Public Health England

Protecting and improving the nation's health

UK Standards for Microbiology Investigations

Review of Users' Comments received by Working Group for Microbiology Standards in Clinical Bacteriology

B 58 Detection of Carriage of Group B Streptococci

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Recommendations are listed as ACCEPT/ PARTIAL ACCEPT/DEFER/ NONE or PENDING

1st Consultation 18.08.14 – 22.09.14

Version of document consulted on – B 58do+

PROPOSAL FOR CHANGES

Comment Number	1		
Date Received	19/09/2014	**Stakeholder Group**	Group B Strep Support
Section	Various		
Comment			

a. Page 7/19 – Colonisation.

   What evidence has been used to support the change of carriage rates for the UK from up to 30% in the previous document to up to 20% in this? Daniels et al (2011 Intrapartum tests for GBS accuracy) found 21% (range 19-24%). Unpublished information provided to Group B Strep Support (GBSS) would suggest the 'up to 30%' statement is true for the UK.

b. Page 7/19 - Infection - Para 1

   Suggest rewording the first sentence to say "Although GBS colonisation is not associated with disease in non-pregnant women, GBS can cause infection including bacteraemia, in pregnant women". As the statement in your draft was written, it implies that pregnant women are not healthy. It is also important to include bacteraemia as well as infection in this statement.

c. Page 7/19 – Infection.

   This section no longer includes the rate of GBS infection in babies. The previous version stated ... enhanced surveillance was undertaken in conjunction with the British Paediatric Surveillance Unit (London). The surveillance showed an incidence of 0.74 cases per 1000 live births and a mortality rate of 9.7%. The predominant GBS serotypes were III, Ia and V. This is important information and should be included.

d. Page 8/19 – Infection. Final paragraph in this section

   2nd sentence: please change to say, "However, according to local protocols, women whose babies are judged clinically to be at high risk for the development of group B Streptococcal infection may be investigated for carriage."

e. Page 8-9/19 - Method of Investigation.

   If the statement "However, this enrichment broth is not totally selective for GBS, and other Gram positive cocci may be enriched by this method, possibly hiding GBS and leading to false negative results" is to be included, references are needed to support it, including the parameters of the likelihood of this happening and how the enriched culture method compares with a) the non-enriched culture method and b) the currently recommended risk based approach for false positive & false negative results.

f. Page 9/19 – Treatment.

   The section on treatment has been removed and should be reinstated. This is important in putting the SMI in context. The text should be expanded to include

reference to the National Institute for Health and Care Excellence (NICE) Antibiotics for Neonatal Infection guideline which was published August 2012.

g. Page 11/19 - Optimal Time and Method of Collection. The 5th paragraph refers to cultures being taken at 35-37 weeks of pregnancy.

   Although this is internationally recognised as the optimal time for samples to be taken for national screening programmes, some clinicians may wish to test women earlier, eg if the woman's at high risk of preterm labour, or indeed later. A statement needs to be included so that these groups are not excluded.

h. Page 14/19 - Antimicrobial Susceptibility Testing.

   This section should be expanded to state that antimicrobial susceptibility testing is always necessary as there is growing problem of clindamycin resistance and clindamycin has been recommended for penicillin allergic patients.

i. Page 16/19 - Appendix: Detecting method for Group B Streptococci Antimicrobial susceptibility testing has been left out of the flow-diagram. Please include it.

Evidence

Quoted in the above

Financial Barriers

None.

Health Benefits

Updating this SMI as described may help health professionals to improve the detection of group B Streptococcal carriage in pregnant women. Using this method, rather than the method described in UK SMI B 28 – *Investigation of genital tract and associated specimens* to investigate Group B Strep carriage, will enable significantly more accurate detection and thereby provide better information to the clinicians and the pregnant woman to inform her and her baby's care. Provided this method of testing is made available within the NHS for health professionals to access for pregnant women in their care, it will result in greater prevention of early-onset group B Strep infections in babies, which will save lives, prevent disability, reduce anxiety and reduce the costs associated with preventable group B Strep infection.

