



Culture-based versus risk-based screening for the prevention of group B streptococcal disease in newborns: A review of national guidelines



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ABSTRACT

Background: Maternal colonisation with group B streptococcus (GBS) is recognised as the most frequent cause of severe early onset infection in newborns. National and international guidelines outline two approaches to the prevention of early onset disease in the neonate: risk based management and antenatal culture-based screening. We undertook an analysis of existing national and international guidelines in relation to GBS in pregnancy using a standardised and validated instrument to highlight the different recommended approaches to care.

Methods: English language guidelines on the screening and management of GBS colonisation in pregnant women and the prevention of early-onset group B streptococcal disease in newborns were sought.

Results: Four guidelines met the inclusion criteria, one from the United States of America (USA), the United Kingdom (UK), Canada and New Zealand. All four were appraised as at a high standard in terms of development using the AGREE II tool. Both approaches were recommended in the guidelines with different regions of the world advocating different approaches often based on the same evidence. Guidelines from the USA recommend an antenatal culture-based approach while the UK guidelines recommend risk-based management.

Conclusion: Based on an AGREE II analysis, the standard of the guidelines was high despite having disparate recommendations. Both approaches to the prevention of early onset GBS infection in neonates are recommended with the split being geographically-based.

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1. Introduction

Group B streptococcus (GBS) is a Gram positive bacterium (*Streptococcus agalactiae*)¹ found primarily in the vagina, gastrointestinal tract and urethra.² The bacterium can cause serious illness in infants and the elderly.³ GBS colonisation is not always pathogenic² though it can lead to aggressive infections in adults.^{4,5}

The highest incidence of GBS infection is in young infants and it is a significant cause of morbidity and mortality in newborns.³ Neonatal early onset (less than 7 days of age) group B streptococcal disease (EOGBSD) is a major cause of serious infection, mostly (90%) occurring in the first 24 h of life.^{3,6} EOGBSD is characterised by rapid deterioration of the neonate demonstrating mainly

respiratory, cardiovascular, and neurological symptoms.⁷ Maternal colonisation of GBS in the lower genital tract during pregnancy increases the risk of neonatal infection by vertical transmission during labour and birth especially following rupture of the membranes,^{4,6} and preterm infants are at higher risk of infection.⁸ Without prophylactic intervention, the incidence of EOGBSD in Australia, the United States and Western Europe has been estimated at between 0.4 and 4 per 1000 live births.^{9–11} Though not as well understood as early-onset GBS disease, late-onset GBS disease occurring in infants greater than 7 days of age, occurs less often and is less often fatal when compared with early infection.¹²

Maternal colonisation rates of GBS during pregnancy vary between 10 and 30%.^{7,13} Approximately 40–50% of babies born to colonised mothers will become colonised with GBS.¹⁴ A systematic review of studies reporting maternal vaginal GBS colonisation rates in European countries found that rates ranged from 6.5% (Southern Europe) to 36% (Scandinavia).^{14,15} One third of studies reported rates of 20% or greater. A diagnostic cohort study involving 865 low risk women in South Australia found that 20% of their sample had a

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positive vaginal swab for GBS¹⁶ and in Newcastle, New South Wales, 24% of women giving birth in 2004 tested positive for GBS.¹⁷ Small studies in the United Kingdom (UK) and New Zealand (NZ) identify colonisation rates of 19%¹⁸ and 20%¹⁹ respectively.

Colonisation may also be transient. While culture-based screening in labour would be ideal, until a suitable rapid test is available, screening between 35 and 37 weeks gestation correlates best with colonisation status at time of labour.^{2,4} For example, one study compared a risk-based approach with culture-based screening at two gestations (31–33 versus 35–37 weeks).¹⁶ This found that a culture conducted at 36 weeks had the highest test characteristics (sensitivity 81%, specificity 93%, positive predictive value 77% and negative predictive value 94%). In colonised women, the intensity of colonisation is directly related to the risk of transmission to the neonate.²⁰ GBS bacteriuria reflects heavy colonisation²¹ and increases the risk of GBS disease in the neonate.²² Early neonatal colonisation risk is increased if there has been prolonged rupture of membranes (>18 h), maternal intrapartum pyrexia, chorioamnionitis or a previous infant with GBS infection, low birth weight or prematurity (<37 weeks).²² Although approximately 70% of cases of EOGBSD are in term babies (≥37 weeks gestation), mortality case-fatality rates of approximately 20% have been documented in preterm infants, compared with 2–3% in term infants.^{1,23} In a population-based study in the United States of America (USA), the mortality rate for preterm infants with EOGBSD was 23% highlighting the risks for this group.²⁴

