



Neonatal Health: The Impact of Group B Streptococcus Screening, NAAT-based Detection, and Prophylactic Interventions

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Program Objectives

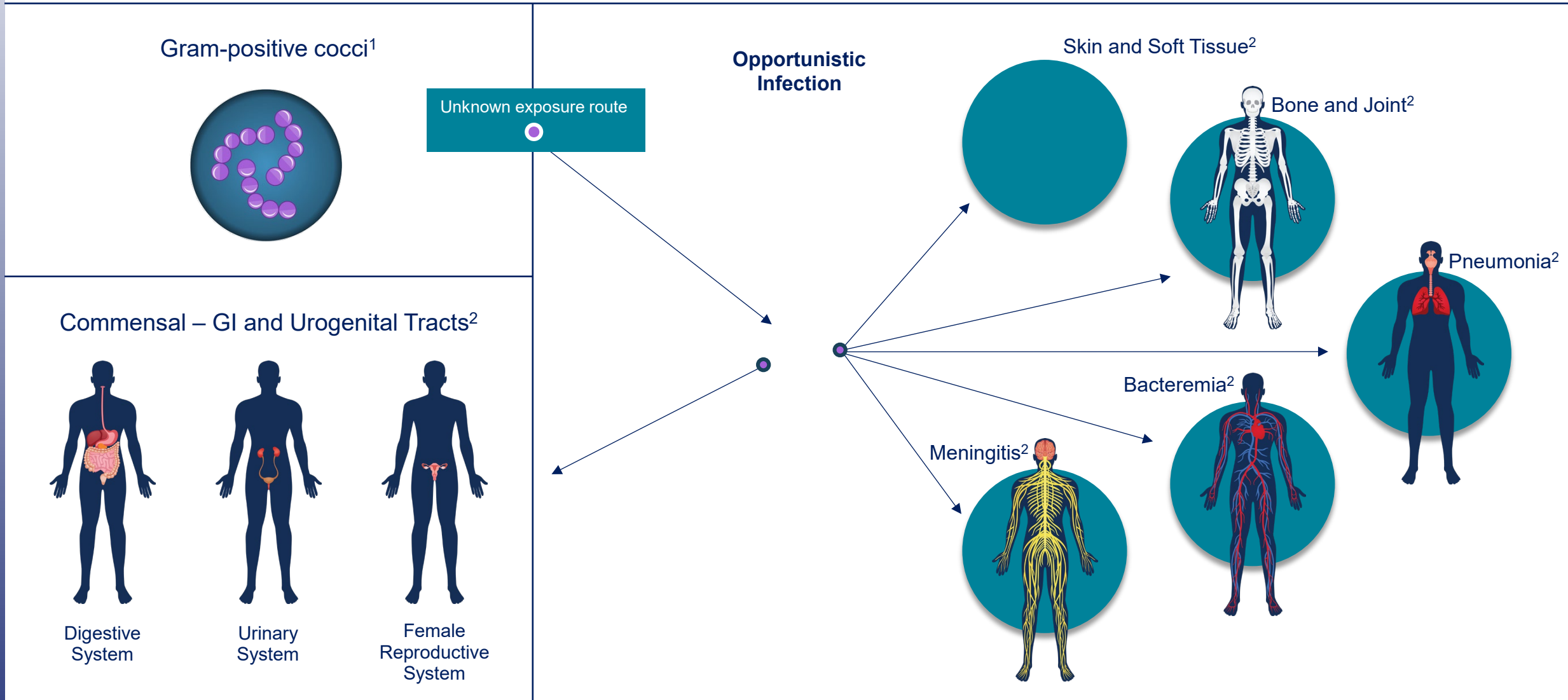
- ✓ **Review of Group B strep (GBS)**
 - Causes
 - Risks
 - Symptoms
- ✓ **Guidelines**
 - ASM
 - ACOG
- ✓ **Diagnostic Testing Methods**
 - Culture
 - Nucleic Acid Amplification Testing (NAAT)
- ✓ **Screening Success Examples**





GBS Overview

Group B *Streptococcus* (GBS), *Streptococcus agalactiae*



GBS During Pregnancy

Prevalence of GBS

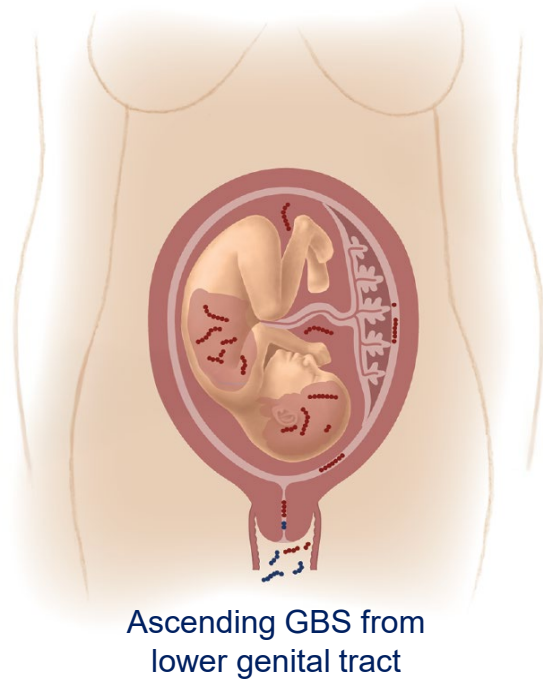
- GBS can asymptotically colonize genitourinary and gastrointestinal tracts in 10-30% of pregnant women¹
- Prevalence in women can vary by race and geographic location¹

Approximately 50% of women colonized with GBS will transmit the bacteria to their newborns¹

Routes of transmission²⁻⁴

- Vertical
 - Ascending, during pregnancy
 - Ascending, during labor
 - Inoculation in the birth canal
- Horizontal
 - From mother, hospital/community environment

GBS During Pregnancy



Pregnancy-related infections and complications include¹⁻²:

| | |
|---|------------------|
| Bloodstream infections (including sepsis) | Endometritis |
| Intraamniotic infection | Preterm delivery |
| Urinary tract infection | Stillbirth |

Image adapted from: Brokaw A, Furuta A, Dacanay M, Rajagopal L and Adams Waldorf KM (2021) Bacterial and Host Determinants of Group B Streptococcal Vaginal Colonization and Ascending Infection in Pregnancy. *Front. Cell. Infect. Microbiol.* 11:720789.

1. Prevention of group B streptococcal early-onset disease in newborns. ACOG Committee Opinion No. 797. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2020; 135:e51-72. 2. CDC. Clinical Overview of Group B Strep Disease. Published May 1st, 2025. Accessed February 4th, 2026. <https://www.cdc.gov/group-b-strep/hcp/clinical-overview/index.html>.

GBS in Newborns



Symptoms:¹

- Fever
- Difficulty feeding
- Urinary tract infection
- Irritability or lethargy (limpness or hard to wake up the baby)
- Difficulty breathing
- Blue-ish color to skin

GBS in Newborns



Early Onset Disease (EOD):¹

- Vertical transmission during labor/birth
 - Presents < 7 days old
-

Late Onset Disease (LOD):¹

- Horizontal transmission (mother)
 - Environment
 - Presents 7-89 days old
-

EOD and LOD

- Both EOD and LOD can manifest as bacteremia, sepsis, pneumonia, and meningitis²

Risk Factors for EOD

Primary Risk Factor: Maternal GBS colonization of the genitourinary or GI tract in current pregnancy.¹

Women with a history of GBS colonization in a prior pregnancy have a high risk of being recolonized in subsequent pregnancies (50.2%).¹

Other Risk Factors Include:¹

Maternal Risk Factors

- Young maternal age
- Maternal black race
- Previous child affected by EOD
- GBS bacteriuria in pregnancy

Intrapartum Risk Factors

- Intraamniotic infection
- Intrapartum fever
- Preterm prelabor rupture of membranes (PPROM)
- Prolonged rupture of membranes