Recommended Action	a. **ACCEPT** The section has been amended with an additional reference. b. **ACCEPT** Amendments made. c. **ACCEPT** The incidence rate stated by The British Paediatric Surveillance Unit (BPSU) study has been re-inserted. d. **NONE** The paragraph has been removed. e. **NONE**

	The paragraph has been removed. f. **NONE** Recommendations on treatment is outside the scope of this SMI. g. **NONE** The sentence has been removed. h. **NONE** This is standard text for all SMIs. i. **NONE** It is not our practice to include susceptibility testing in the flowchart.

Comment Number	2		
Date Received	22/09/2014	**Professional Body**	UK National Screening Committee
Section	Pages 7-11		
Comment			

a. Scope [Page 7]

Acknowledgement of the screening recommendation is welcome. The aim of operating within the clinical guidance from the Royal College of Obstetricians and Gynaecologists (RCOG) and the National Institute for Health and Care Excellence (NICE) is appropriate for a document of this type and status. However the statement on 'clinical indications or when the test is requested' and recommendations later in the document are problematic in relation to this aim. It is also unclear how this SMI will be used in conjunction with other SMIs. If the changes we suggest are made, then the B28 - *Investigation of genital tract and associated specimens* would also have to be amended in order to align and present a consistent message.

b. Infection [page 7]

It would be useful to indicate the incidence of maternal and neonatal infection to put this into context; both are rare when the number of women who carry GBS is considered. An appropriate figure to cite would be from the British Paediatric Surveillance Unit surveillance study. The overall EOGBS rate of 0.48 / 1000 could be given along with the rate in term babies (~0.33 / 1000) to emphasise the point made about incidence rising with decreasing birth weight and prematurity.

c. “In addition stillbirths and premature delivery have also been attributed to GBS”. [page 7]

This sentence should acknowledge that the association between GBS carriage and preterm birth is uncertain and is still debated.

d. Infection [page 8] “In the UK, routine antenatal screening……”

Current guidance from RCOG and NICE does not identify any clinical indications for which an Enrichment Culture Medium (ECM) test for GBS is recommended. The risk factors mentioned in the cited paragraph are addressed in these guidelines and have been discussed in another Public Health England document (ref 7) as candidate sub-populations for ECM testing. This document should provide a more prominent point of reference in the further consideration of the purpose of this SMI. Other risk groups for which an ECM test may be indicated should be identified and the evidence base for its use referenced.

The note about local protocols ignores national guidelines, which should take precedence in an SMI. The protocols are mentioned as exceptions to national guidance but are not referenced or explored in terms of the relevant risk groups or the evidence base.

Reference 4 is the UK National Screening Committee (UK NSC) review of screening and is not used appropriately at the end of the cited paragraph. The UK NSC document makes no recommendations regarding management of maternal risk factors. This should be replaced with reference to the RCOG and NICE guidelines. Both of these guidelines assume that 'known carriage' of GBS is from incidental detection arising from tests undertaken to explore vaginal or urinary tract infections. For consistency with the guidelines this should be emphasised.

e. Method of investigation [page 8] “Optimum yield will be achieved…..”

The CDC recommends screening for GBS carriage. This same strategy was considered by the UKNSC which recommended not to introduce screening in the UK.

Current prevention guidance from RCOG and NICE identified no clinical indication for testing for GBS carriage, therefore, the use of selective broth medium is not recommended. The only investigations recommended for infection and colonisations are not specific to a single bacterium, for example in cases of symptomatic presentation for severe or recurrent UTI. The non-selective media in this scenario would be a more appropriate choice as the cause of the UTI can be from a range of organisations of which GBS is one of the rarer types.

Therefore, there is no requirement for selective media to be used routinely for GBS specific investigation because there is no known indication or scenario outlined by RCOG/NICE where a clinician would ever just request GBS testing. As pointed out in the cited text, the preferential use of selective media will inhibit the sensitivity for other bacteria. This could be to the detriment of recommended investigations.

