

## Consultation Report

### Topic details

<b>Title of policy or policy statement:</b>	Maternal intravenous immunoglobulin (IVIg) for the prevention of allo-immune fetal and neonatal haemochromatosis
<b>Programme of Care:</b>	Women & Children
<b>Clinical Reference Group:</b>	Neonatal Critical Care
<b>URN:</b>	1864

### 1. Summary

This report summarises the outcome of a public consultation that was undertaken to test the policy proposal.

### 2. Background

Allo-immune neonatal haemochromatosis (NH) is a rare condition, which can have fatal consequences during pregnancy or the neonatal period, resulting in acute liver failure, stillbirth and death of the newborn baby (Whittington, 2008). The number of pregnancies and babies affected by the condition is relatively unknown and it is likely to be under recognised. There is no standard treatment at present other than the Urgent Policy Statement published in July 2019.

IVIg has been shown to successfully reduce the risk of liver damage/failure, the need for intensive care support in hospital, donor liver transplant and intrauterine death during pregnancy or neonatal death after birth. A woman who has had a previous baby affected by NH should receive treatment during any subsequent pregnancy to prevent recurrence of neonatal haemochromatosis.

The policy will supersede the existing published urgent policy statement NHS England 170124/P Maternal intravenous immunoglobulin administration for prevention of alloimmune fetal and neonatal haemochromatosis. The policy does not propose any change from the published commissioning position.

### 3. Publication of consultation

The policy was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 30 days from 8<sup>th</sup> August to 7<sup>th</sup> September 2019. Consultation comments have then been shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the policy might be recommended.

Respondents were asked the following consultation questions:

- Has all the relevant evidence been taken into account?

- Does the impact assessment fairly reflect the likely activity, budget and service impact? If not, what is inaccurate?
- Does the policy proposition accurately describe the current patient pathway that patients experience? If not, what is different?
- Please provide any comments that you may have about the potential impact on equality and health inequalities which might arise as a result of the proposed changes that have been described?
- Are there any changes or additions you think need to be made to this document, and why?

#### **4. Results of consultation**

Four (4) responses were received during the period of public consultation. Three (3) responses were received on behalf of an organisation and one (1) was submitted by an individual. Both responses agreed with the policy proposition as it stands and agreed that all relevant evidence had been taken into account and that the impact assessment reflected the likely activity, budget and service impact. No further detail was provided and therefore no revisions to the policy proposition were made.

#### **5. How have consultation responses been considered?**

Responses have been carefully considered and noted in line with the following categories:

- Level 1: Incorporated into draft document immediately to improve accuracy or clarity
- Level 2: Issue has already been considered by the CRG in its development and therefore draft document requires no further change
- Level 3: Could result in a more substantial change, requiring further consideration by the CRG in its work programme and as part of the next iteration of the document
- Level 4: Falls outside of the scope of the specification and NHS England's direct commissioning responsibility

#### **6. Has anything been changed in the policy as a result of the consultation?**

No. All responses received were supportive of the current policy proposition, evidence review and impact assessment therefore no changes have been made as a result of public consultation.

#### **7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposal?**

No.