Neonatal Risk Factors

- Gestational age <37 weeks
- Very low birth weight

Consequences of GBS Disease in Neonates

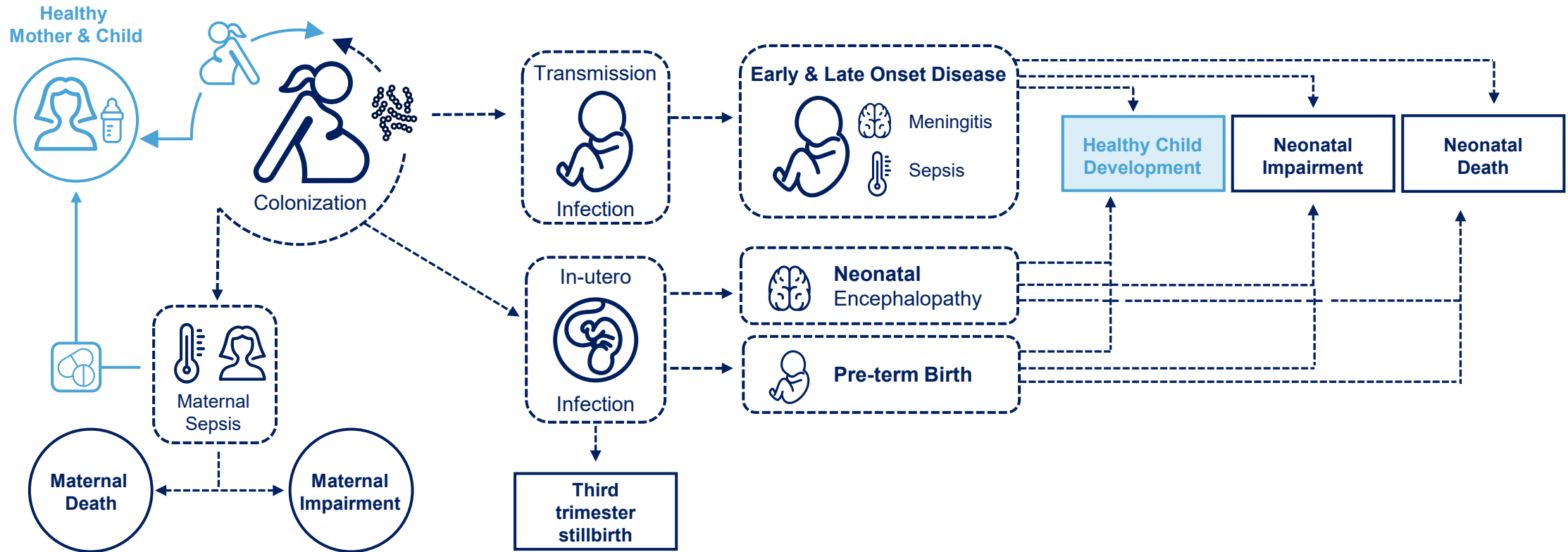
4-6%

of newborns who develop GBS disease die¹

Potential long term adverse health outcomes include:

vision loss², hearing loss¹, developmental disabilities¹, cerebral palsy²

Outcomes of Perinatal GBS Infection



GBS Intervention

Intrapartum Antibiotic Prophylaxis (IAP)

What is IAP?

The administration of intravenous antibiotics to a pregnant woman during labor to prevent the transmission of GBS to her newborn, thereby reducing the risk of EOD¹

Clinical Utility

An effective intervention to prevent EOD in neonates¹

Effective strategies to prevent LOD have not yet been identified²



Guidelines

Collaboration for Prevention

Since 1996



The CDC has published recommendations for GBS screening in collaboration with several professional societies since 1996.¹

Today



American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®



CLINICAL GUIDELINES

responsible for **guidelines for prophylaxis, treatment of GBS infection in pregnant women and newborns**



AMERICAN
SOCIETY FOR
MICROBIOLOGY

LABORATORY GUIDELINES

responsible for **guidelines for standard laboratory practices** related to detection and identification of GBS

Medical Education

ACOG Prophylaxis and Treatment Guidelines

“Prevention of Group B Streptococcal Early-Onset Disease in Newborns”

ACOG Committee Opinion

February 2020

Medical Education

ACOG Guidelines for EOD Prevention

“Key components of screening and prophylaxis for Group B streptococcal (GBS) early-onset neonatal disease include:

Targeted intravenous intrapartum antibiotic prophylaxis (IAP) has demonstrated efficacy for prevention of GBS early-onset disease (EOD) in neonates born to women with positive antepartum GBS cultures and women who have other risk factors for intrapartum GBS colonization. ...”

ACOG Guidelines for EOD Prevention

IAP INDICATED*

Maternal History

- Previous neonate with invasive GBS disease

Current Pregnancy

- Positive Maternal Screening Test: GBS+ by culture/NAAT at ≥ 36 0/7 weeks
- GBS bacteriuria in any trimester

Intrapartum

Unknown GBS status at onset of labor (GBS maternal screening not done or result not known) –AND– any of the following:

- Gestational age < 37 0/7 weeks
- Amniotic membrane rupture ≥ 18 hrs
- Maternal Fever: $\geq 100.4^{\circ}\text{F}$ ($\geq 38.0^{\circ}\text{C}$)**
- Intrapartum GBS NAAT result: positive
- Intrapartum GBS NAAT result: negative, but risk factors listed above develop
- Known GBS positive status in previous pregnancy

*Unless a cesarean birth performed before labor onset with intact amniotic membranes

**If intraamniotic infection is suspected, broad-spectrum antibiotic therapy that includes an agent known to be active against GBS should replace GBS prophylaxis

ACOG Guidelines for EOD Prevention

IAP NOT INDICATED

Maternal History

- GBS colonization during a previous pregnancy

Current Pregnancy

- Negative GBS status at $\geq 36\ 0/7$ weeks*
- Cesarean birth performed before labor onset with intact amniotic membranes, regardless of maternal GBS colonization status or gestational age

Intrapartum

- Negative GBS status at $\geq 36\ 0/7$ weeks, regardless of intrapartum risk factors
- Unknown GBS status at onset of labor, NAAT result negative and no intrapartum risk factors present, including:
 - Gestational age $< 37\ 0/7$ weeks
 - Amniotic membrane rupture ≥ 18 hrs
 - Maternal Fever: $\geq 100.4^{\circ}\text{F}$ ($\geq 38.0^{\circ}\text{C}$)

*Assuming last GBS testing was performed <5 weeks prior

ACOG Guidelines for EOD Prevention

Other specific scenarios covered in the ACOG Guidelines include:

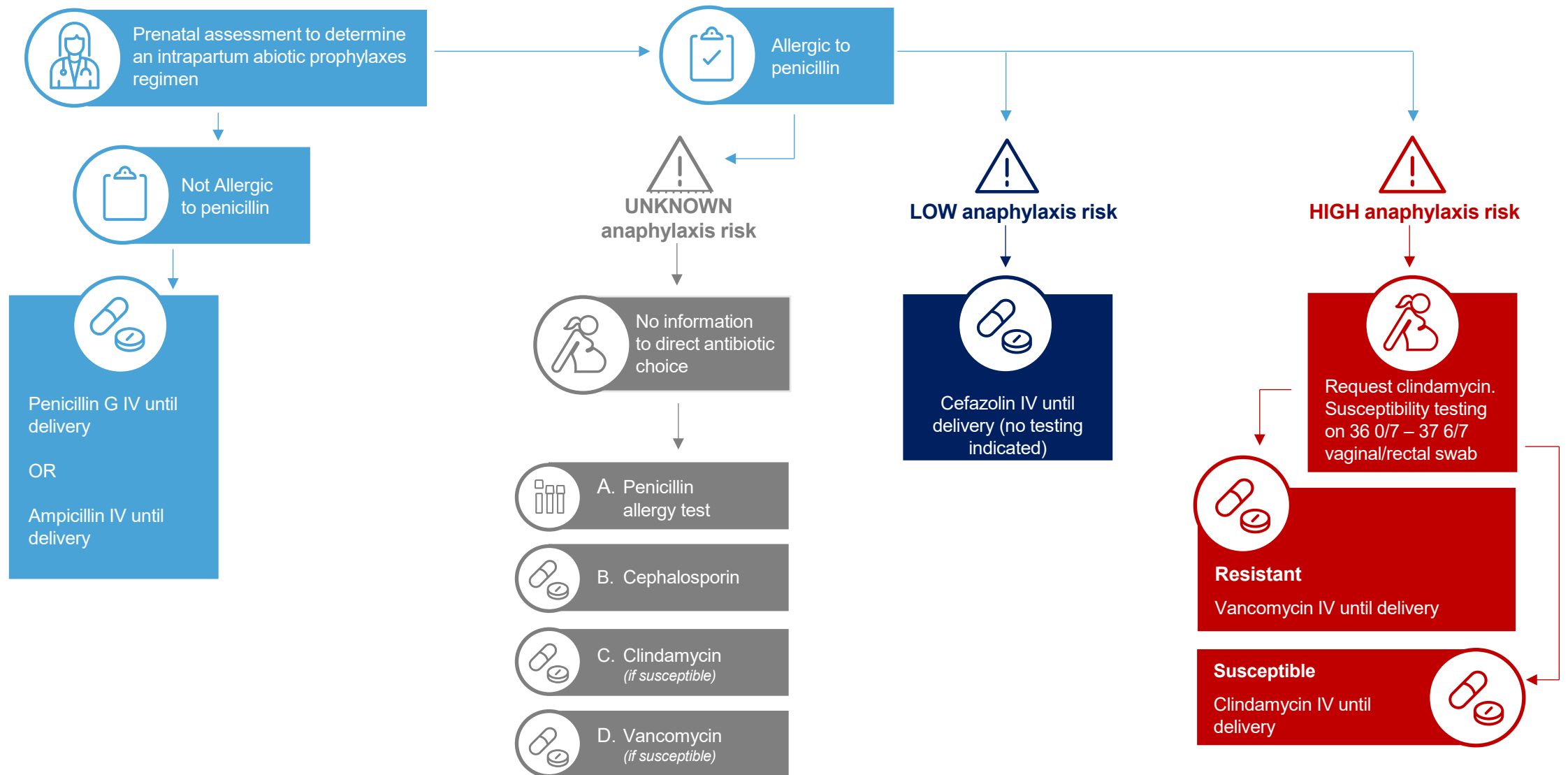
Management of
preterm labor

GBS bacteriuria
management


Management of
PPROM

Planned
cesarean birth

Recommended IAP Regimens



Penicillin Allergy and Anaphylaxis Risk

| Risk | Definition |
|--|---|
| Low Risk | <ul style="list-style-type: none"> • Nonspecific symptoms unlikely to be allergic (gastrointestinal distress, headaches, yeast vaginitis) |
| | <ul style="list-style-type: none"> • Nonurticarial maculopapular (morbilliform) rash without systemic symptoms* |
| | <ul style="list-style-type: none"> • Pruritis without rash |
| | <ul style="list-style-type: none"> • Family history of penicillin allergy but no personal history |
| High Risk  | <ul style="list-style-type: none"> • High risk for anaphylaxis: A history suggestive of an IgE-mediated event[†]: pruritic rash, urticaria (hives), immediate flushing, hypotension, angioedema, respiratory distress or anaphylaxis[‡] |
| | <ul style="list-style-type: none"> • Recurrent reactions, reactions to multiple beta-lactam antibiotics, or positive penicillin allergy test |
| | <ul style="list-style-type: none"> • High risk for severe non IgE-mediated reaction: Severe rare delayed-onset cutaneous or systemic reactions, such as eosinophilia and systemic symptoms/drug-induced hypersensitivity syndrome, Stevens-Johnson syndrome, or toxic epidermal necrolysis[§] |

ASM Laboratory Guidelines

“Guidelines for the Detection and Identification of Group B *Streptococcus*”

Laura Filkins, PhD, D(ABMM), et al.

Initial Release: March 10, 2020

Updated: July 23, 2021

ASM Guidelines for GBS Screening

Sections of Guidelines



Collection, storage, and transport

Maximize GBS recovery

1. Single swab, **dual site sampling vagina followed by rectum**
2. **Flocked swab** (vs fiber wrapped)
3. Transport in **non-nutritive liquid media**
4. Transport samples to lab **within 24 hrs**



Detection

Maximize GBS detection

1. Incubate in **selective enrichment** broth prior to plating or NAAT
2. Include both **hemolytic and non-hemolytic strains** in detection
3. **Report GBS in urine** at any quantity, any trimester



Identification

1. **NAAT-based identification** from enrichment broth is an acceptable identification method (reflex AST only as needed*)
2. Phenotypic and proteomic ID methods = CAMP test, latex agglutination, mass spectrometry
3. Latex agglutination direct from enrichment or direct-from-specimen are not acceptable



AST

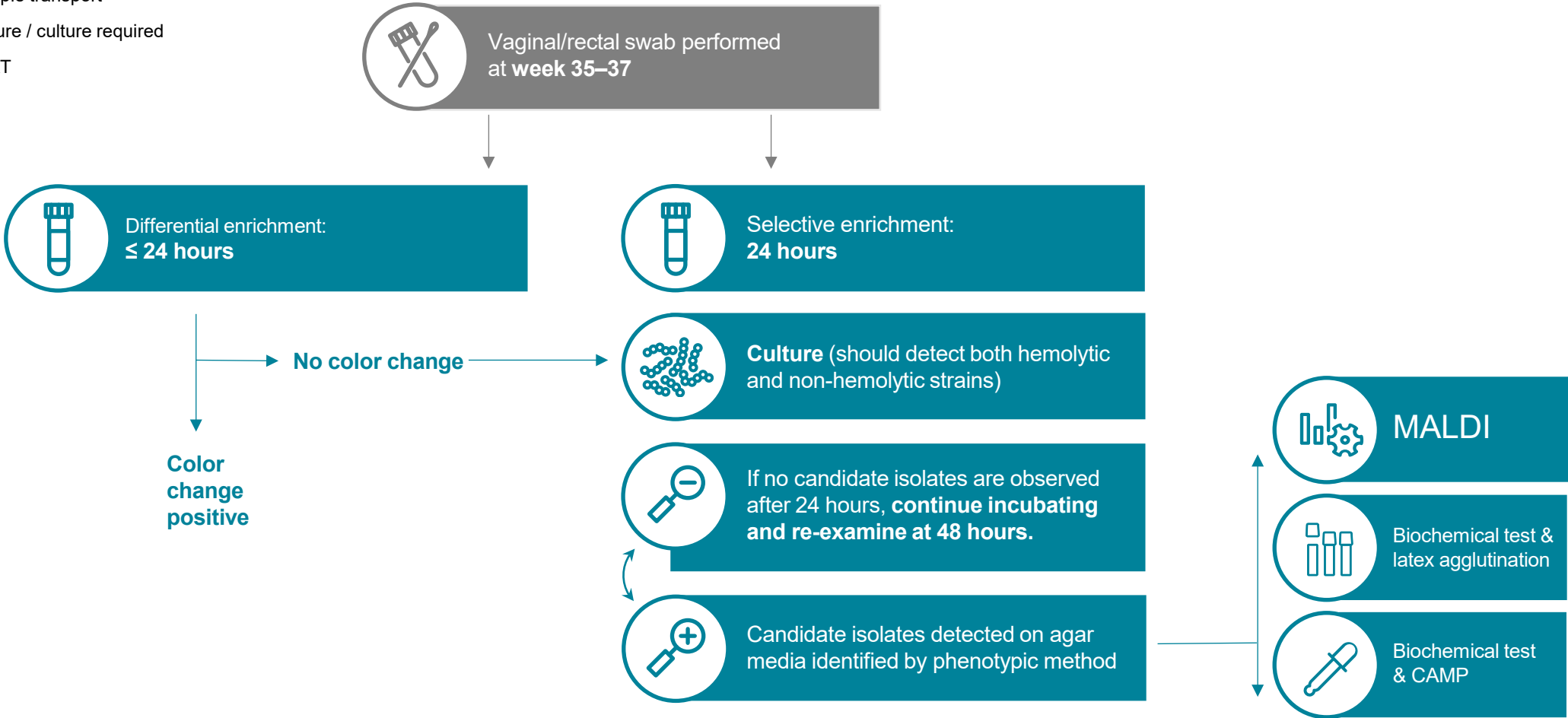
1. *Perform antimicrobial susceptibility testing (AST) on all GBS isolates from pregnant women with severe **penicillin allergy**
2. Clindamycin is the preferred antibiotic for women with severe penicillin allergy, but rates of resistance are rising, and **susceptibility should be confirmed to guide IAP**



