1. Sheila Adam (agreed)

2. Lady Hayman

From: Mike McGovern

Date: 19 May 1999

Copies
Simon Stevens
Jeremy Metters
David Hewlett
Charles Dobson
Kathryn Tyson
Gwyneth Lewis
Frances Rotblat
Laurence Knight
Charles Lister
Colin Startup
Gwen Skinner

Minister - I'm sorry I don't know if there was a particular concern query from v CSO - (para 5).
Is there anything you want followed up?
Summary at para 8 sounds v. reassuring.
[illegible] 19/5

No, it's helpful.
O.K. thank you
GRO-C

f re blood

Update on anti-D

You asked for an update yesterday on anti-D. This note sets out the current position on supply, current practice, the new guideline from RCOG, and action.

Supply

2. The Bio Products Laboratory (BPL) will be providing anti-D made from non UK plasma from 24 May. They now have a sufficient and secure supply to satisfy demand, even if this were to treble. They will be instituting a recovery and exchange programme for remaining UK derived product as they have already done for the main blood products such as Factor VIII, Factor IX and Albumin. The production changeover for anti-D has gone very successfully and to schedule. In addition the licensed indication for antenatal prophylaxis will be re-instituted for the new non UK derived product. BPL are writing to the suppliers and relevant clinicians about how the change over will be handled, in line earlier action on mainline products.

Current practice

3. Current practice and advice from the Royal College of Obstetricians and Gynaecologists is that all pregnant rhesus negative women (80,000 pa) should receive routine post natal prophylaxis with anti-D to prevent the development of rhesus haemolytic disease of the newborn. However following a conference in Edinburgh two years ago, there was consensus that the programme should be extended to include routine antenatal prophylaxis. This would involve two extra doses of anti-D given at 28 and 34 weeks of pregnancy as well as postnatally.

Impact of antenatal prophylaxis

4. The extended programme is aimed at reducing rhesus immunisation arising from unrecognised feto-maternal bleeding during pregnancy, which along with failure to give anti-D post-natally is now the main remaining cause of rhesus haemolytic disease. Information suggests that the introduction of antenatal prophylaxis would reduce current incidence from 1% to 0.2% (of 80,000 women every year) ie from

about 3200 cases a year to 640.

The RCOG Guidelines

5. The Department of Health supported the development of guidelines on the management of rhesus haemolytic disease by the RCOG following the Edinburgh consensus conference. This included the recommendation to extend the use of anti-D to routine antenatal prophylaxis. However because of the uncertainty about the safety of UK sourced anti-D in the context of vCJD, the College agreed to delay publication of this work until a suitable non UK alternative became available. The rationale was that if there was a risk of contracting vCJD from UK anti-D, routine antenatal treatment would not only affect the mother but also their unborn children. The plan now is to put the guidelines to NICE for endorsement and publish thereafter.

Unofficial guideline

6. A slightly unhelpful complication is that while the RCOG agreed to hold back publication of their new guidelines, an independent breakaway group (members of the earlier Edinburgh group supported originally by Industry) formulated their own. The recommendations are essentially the same as those of the RCOG, and they have now been published in the journal, 'Transfusion Medicine'. By the time we were alerted to this, the article was in press. Any high profile action or criticism of the article could have resurrected media interest in anti-D, led to further concern on the part of pregnant rhesus negative women and rejection of routine post natal prophylaxis by some as happened on previous occasions. We did not therefore attempt to delay publication; there has been no publicity.

Consensus about ante natal anti-D prophylaxis

7. We met with the UKCC earlier in the year in an effort to clear up uncertainties about anti-D. The representatives had a clear understanding of the issues in relation to non UK sourced anti-D. They were, though, concerned that a minority of prominent clinicians were not in favour of the move to routine antinatal prophylaxis. However this is a grade A recommendation in the RCOG guideline and in our view it is unlikely to provoke serious professional opposition particularly if endorsed by NICE.

Summary and action

8. BPL is on target to supply the NHS with non UK derived anti-D from 24 May. The indication 'antenatal prophylaxis' will be reinstated on the licence at the same time. There will be sufficient anti-D to allow for increased demand due to extending its use to routine antenatal prophylaxis. There is general professional consensus in favour of routine antenatal prophylaxis with anti-D and grade A evidence to support it. Endorsement of the RCOG guideline by NICE will be sought.

Dr Mike McGovern

Health Services Directorate