%	50%	4%
Flucytosine	11	55%	17%	18%