Diagnostic Testing Methods

Traditional Culture Workflow

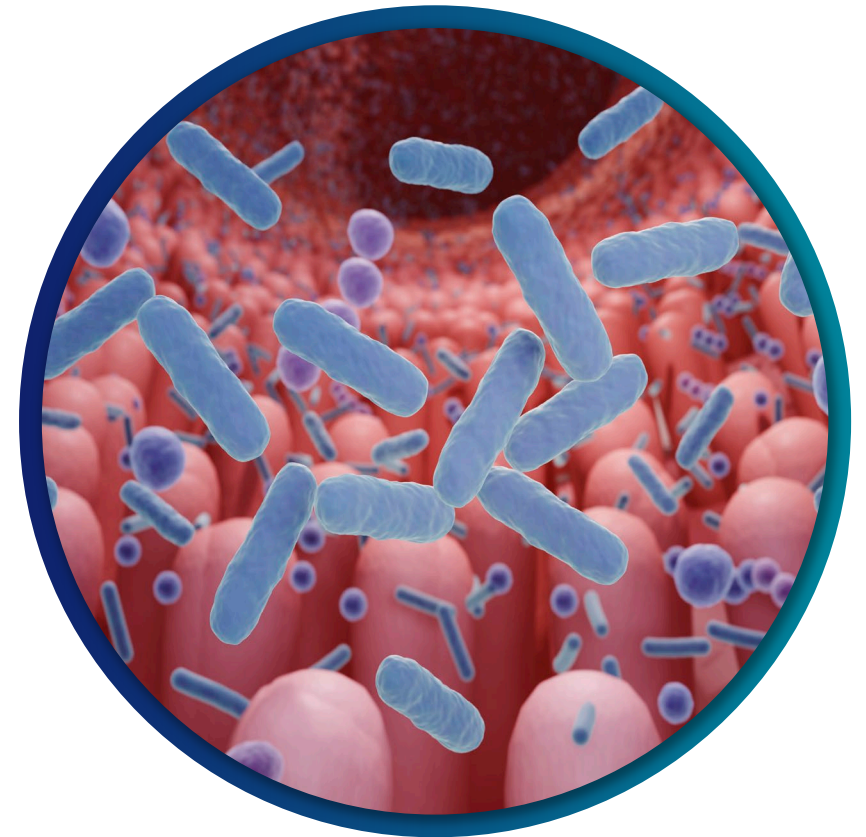
- Sample transport
- Culture / culture required
- NAAT



Filkins L, Hauser J, Robinson-Dunn B, Tibbetts R, Boyanton B, Revell P. Published 10 March 2020. Updated 23 July 2021. Guidelines for the Detection and Identification of Group B Streptococcus. American Society for Microbiology. <https://asm.org/Guideline/Guidelines-for-the-Detection-and-Identification-of->

Selective Enrichment

- Selective broths inhibit the growth of enteric organisms and some Gram-positive bacteria
- Recommended selective enrichment broths include:
 - Trans-Vag Broth (Todd-Hewitt broth with gentamicin and nalidixic acid)
 - Lim Broth (Todd-Hewitt broth with colistin and nalidixic acid)
- Despite being selective, other microorganisms commonly found in vaginal-rectal specimens may still grow³:
 - *Enterococcus faecalis*
 - Other *Streptococcus* species
 - Some strains of *Staphylococcus* and *Corynebacterium*
 - Resistant Gram-negative rods
 - Yeasts
- Recommended culture conditions in selective enrichment broth:
 - When collected with Eswab, inoculate 1:10-1:20 volumetric ratio of specimen to enrichment broth medium¹
 - Incubate for 18-24 hours at 35-37°C in ambient or 5% CO₂ conditions¹



Incubation in broth media increases sensitivity of screening methods **two-fold** compared to direct plating^{1,2}

¹ Filkins L, Hauser J, Robinson-Dunn B, Tibbetts R, Boyanton B, Revell P. Published 10 March 2020. Updated 23 July 2021. Guidelines for the Detection and Identification of Group B Streptococcus. American Society for Microbiology. <https://asm.org/Guideline/Guidelines-for-the-Detection-and-Identification-of-Group-B-Streptococcus>.
² Philipson E, Palermino D, Robinson A. 1995. Enhanced Antenatal Detection of Group B Streptococcus Colonization. *Obstet Gynecol* 3 Choi Y, Han HS, Chong GO, Le TM, Nguyen HDT, Lee OE, Lee D, Seong WJ, Seo I, Cha HH. Updates on Group B Streptococcus Infection in the Field of Obstetrics and Gynecology. *Microorganisms*. 2022 Dec

Culture on Solid Media After Selective Enrichment

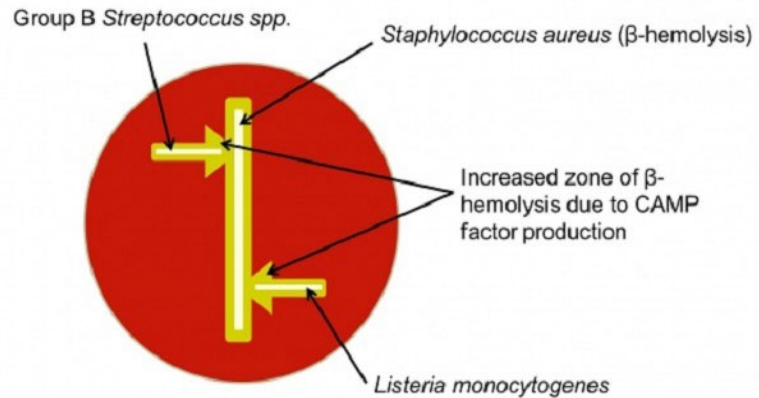
- **Acceptable agar media include¹:**
 - Tryptic Soy Agar or Columbia Agar with 5% Sheep's blood (Non-selective)
 - Columbia Agar with colistin and nalidixic acid (CNA) (Selective)
 - Differential Chromogenic medias
- **Selective medias further reduce growth of other flora making isolation of GBS easier¹**
- **Non-selective media may require higher number of candidate isolate screening¹**
- **Chromogenic medias facilitate GBS detection²**
 - Many chromogenic medias fail to identify non-hemolytic strains
 - Susceptibility testing cannot be performed from chromogenic media



With normal flora present, it may be difficult to identify GBS without differential media³

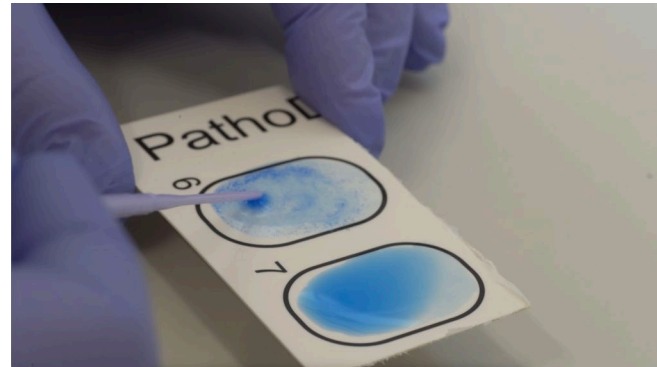
¹ Filkins L, Hauser J, Robinson-Dunn B, Tibbetts R, Boyanton B, Revell P. Published 10 March 2020. Updated 23 July 2021. Guidelines for the Detection and Identification of Group B Streptococcus. American Society for Microbiology. <https://asm.org/Guideline/Guidelines-for-the-Detection-and-Identification-of-> ² Smith D, Perry JD, Laine L, Galloway A, Gould FK. 2008. Comparison of BD GeneOhm realtime polymerase chain reaction with chromogenic and conventional culture methods for detection of group B Streptococcus in clinical samples. Diagn Microbiol Infect Dis 3 Morita T, Feng D, Kamio Y, Kanno I, Somaya T, Imai K, Inoue M, Fujiwara M, Miyauchi A. Evaluation of chromID strepto B as a screening media for Streptococcus agalactiae. BMC Infect Dis. 2014

