

Xpert® Xpress GBS (Cepheid) as a Point-of-Care test for the intrapartum screening of Group B streptococcus

Clinical evaluation in the University Hospital of Liège, Belgium
Preliminary results

Group B Strep in Pregnancy & Babies Conference 2025

Ph. Biol. Cécile Meex

National Reference Center for *Streptococcus agalactiae*
Clinical Microbiology, University Hospital Liège, Belgium

Hospital introduction



University Hospital of Liège

1.038 beds

Part of the Elipse network

2nd biggest hospital network in Belgium



Hospital introduction

Clinical Microbiology lab
Belgian National Reference Center
for *Streptococcus agalactiae*

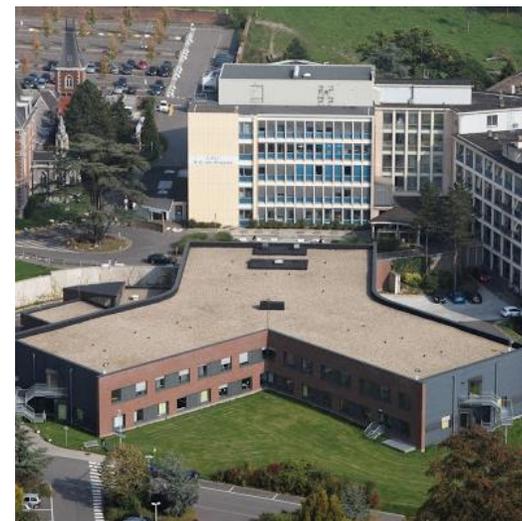


Main site

- Sart Tilman hospital

Decentralized

- Notre-Dame des Bruyères hospital
- Ourthe-Amblève hospital
- Fraiture Neurological and functional rehabilitation center



Maternity ward:
25 beds
1000 deliveries/year
60 midwives

Belgian Guidelines

PREVENTION OF PERINATAL GROUP B STREPTOCOCCAL INFECTIONS Guidelines from the Belgian Health Council, 2003 (SHC.7721)

- Recto-vaginal GBS screening culture at 35-37 weeks' gestation for ALL pregnant women
- Intrapartum antibiotic prophylaxis indicated for women with:
 - Previous infant with invasive GBS disease
 - GBS bacteriuria during the current pregnancy
 - Positive GBS screening culture during the current pregnancy
 - Unknown GBS status **AND** any of the following:
 - Delivery at < 37 weeks' gestation
 - Amniotic membrane rupture \geq 18 hours
 - Intrapartum temperature \geq 38°C

European consensus

Intrapartum GBS screening and antibiotic prophylaxis: a European consensus conference

G. C. Di Renzo, P. Melin, A. Berardi, M. Blennow, X. Carbonell-Estrany, G. P. Donzelli, S. Hakansson, M. Hod, R. Hughes, M. Kurtzer, C. Poyart, E. Shinwell, B. Stray-Pedersen, M. Wielgos & N. El Helali

- Recto-vaginal GBS screening culture at 35-37 weeks' gestation for ALL pregnant women
- OR
- point-of-care test for GBS detection performed in the delivery department

Intrapartum test requirements:

- a) a short turnaround time
- b) accuracy with high sensitivity and specificity, not inferior to 90–95% and 95–98% respectively
- c) easiness to perform and to interpret by labor and delivery staff with a minimum of skill and training
- d) availability at all times 24 hours a day, seven days a week

Xpert® Xpress GBS (Cepheid)

- Optimized Real-time PCR test on GeneXpert system
 - 2 GBS targets:
 - glycosyl transferase protein
 - transcriptional regulator *LysR*
 - 2 internal controls:
 - Presence of human cells or DNA
 - Sample treatment control
- CE-IVD marked
 - on vaginal-rectal samples
- Easy to perform
- Result in 30 to 42 minutes



 **Cepheid**[®]
A better way.



Clinical evaluation: Objectives

1. To evaluate **the accuracy of the Xpert® Xpress GBS assay**
 - performed intrapartum by midwives
 - by comparison with the reference semi-quantitative selective primary and enriched culture
 2. To evaluate **the expected clinical advantages of the Xpert® Xpress GBS assay performed at admission for delivery:**
 - Xpert® Xpress GBS assay vs 35-37 weeks' gestation screening culture.
- Consolidate the proposal of the European expert group
- Advise for revision and optimization of the National Belgian Guidelines

Population

- Prospective study in the University Hospital of Liège – Site Notre-Dame des Bruyères
 - GeneXpert system and 550 Xpert[®] Xpress GBS tests provided by Cepheid
 - Installed in the obstetrical ward
- All women admitted for giving birth in the obstetrical department
- Case-report form:
 - Demographic and obstetrical data
 - Result of the 35-37 weeks' gestation screening culture

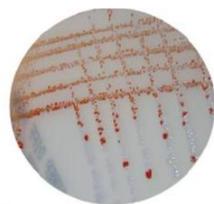
Samples

Antenatal screening

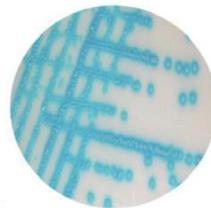
- Recto-vaginal sample at 35-37 weeks' gestation

Intrapartum screening

- Recto-vaginal double swab at the admission for delivery



a.



b.

a/Granada, b/StrepB Select

Direct culture + subculture of selective enrichment in Lim broth



Xpert® Xpress GBS test performed by labor/delivery staff

Results (1)

Study period: 30/04/2024 to 01/04/2025

- 482 patients enrolled
 - 20 excluded because of PCR result in error (4,1%)
Mainly due to wrong manipulations at the beginning of the study

	1st trimester May-July 24	2 nd trimester Aug-Oct 24	3rd trimester Nov 24-Jan 25	4th trimester Feb-Apr 25
Number of errors	13	4	3	0

- No PCR result inconclusive because of inhibition
- Intrapartum colonization rate: 16,2%

Results (2)

1. Accuracy of the Xpert® Xpress GBS assay

vs intrapartum culture

Sensitivity: 89,5%



Specificity : 98,2%

PPV : 90,7%

NPV: 97,9%

Negative PCR and positive culture: 8

3 : culture positive only after enrichment

3 : culture 1+ positive

1 : culture 3+ positive

1 : culture 4+ positive



Insufficient homogeneization of the double swabs??

No more major discrepancies observed after reminder of the correct procedure

Results (2)

1. Accuracy of the Xpert[®] Xpress GBS assay

vs intrapartum culture

Sensitivity: 89,5%

Specificity : 98,2%

PPV : 90,7%

NPV: 97,9%



Positive PCR and negative culture (and PCR < Lim broth): 7
all with PCR Ct values >37

Results (3)

2. Accuracy of the 35-37 weeks' gestation screening culture

vs intrapartum culture

Sensitivity : 77,1%

Specificity : 95,6%

PPV : 76,1%

NPV : 95,8%

33 patients changed their GBS-colonization status :

- 16 negative-patients became positive
- 17 positive-patients became negative

Conclusion

Xpert[®] Xpress GBS assay:

- Easy to perform by midwives
 - Full proficiency only after a few months
 - Continuous training mandatory
- Short turnaround time: 30-42 minutes
- No inhibition
- Sensitivity and specificity in line with the requirements of the European consensus
- **Superior to antenatal screening in identifying candidates for IAP**

Perpectives

- Completion of the study by end June 2025
- Cost-benefit analysis
- Revision and optimization of the National Belgian Guidelines

Thank you!