NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of TA156; Pregnancy - routine anti-D prophylaxis for rhesus negative women (review of TA41)

This guidance was issued August 2008 with a review date of May 2011.

Background

At the GE meeting of 24 May 2011 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

Proposal put to consultees:	A review of the guidance should be transferred to the static guidance list.
Rationale for selecting this proposal	No new evidence has become available that is relevant to the effectiveness and cost effectiveness of RAADP. There is some new research on topics associated with the technology, notably the use of noninvasive fetal blood-group determination, but this would not alter the recommendations of TA156.

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

Recommendation post consultation:	The guidance should be transferred to the static guidance list.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Healthcare Improvement Scotland	No comment	Healthcare Improvement Scotland has no comment to make on the proposal to transfer this guidance to the static list.	Comment noted.
Department of Health	No comment	This is to confirm that the Department of Health has no comments to make, other than we are content with the decision regarding the proposal to transfer this Technology Appraisal on Anti-D prophylaxis to the static list	Comment noted.
British Society for Haematology / Royal College of Pathologists	Disagree	The BSH and RC Pathology would like to make the following comment on the proposal to move this TA to the static list. We are aware that an NIHR grant funded study of the RHD genotyping of the fetuses of mothers who are RhD negative in early pregnancy is nearing completion and the results will be published before the end of this year. The results of this study may allow for the creation of a new economic model with a reduction in anti-D usage of up to 30-40% as prophylaxis (plus reduced usage for sensitising events). We would like to alert NICE to the necessity of taking the results of this study into account and suggest that the decision as to whether to review the guidance or put it on the static list should instead be taken in three to four months time once the results have been published and their implications assessed. Is this a possible decision?	Comment noted. Thank you for highlighting ongoing research on new diagnostic techniques of early detection of fetus RhD status in RHD negative women. The implication of RhD genotyping in early pregnancy on routine antenatal anti-D prophylaxis was considered and it was concluded that potential cost savings (through a targeted prophylaxis of RhD negative women having RhD positive fetuses) need to be evaluated against the potential risk associated with false results and additional cost of the new diagnostic technology.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
			It could be a potential topic for the diagnostics assessment programme but it is clearly outside the remit of this guidance.
CSL Behring	Agree	We are happy for this to be moved to the static list at this time.	Comment noted.
Royal College of Nursing	Agree	The Royal College of Nursing welcomes the opportunity to review this document. The RCN's response is set out below: Section 6: New Evidence We are satisfied with the relevant online search strategy and reference to ongoing and unpublished data - which will consider provision of anti-D prophylaxis for women with miscarriage and/or ectopic pregnancy. Section 7: Summary of Evidence & Implications for Review The reason for withdrawal of the preparation WinRhoSDF appears to be one of procurement, and not efficacy, which is consistent with the use of most cost effective preparations. We note the new preparation currently at Phase II dose-finding stage. We read with interest the information about a proposed diagnostic programme (as a result of ongoing study comparing costs and effects of management with and without non-invasive fetal RhD) to determine fetal blood type by genotyping fetal DNA in maternal	Comment noted. Topics on the static list can be transferred back to the active list for further appraisal if new evidence becomes available that is likely to have a substantial effect on the existing guidance.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
		circulation. Whilst we agree this is outside the remit of this appraisal, we would welcome inclusion of reference to study (if funded) in any future updates of the guidance. Section 9: Equality Issues We welcome the inclusion of further studies (such as (Monoclonal anti-D), which respect cultural and/or religious affiliations which affect acceptance of blood related products. Conclusion: We agree with the proposal that the guideline should be transferred to the 'Static' list and that 5 yearly literature searches will continue, unless new evidence becomes available before then.	
Medicines and Healthcare products Regulatory Agency	Agree	We are not aware of any new evidence that affects the proposal relating to the NICE guidance on routine anti-D prophylaxis for rhesus-negative women. As noted in section 7 of the proposal paper, the product WinRho SDF (Baxter) has been withdrawn; health professionals therefore need to understand that this product should no longer be prescribed even though it features in the 2008 guidance	Comment noted.

No response received from:

Manufacturers/sponsors • Baxter BioScience (Partobulin SDF) • Bio Products Laboratory (D-Gam) Patient/carer groups • Afiya Trust • Black Health Agency • Chinese National Healthy Living Centre • Counsel and Care • Equalities National Council • Muslim Council of Britain • Muslim Health Network • South Asian Health Foundation • Specialised Healthcare Alliance • WellBeing of Women • Women's Health Concern Professional groups • British Committee for Standards in Haematology • Royal College of General Practitioners • Royal College of Midwives • Royal College of Obstetricians & Gynaecologists • Royal College of Physicians • Royal Society of Medicine Others • NHS Richmond	General • Board of Community Health Councils in Wales • British National Formulary • Care Quality Commission • Commissioning Support Appraisals Service (CSAS) • Department of Health, Social Services and Public Safety for Northern Ireland • National Association of Primary Care • National Pharmacy Association • NHS Alliance • NHS Commercial Medicines Unit • NHS Confederation • Public Health Wales NHS Trust • Scottish Medicines Consortium Comparator manufacturers • none Relevant research groups • MRC Clinical Trials Unit • National Institute for Health Research Assessment Group • Assessment Group tbc • National Institute for Health Research (NIHR) Health Technology Assessment Programme

• Sunderland NHS Teaching PCT • Welsh Assembly Government	<u>Associated Guideline Groups</u> • National Collaborating Centre for Women's and Children's Health <u>Associated Public Health Groups</u> • None

GE paper sign-off: Dr Elisabeth George, Associate Director – Technology Appraisals Programme

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