Prophylaxis strategies for GBS have become commonplace in many maternity systems, though strategies for screening and treatments have differed. Until 1996, two approaches, that is, risk-factor based and universal culture-based screening, were recommended in guidelines from the Centers for Disease Control (CDC) in the USA as there was insufficient evidence to recommend one approach over the other. In 2002, the CDC guidelines were reviewed in response to further evidence demonstrating that the risk of EOGBSD was significantly lower among the infants of universally screened women than among those in the risk-based group.²⁵ Further revision of CDC guidelines in 2010 concentrated upon a preterm labour algorithm, laboratory methods, and antibiotic administration with regard to dosages and alternatives when maternal allergy is present.³

Across Australia, there are differences in practice and position in relation to the prevention of EOGBSD. The only national document is a College Statement from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists.²⁶ This provides both options stating that guidelines for prevention of early onset neonatal GBS have recommended either a risk-based or culture-based screening approach (at 35–37 weeks) to identify pregnant women for intrapartum antibiotic prophylaxis.

Specific protocols or policies exist in Victoria, NSW, South Australia, Queensland and Western Australia (Table 1). Victoria recommends that a protocol for preventing EOGBS should be consistently followed²⁷ and that prevention strategies for EOGBS should be included in routine antenatal care using either bacteriological screening strategies or risk based treatment strategies. South Australia does not have a specific policy for the prevention of EOGBSD referring to the policy for normal labour and birth.²⁸ In Queensland, a risk based approach is recommended.²⁹ Western Australia has taken a culture-based screening approach recommending that all antenatal women should be offered screening at 35–37 weeks gestation for rectovaginal GBS colonisation via a low vaginal and a rectal swab.³⁰ In the Australian Capital Territory, a culture-based screening approach – ‘a low vaginal swab is offered to all women at 36 weeks’ (page 31) is recommended.³¹

Given these differences across the country, we undertook an analysis of formal international guidelines using the Appraisal of Guidelines for Research and Evaluation (AGREE II)³² Instrument.

2. Methods

International guidelines and guidelines of national professional bodies were sought from the following countries: Australia, USA, the United Kingdom (UK), Ireland, Canada, New Zealand (NZ), and major European countries. The analysis of the guidelines was based on two factors: Recommendation for Screening and the Recommendation for Management.

2.1. Definition of a guideline

The purpose or function of a clinical guideline is to assist practitioners and patients in making appropriate decisions relating to healthcare for specific clinical circumstances. Guidelines should be systematically developed, describe appropriate care based on relevant evidence with a broad consensus in the development process, taking into account justifiable variations in practice due to organisational and community characteristics.^{33,34} Guidelines provide a framework for audit and evaluation of care thus supporting quality assurance.³³ The purpose and content of the guideline should be explicit, clearly defining the health problem, the patient population and target users, and outcomes and evidence used to formulate the recommendations.³⁵ We therefore defined a guideline as including clinically relevant questions, a structured search of the literature, a detailed critical appraisal and recommendations for management. We were most interested in countries that were similar to Australia in terms of their availability and delivery of healthcare.

Table 1
Table of guidelines from Australian states and territories.

| No | State or territory | Year updated | Entity | Title | Approach recommended |
|----|------------------------------|--------------|---|--|---|
| 1 | NSW | 2005 | NSW Health | Policy directive: Neonatal minimisation of early onset group B streptococcal (EOGBS) infection ⁴³ | Either approach acceptable |
| 2 | Victoria | 2010 | The 3Centres Collaboration | Prevention of Early Onset Group B Streptococcus Disease ²⁷ | Does not state which approach should be used. |
| 3 | South Australia | 2012 | SA Health | Normal pregnancy, labour and puerperium management ²⁸ | Does not state which approach should be used. |
| 4 | Queensland | 2010 | Qld Health | Early onset Group B streptococcal disease ²⁹ | Risk-based approach |
| 5 | Western Australia | 2010 | Women and Newborn Health Service, King Edward Memorial Hospital | Group B Streptococcal Disease: Clinical Guideline ³⁰ | Screening approach |
| 6 | Australian Capital Territory | 2010 | ACT Health Maternity Shared Care Guidelines | Maternity Shared Care Guidelines ³¹ | Screening approach |
| 7 | Tasmania | | | No specific guideline found | |
| 8 | Northern Territory | | | No specific guideline found | |

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