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

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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. 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.

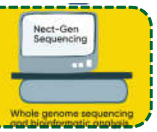
In 2017 the Belgian government adopted a law allowing all pregnant women to perform a NIPT test from 12th week of pregnancy to detect fetal risk of trisomy 21. Performing an NIPT test was then no longer the matter of genetic centers but a routine test performed in medical laboratories. To offer to patient 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.
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.

Method

Collect of the analysis request of the participating laboratories

Sending of the corresponding request with the EQA sample: commercially available 1mL simulated plasma with encapsulated fetal DNA carrying a chromosomal aneuploidy

Analysis of the sample by the laboratories and collect of the clinical report as result form



Screening of the clinical reports for completeness following National[1] and European[2] guidelines and mandatory information to be on the clinical report :

Patient ID, high risk/low risk of Trisomy 21, invasive test obligation if high risk, date of sample collection, date of sample reception and date of report

Results

For our last EQA in 2024, we had 15 participating labs. We evaluated our laboratories concerning the results of the genetic analysis and also concerning mandatory info to be mentioned on the clinical report.

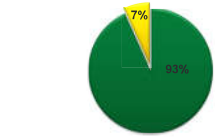
Genotypering and analysis

- ✓ All laboratories have indicated a low risk of Trisomy 21 and a high risk of Trisomy 13
- ✓ All laboratories stated the obligation of an invasive test due to high risk T13
- ✓ All laboratories notified the limits of the test on the report

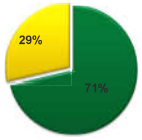
Clerical accuracy

- ✓ All laboratories have correctly identified the patient (name, surname and date of birth) but 5 didn't mentioned the address and 1 an incorrect one
- ➢ 1 lab didn't mentioned the sex of the foetus although asked in the analysis request
- ➢ 3 laboratories have given a wrong gestational age and 2 didn't mentioned it

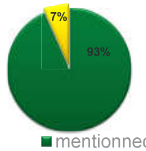
Receipt date



Collection date (04/09)



Report's date



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[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.

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