Phenotypic Identification Methods of GBS from Culture



Christie, Atkins, Munch-Peterson (CAMP) reaction:¹

- Prior to MALDI-TOF was common identification method
- GBS isolates are CAMP positive and Catalase negative
- Increases time to results 18-24 hours²



Latex agglutination:³

- Detects groups of carbohydrate antigens known as Lancefield groups
- Performing PYR is recommended to distinguish from other *Streptococcus* spp.²



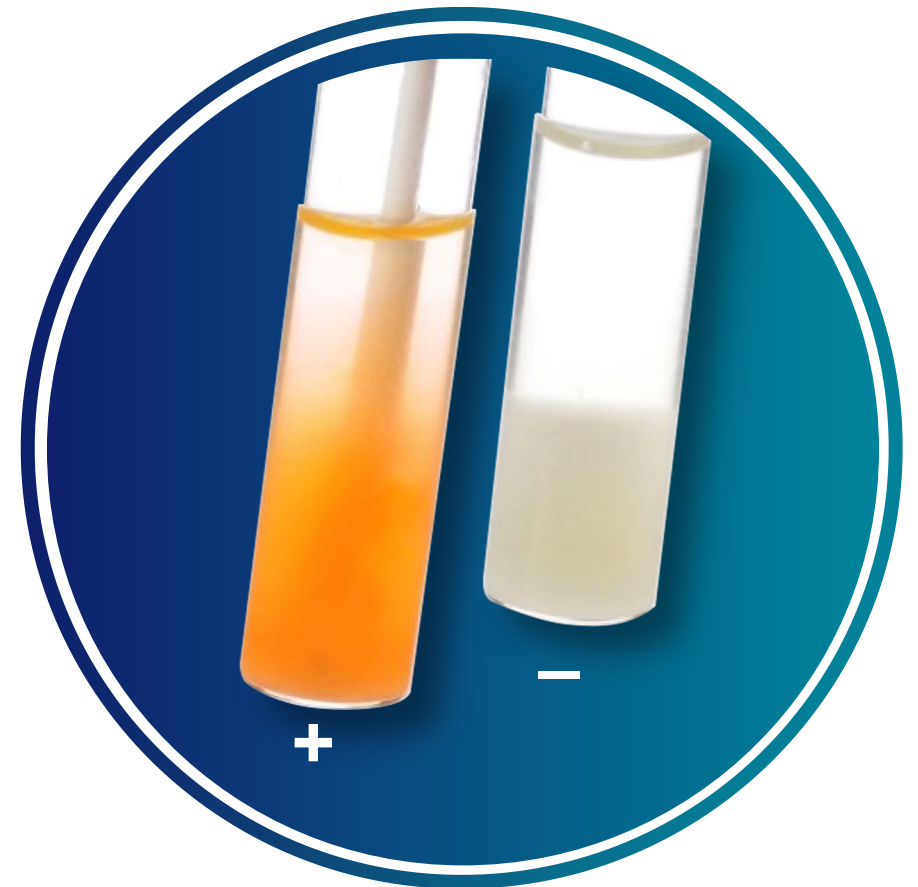
MALDI-TOF MS:²

- Most common method to identify GBS in culture

¹ Christie K, Atkins N, Munch-Petersen E. 1944. A note on a lytic phenomenon shown by group B streptococci. *Aust J Exp Biol Med Sci* 22:197–200. ² Filkins L, Hauser J, Robinson-Dunn B, Tibbetts R, Boyanton B, Revell P. Published 10 March 2020. Updated 23 July 2021. Guidelines for the Detection and Identification of Group B Streptococcus. American Society for Microbiology. <https://asm.org/Guideline/Guidelines-for-the-Detection-and-Identification-of-> ³ Lancefield RC. 1933. A Serological Differentiation of Human and Other Groups of Hemolytic Streptococci. *J Exp Med* 57:571–595.

Differential Enrichment Medias

- **Types of broth enrichment medias:**
 - Granada liquid biphasic broths
 - Carrot Broth™ OneStep
- **Differential Enrichment medias change pigment to orange-red in presence of hemolytic GBS**
- **No pigment change is observed if GBS is not present OR non-hemolytic strain of GBS (5-6%)¹**
- **Broth with no pigment change are subcultured to solid media after 24 hours of incubation to look for non-hemolytic strains**
- **Pigment change for positive results observed within 6-24 hours²**