Finally, the selective media may be more sensitive in the detection of GBS colonisation when compared with non-selective media. However, there is no data to support the suggestion that the use of selective media is significantly better for the prediction neonatal infection, which should be the main outcome used to determine its value, furthermore the lower bacterial loads found using an ECM are thought to present a lower risk than the high bacterial loads that are more easily identified using non-selective media.

f. Rapid test assays [page 9] “However, the assays generally……”

This statement could be a little misleading, a number of studies have shown that the sensitivity of rapid tests has a detection rate of 70-90% compared to selective media cultures. It may be more appropriate to cite that United States Centers for Disease Control and Prevention (CDC) criteria for a good test (time required for

testing and 90% sensitivity/specificity threshold) is main reason why these methods aren't in common use.

g. Limitations of UK SMIs (page 9]

This section should provide references for sensitivity and specificity of selective media [it is not 100%] and the number of cases that transition between positive and negative (and visa versa) between delivery and 35-37 weeks.

Furthermore no studies have shown that selective media has an acceptable predictive value for neonatal infection, prediction of carriage at delivery has been the focus of studies of testing using the ECM. Two systematic reviews have been published on this (Health Technology Assessment, Health Technology Assessment Colbourn and Valkenburg).The predictive value for early onset disease would be much lower.

h. Selective Media in Screening Procedures [page 9]

GBS screening is not recommended. Furthermore, this use of selective media investigation for GBS is also not recommended within current prevention strategies. As it currently worded the statement does not fit with the SMI's aim of working within current guidance and recommendations.

i. Optimal Time and Method of Collection [Page 11] “At 35-37 weeks of gestation...”

This would imply that the test should be done to fit with a screening programme it is also noted elsewhere in the document that the sensitivity within a screening programme would be optimal at this time. It should be reinforced that there is no screening programme recommended in the UK and therefore this statement is out of place.

j. General comment

If the SMI is for GBS testing in clinically indicated circumstances and not for screening this is currently unclear. The circumstances in which the test might be used are not defined and explained within the document. The relationship of this SMI to others is not explained.

Without further information on these issues it is not possible to determine whether the SMI achieves its aim of operating within and supporting current guidance or whether the SMI contradicts current guidance.

It should also be noted that there is a forthcoming PHE position paper that will be published in the near future that will summarise, and provide evidence to support, the recommendations made to not offer ECM testing. When you look at both documents, it might appear that the two contradict one another “as both are PHE documents we would be eager to avoid any confusion that two publications might cause.

Evidence

Heath et al., 2004 Weisner et al., 2004 Schrag and Verani., 2012 Centre for Disease Control and Prevention Valkenburg et al., 2010 Colbourn et al., 2007 Group B Streptococcal Disease, Early Onset (Green-top 36) CG149 Antibiotics for early-onset neonatal infection: NICE guideline.

Financial Barriers

Yes, there is a potential policy clash with other PHE statements on GBS.

Health Benefits	
These issues have been addressed in the main body of comments.	
Recommended Action	a. **ACCEPT** The scope of the document has been amended to clarify the aims of the SMI. Associated SMIs will be updated to ensure consistency. b. **ACCEPT** The incidence rate stated by The British Paediatric Surveillance Unit (BPSU) study has been re-inserted. c. **NONE** The sentence has been removed. d. **NONE** The paragraph has been removed. e. **NONE** Outside the scope of SMI. f. **ACCEPT** The sentence has been amended. g. **NONE** This is a standard statement and is relevant to the SMI. h. **NONE** The scope of the document has been amended to clarify the aims of the SMI. i. **ACCEPT** The sentence had been removed. j. **NONE** It is the opinion of the working group that the scope of the amended SMI will be clear and that it does not contradict UK policy.

RESPONDENTS INDICATING THEY WERE HAPPY WITH THE CONTENTS OF THE DOCUMENT

Overall number of comments: 3			
Date Received	21/08/2014	**Lab Name**	Public Health Wales
Date Received	16/09/2014	**Professional Body**	HIS
Date Received	19/09/2014	**Lab Name**	Truro Microbiology