LABQUALITY DAYS

Towards value-based laboratory medicine : How to improve our EQAs ?

The example of the NIPT EQA in Belgium

Joséphine Lantoine*

* Sciensano, Brussels, Belgium, rue Juliette Wytsman 14 1050 Ixelles

Introduction

In 2017 the Belgian government adopted a law allowing all pregnant women to perform a NIPT test from 12th week of pregnancy to detect fetal risk of trisomy 21. Performing an NIPT test was then no longer the matter of genetic centers but a routine test performed in medical laboratories. To offer to patient analyses and care of quality, medical laboratories must be licensed by the Belgian Institute for Health, Sciensano to perform molecular biology analyses as NIPT, and as the genetic centers, they must be accredited according to ISO15189.

Aims

As licensing and accreditation are linked to the participation to EQA, the service Quality of laboratories of Sciensano (national EQA organizer) has launched an NIPT EQA in 2020. It quickly became an evidence that we should assess the extra-analytical phases in order to align our EQA with the willingness of the laboratories to go into value-based laboratory medicine and to test the entire process of analyses from the analyses' request to the clinical report and the impact for the patient.

Methods

In 2022, the first Belgian NIPT EQA was launched using commercially available 1mL simulated plasma samples with encapsulated fetal DNA carrying a chromosomal aneuploidy. The sample is now accompanied by the analysis request of the corresponding laboratory. Laboratories were asked to analyze the sample and send us their clinical report.

Clinical reports were then screened for completeness following National[1] and European[2] guidelines concerning the way to report a trisomy and the mandatory information of the clinical report : identification of the patient, report of trisomy 21 in terms of high risk/low risk, invasive test obligation in case of high risk, date of sample collection, date of sample reception and date of report.

Results

15 medical laboratories have participated to our EQA in 2024. Among these laboratories, 4 reported a subcontract to a genetic center and 1 to another medical laboratory.

All laboratories reported a risk of trisomy and reported an obligation of an invasive test as confirmation in comparison to the previous years. Nevertheless, 6 laboratories did not reported the address of the patient in the clinical report and 5 reported an incorrect sample collection date. 2 laboratories did not reported fetal age. For one laboratory, the date of the report was not mentioned.

Conclusions

In conclusion, the set-up of this NIPT EQA in Belgium allows us to detect some "negligence" of laboratories when reporting NIPT results in accordance with Belgian[1] and European[2] guidelines for reporting those type of results. By continuing this EQA, we saw an improvement in the laboratories as they adapted their report meaning that this EQA scheme has had an added value for the laboratories but we need to continue to monitor the clinical report and post-analytical phases in order to lower the impact for the patient as laboratories are not always aware of reporting guidelines.

---

[1] Belgium Society of Human Genetics prenatal working group. NIPT good clinical practice guidelines, https://www.college-genetics.be/assets/recommendations/fr/guidelines/BeSHG%20prenatal%20consortium_guidelines%20for%20NIPT%20good%20clinical%20practice.pdf

[2] Deans ZC, Allen S, Jenkins L, Khawaja F, Hastings RJ, Mann K, *et al*. *Recommended practice for laboratory reporting of non-invasive prenatal testing of trisomies 13, 18 and 21: a consensus opinion,* Prenat Diagn. 2017 Jul;37(7):699-704. doi: 10.1002/pd.5068.