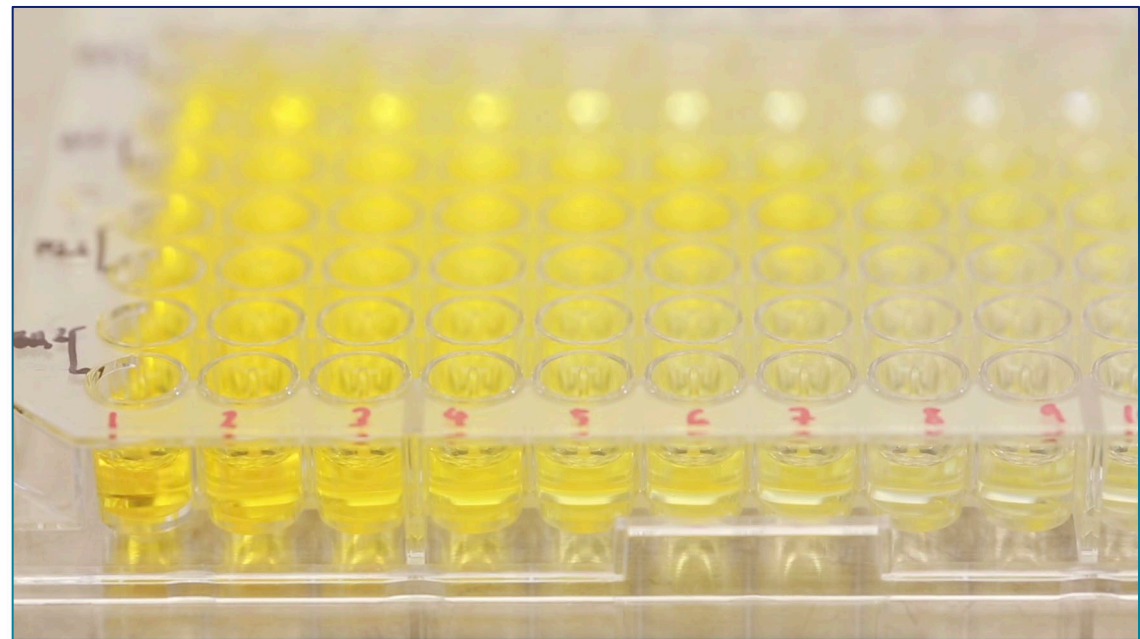
GBS Susceptibility Testing Methods

Susceptibility testing is only performed for those with high risk of anaphylaxis

Disk Diffusion



Broth Microdilution

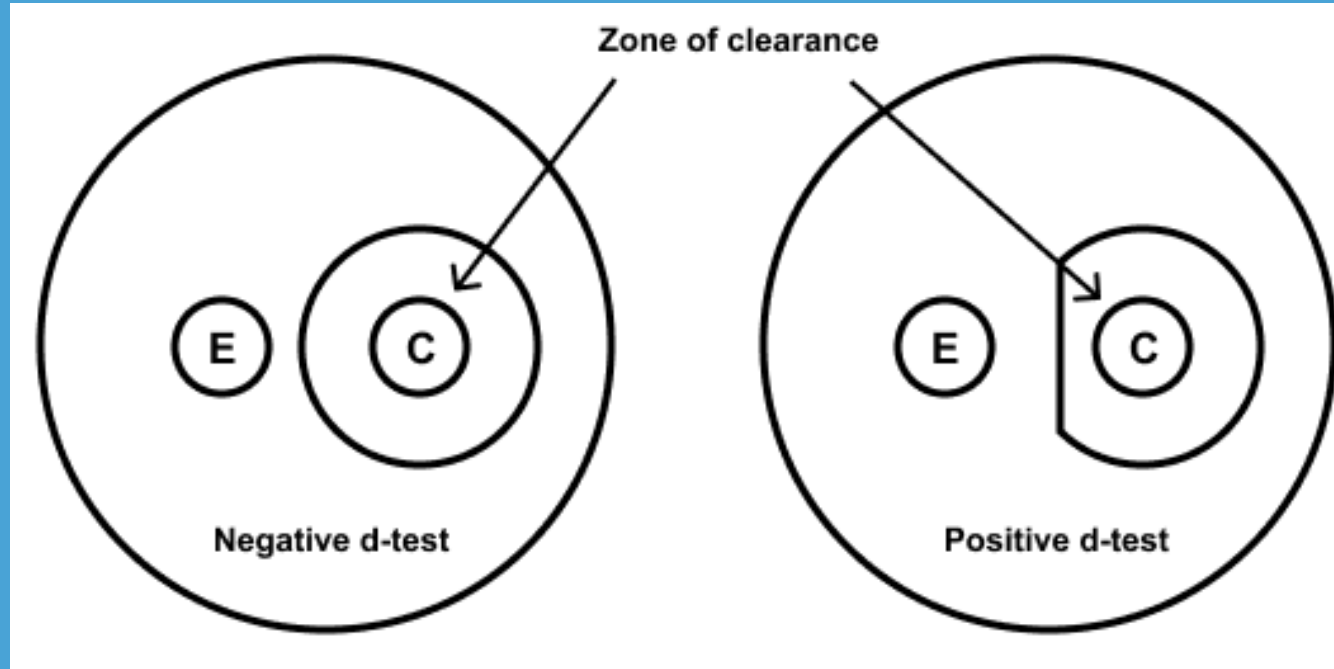


Macrolide Induced Clindamycin Resistance

- In those with high risk of anaphylaxis, Erythromycin and Clindamycin should both be tested
- Erythromycin is NOT reported
- Isolates testing Erythromycin resistant and Clindamycin susceptible or intermediate should be tested for Macrolide Induced Clindamycin resistance
- Methods to test for Macrolide Induced Clindamycin resistance include:
 - D-Zone test
 - Broth microdilution
 - FDA-cleared automated AST methods
- Isolates positive for Macrolide Induced Clindamycin resistance should be reported as resistant

D-Zone test

E = Erythromycin
C = Clindamycin



Zone of bacterial killing maintained,
Negative D-Test:
No inducible resistance

Modified zone of bacterial killing
Positive D-Test:
Inducible resistance present

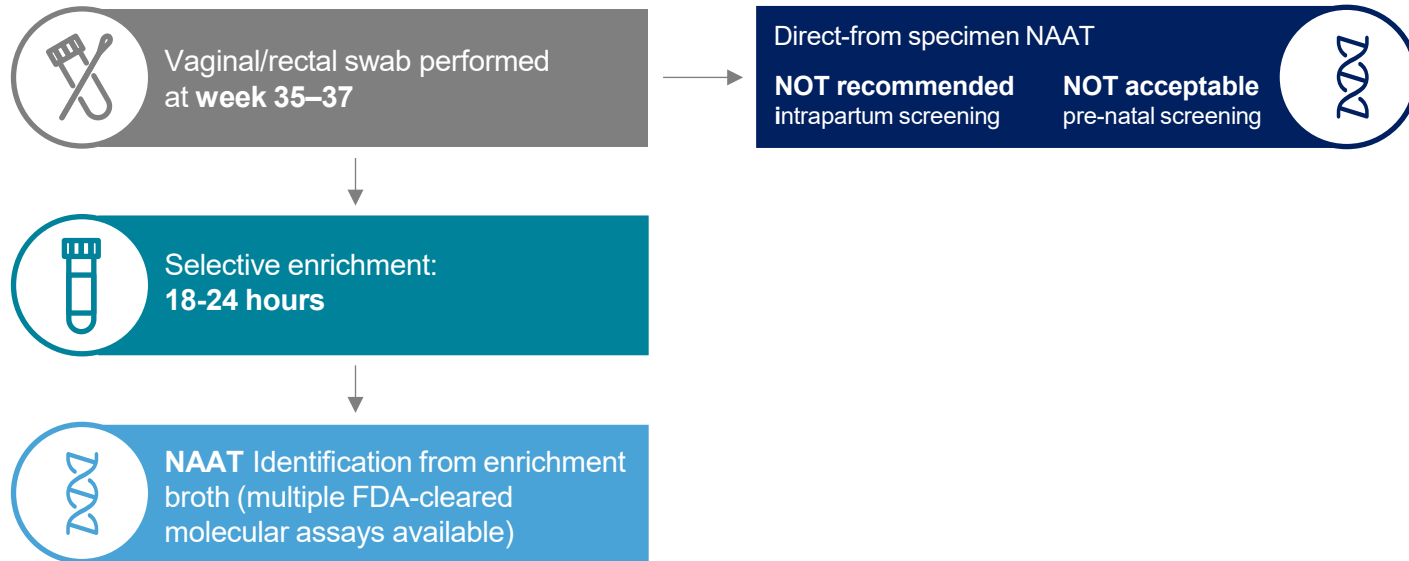
Global Patterns of Antibiotic Resistance in GBS

| Antibiotic | Susceptibility Rate (%) ^{1,2} |
|--------------|--|
| Penicillin | 98.6 - 100 |
| Vancomycin | 98.7 - 100 |
| Erythromycin | 49.5 - 51.7 |
| Clindamycin | 62.8 - 72.1 |

¹ Hsu CY, Moradkasani S, Suliman M, Uthirapathy S, Zwamel AH, HJazi A, Vashishth R, Beig M. Global patterns of antibiotic resistance in group B Streptococcus: a systematic review and meta-analysis. Front Microbiol. 2025 2 Berg BR, Houseman JL, terSteege ZE, LeBar WD, Newton DW. Antimicrobial susceptibilities of group B streptococcus isolates from prenatal screening samples. J Clin Microbiol. 2014

NAAT Workflow

- Sample transport
- Culture / culture required
- NAAT







*“After consensus or discrepancy analysis, **NAATs demonstrate improved detection of GBS** from enrichment broth culture of screening specimens. **Molecular assays typically require less than 5 minutes of hands-on-time** for a single sample and **sample batching increases efficiency.**”*

–Filkins et. al

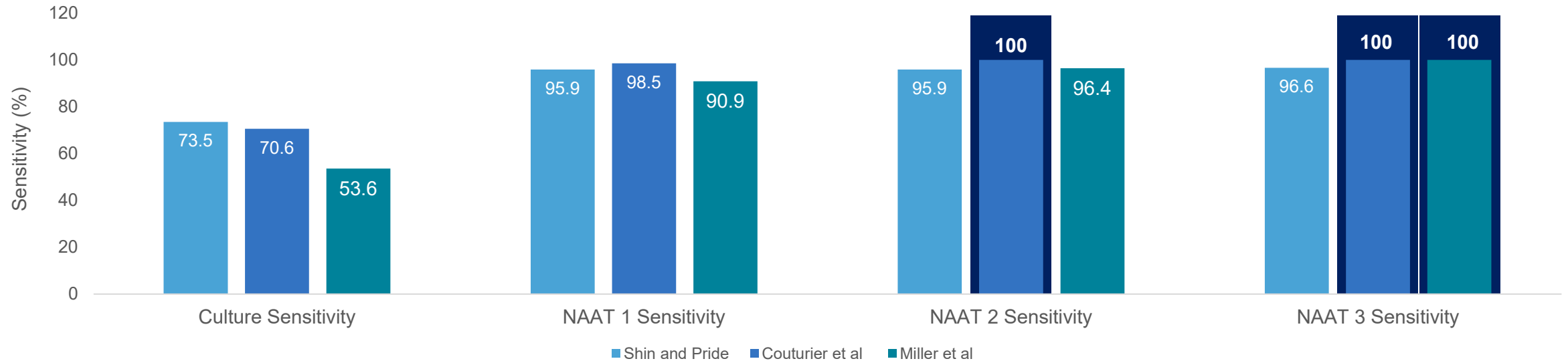
Comparison of Three NAAT and Culture for Detection of GBS from Enrichment Broth

Study shows highly sensitive PCR NAATs are a preferred method for prenatal GBS screening¹

| Clinical Sensitivity (95% CI) | | False Negatives | | | |
|-------------------------------|-------|---|---|---|---|
| Culture | 73.5% | 39 / 147 | 6 / 147 | 6 / 147 | 5 / 147 |
| Panther Fusion® GBS Assay | 95.9% |  |  |  |  |
| GeneXpert® GBS Assay | 95.9% | | | | |
| Aries® GBS Assay | 96.6% | Culture | Panther Fusion® GBS Assay | GeneXpert® GBS Assay | Aries® GBS Assay |

¹Shin JH and Pride DT. Comparison of Three Nucleic Acid Amplification Tests (NAATs) and Culture for Detection of Group B Streptococcus (GBS) from Enrichment Broth. J Clin Microbiology. 2019;57(6):e01958-18.

