

Implementing Kleihauer-Betke test External Quality Assessment Schemes (EQAS) : a French experience.

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BACKGROUND

METHOD

The Kleihauer-Betke test (KBT) is a laboratory test used to quantify foetomaternal hemorrhage. Although this method has proved to be useful clinically for the monitoring of pregnancy but also for the dose adjustment of anti-D for Rhesus prophylaxis, this test is often criticized. It is a manual test with a high level of variability, difficult to standardize and requiring technical expertise. Even if the flow cytometry is used to replace the KBT, it is not widely used and display limitations such as F-cells interferences and the management of urgency. With the legal obligation for French laboratories to be accredited, came the need for an external quality assessment schemes. Since 2015, the CNRHP which integrates in its missions (ministerial circular DGOS 2004) the preparation of standard and quality control collaborated with the association ASQUALAB to set up an external evaluation of the quality

The CNRHP and ASQUALAB has set up an EQAS consisting in sending a stained smear (KHL), a whole blood sample (KHS) associated with a clinical case and a clinical counseling quiz (Rhesus prophylaxis, complementary tests ...). These 2 samples come from 2 calibrated mixtures prepared from adult O RH: -1 group whole blood and O RH: 1 group cord blood. Adult whole blood RH: -1 comes from a donor collected by the French blood establishment. The negativity (absence of interpretable cells) of the Kleihauer test (colorimetric method and flow cytometry) was performed. The target value of each sample is obtained by flow cytometry technique with anti-D labeling (BRAD3). Since 2015, 6 exchanges have been proposed. In this study 4 exchanges (2016-2017) have been analyzed.

Units : Fetal Red Blood Cells (FRBC) / 10000 Adult Red Blood Cells (ARBC)

RESULTS

	First semester 2016		Second semester 2016		First semester 2017		Second semester 2017	
	KHL1601	KHS1601	KHL1602	KHS1602	KHL1701	KHS1701	KHL1702	KHS1702
Labs (N)	45		44		72		71	
Staining techniq for KHS								
KBT			The same mixture for the two samples					
Target value	22	0	104	104	10	97	25	50
Average of labs	29		145	116	14	92	36	63
Interlabs variability	27,3%		27.7%		30%		28.1%	
% of labs having:	47% negative		49%		51%		52%	
≠ accuracy of ± 40% / target value	37% positive		33%		28%		28%	
≠ accuracy of ± 40% / average of labs	13% not interpretable		20%		31%		38%	
Results								
Clinical case % good answers	78%	77%	77%	41.5%	86.5%	86%	78.5%	71%

CONCLUSION

These different exchanges show significant inter-laboratory variability between 25 and 30% with an overestimation of counts compared to the target value probably due to an underestimation of adult red blood cells. The results of the quiz related to the clinical case are very variable. this heterogeneity of practices is essentially based on the control of Kleihauer and Antibody screening, whereas rhesus prophylaxis is generally recommended. This evaluation demonstrates the difficulties to standardize the KBT and the need for an EQAS