Culture vs NAAT Study – Consistent Findings

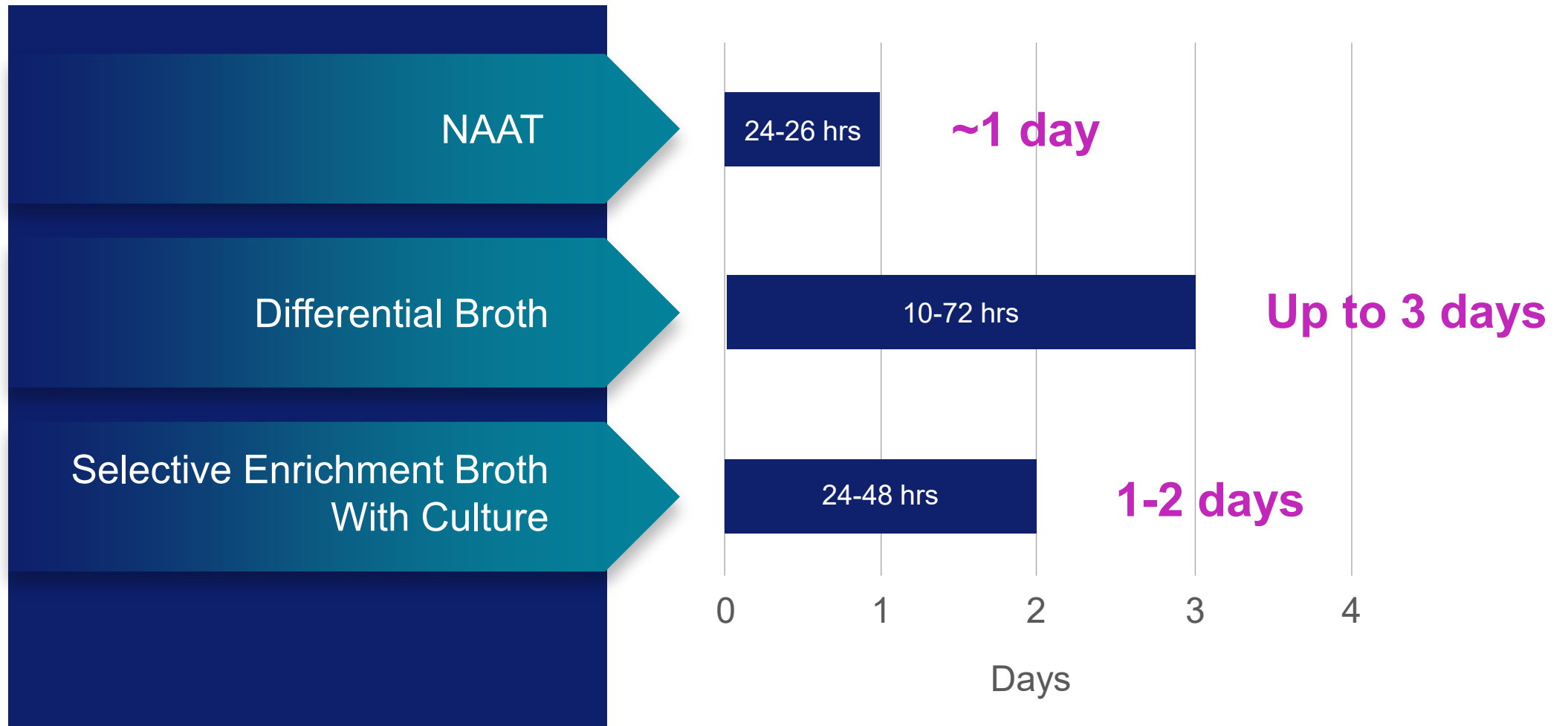


Collectively, these studies highlight the **underestimation of GBS colonization using culture methods.**

With better GBS detection than culture, **NAAT-based screening has the potential to significantly reduce the neonate morbidity and mortality associated with EOD.**¹⁻³

1. Shin JH and Pride DT. Comparison of Three Nucleic Acid Amplification Tests (NAATs) and Culture for Detection of Group B Streptococcus (GBS) from Enrichment Broth. J Clin Microbiology. 2019;57(6):e01958-18. 2. Couturier BA, Weight T, Elmer H, Schlager R. Antepartum screening for group B Streptococcus by three FDA-cleared molecular tests and effect of shortened enrichment culture on molecular detection rates. J Clin Microbiol. 2014 Sep;52(9):3429-32. 3 Miller SA, Deak E, Humphries R. Comparison of the AmpliVue, BD Max System, and illumigene Molecular Assays for Detection of Group B Streptococcus in Antenatal Screening Specimens. J Clin Microbiology. 2015; 53 (6):1938-1941.

Estimated Turn-around Times by Screening Methods¹

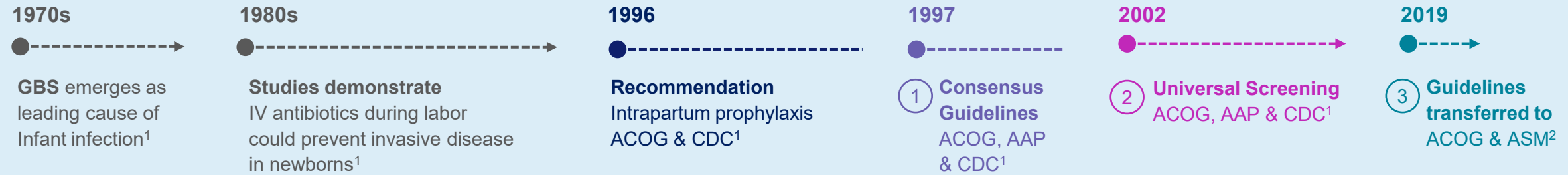


Filkins L, Hauser J, Robinson-Dunn B, Tibbetts R, Boyanton B, Revell P. Published 10 March 2020. Updated 23 July 2021. Guidelines for the Detection and Identification of Group B Streptococcus. American Society for Microbiology. <https://asm.org/Guideline/Guidelines-for-the-Detection-and-Identification-of->

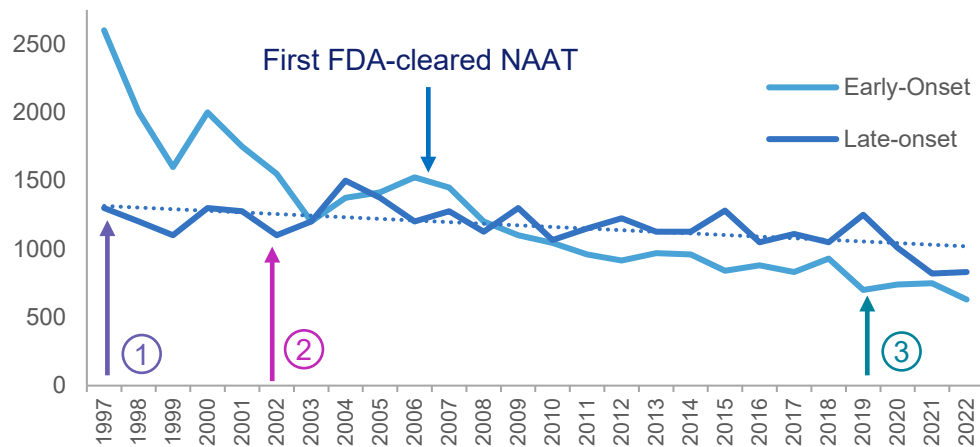


GBS Screening Success Stories

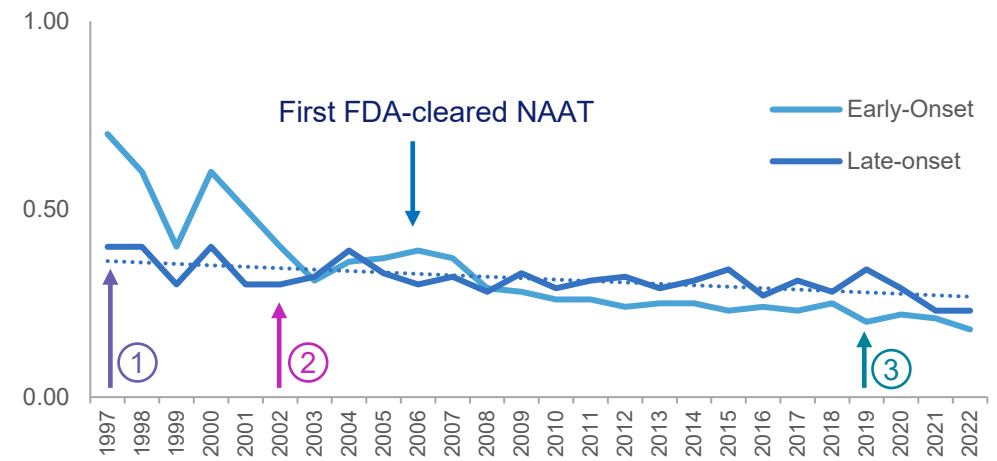
GBS Screening: Implementation Success in the US



Estimated Total GBS infections Early – and Late-Onset³



Rates of GBS Early – and Late-Onset infections per 1,000 births³



1. Verani JR et al. Prevention of perinatal group B streptococcal disease—revised guidelines from CDC, 2010. *MMWR Recomm Rep.* 2010 Nov 19;59(RR-10):1-36. 2. Filkins L, Hauser J, Robinson-Dunn B, Tibbetts R, Boyanton B, Revell P. Published 10 March 2020. Updated 23 July 2021. Guidelines for the Detection and Identification of Group B Streptococcus. American Society for Microbiology. <https://asm.org/Guideline/Guidelines-for-the-Detection-and-Identification-of-> 3. CDC. Active Bacterial Core Surveillance (ABCS). Published May 22, 2024. Accessed February 4th, 2026. . <https://www.cdc.gov/abcs/reports/>

GBS Screening: Implementation Success in the US

“The adoption of universal screening protocols,
led to an impressive **80% reduction of
early-onset GBS disease in newborns.**”¹

GBS Screening: Implementation Success Globally

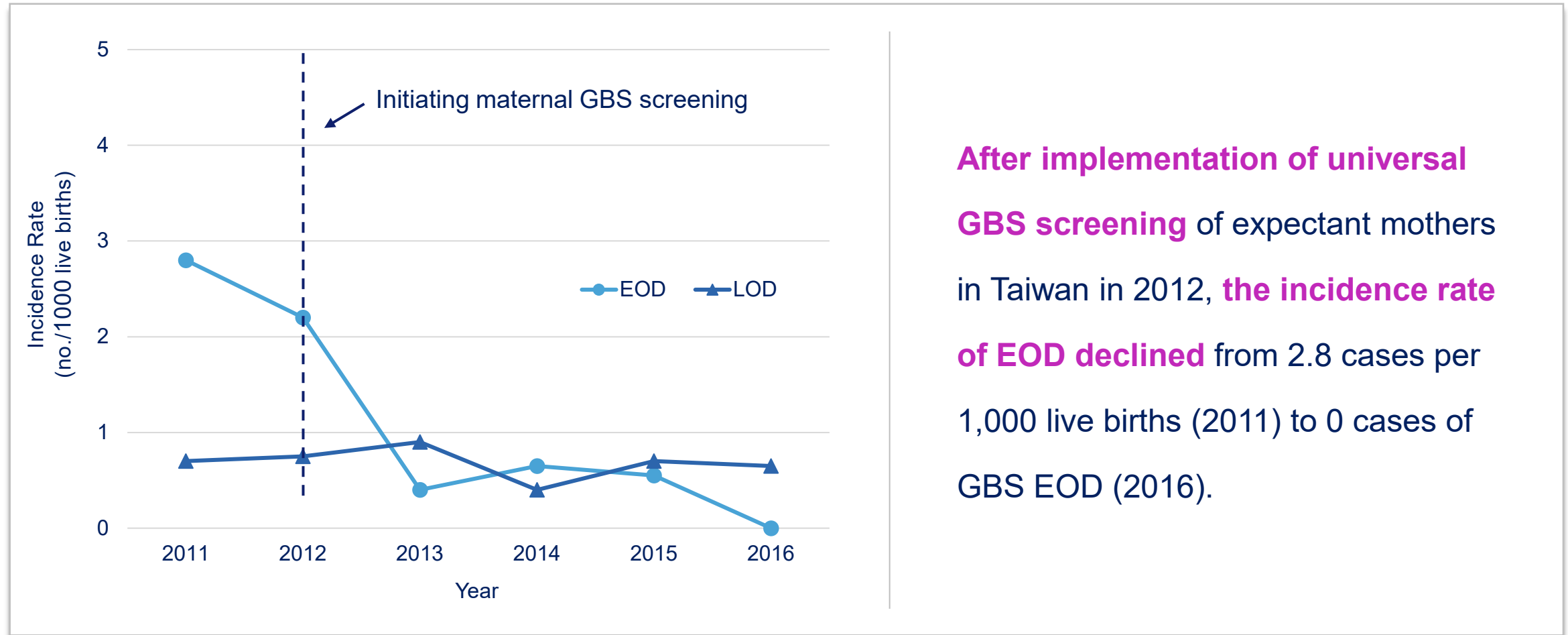
Australia and UK

| Period before implementation of GBS screening (IAP used per risk-based strategy only): | Period after implementation of GBS screening: |
|---|---|
| <p>AUS¹</p> <ul style="list-style-type: none"> • 1994 – 2002 • GBS EOD Rate of 0.84 / 1,000 live births | <ul style="list-style-type: none"> • 2004 – 2006 • GBS EOD Rate of 0.00 / 1,000 live births in the screening group • ZERO cases of GBS EOD in 8,303 live births |
| <p>UK²</p> <ul style="list-style-type: none"> • 2009 – 2013 • GBS EOD Rate of 0.99 / 1,000 live births | <ul style="list-style-type: none"> • 2014 – 2015 • GBS EOD Rate of 0.16 / 1,000 live births in the screening group • 5X lower rate of GBS EOD |

1. Angstetra, D., Ferguson, J. and Giles, W.B. (2007), Institution of universal screening for Group B streptococcus (GBS) from a risk management protocol results in reduction of early-onset GBS disease in a tertiary obstetric unit. Australian and New Zealand Journal of Obstetrics and Gynaecology, 47: 378-382. 2. Gopal Rao G, Nartey G, McAree T, et al. Outcome of a screening programme for the prevention of neonatal invasive early-onset group B Streptococcus infection in a UK maternity unit: an observational studyBMJ Open 2017;7:e014634.

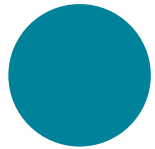
GBS Screening: Implementation Success Globally

Taiwan

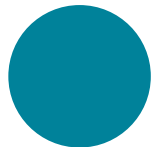


After implementation of universal GBS screening of expectant mothers in Taiwan in 2012, the incidence rate of EOD declined from 2.8 cases per 1,000 live births (2011) to 0 cases of GBS EOD (2016).

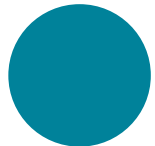
Key Takeaways



GBS infections can have **serious, long-term negative health consequences** for mothers and newborns, including EOD.



IAP is an effective intervention to prevent EOD in neonates.



The CDC, ACOG, AAP, ASM **endorse universal GBS screening of pregnant women** to inform IAP use and aid in the prevention of neonatal EOD.



With better detection than culture, NAAT-based screening has **the potential to reduce neonate morbidity** and mortality associated with EOD.¹



Implementation of universal GBS screening in pregnant women has **successfully decreased the burden of EOD** in many countries.