APPROPRIATE USE OF ANTI-D IMMUNOGLOBULIN IN PREGNANT MOTHERS

GAIN
GUIDELINES AND AUDIT IMPLEMENTATION NETWORK

A REGIONAL AUDIT BY THE NORTHERN IRELAND TRANSFUSION COMMITTEE

INTRODUCTION

Transplacental transfer of RhD positive red cells from a RhD positive fetus into a RhD negative mother's circulation can result in sensitization of the mother, with the development of RhD antibodies. Subsequent pregnancies in a sensitized woman could be complicated by haemolytic disease of the newborn (HDFN), if the fetuses are RhD positive. HDFN is known to cause stillbirths or severe morbidity in surviving babies. In the event of known or suspected exposure to RhD positive red cells in a Rh D negative woman the timely administration of an adequate dose of anti-D Immunoglobulin (anti-D Ig) can prevent maternal sensitization and consequent complications in subsequent pregnancies.

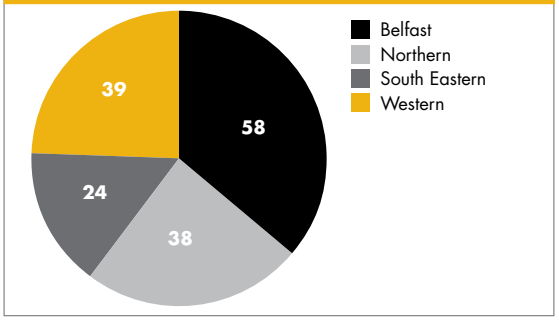
This GAIN sponsored audit, which was coordinated by the Northern Ireland Transfusion Committee (NITC), was undertaken to ascertain whether anti-D Ig was administered appropriately to RhD negative mothers in Northern Ireland.

AUDIT DESIGN

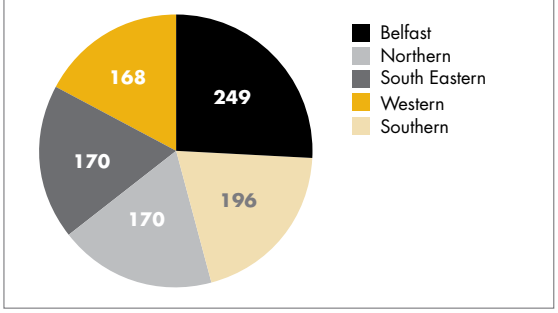
The most recent evidence based national guidance on the use of anti-D Ig was reviewed before six key audit standards were agreed upon. The audit was carried out as a retrospective review of clinical notes in two distinct sections. In the first section Trusts were requested to identify a representative sample of RhD negative women with early pregnancy loss before 20 weeks gestation during a six-month period in 2012. In the second section a much larger sample of RhD negative women who had delivered live or stillbirths at 20 weeks gestation or later during the same six-month was examined.

Trained data collectors audited clinical notes against the six key standards and completed relevant proformas.

Early pregnancy loss by Trust



Live and Stillbirths by Trust



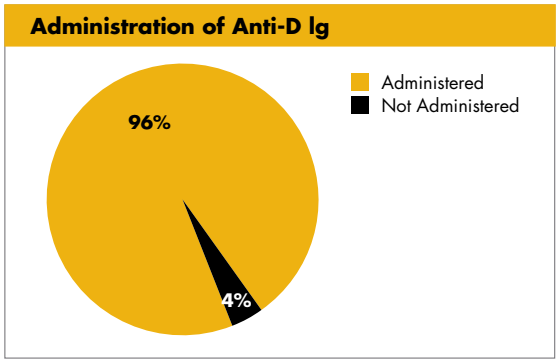
RESULTS

Completed data collection forms for 159 women with early pregnancy loss from four Healthcare Trusts were available for analysis.

In the second section data was collected for 951 women who had live births and details from 2 stillbirth cases were also included.

KEY STANDARD 1: PREVENTION OF SENSITIZATION IN EARLY PREGNANCY LOSS

Anti-D Ig should be given to all non-sensitized RhD negative women who have a spontaneous (complete or incomplete) miscarriage at 12^{+0} weeks of gestation or later. Anti-D Ig should be given to non-sensitized RhD-negative women who undergo surgical or medical management of early pregnancy loss (including therapeutic termination), irrespective of gestation.

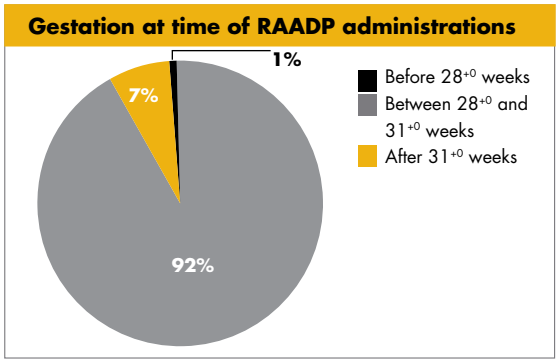


For six (4.1%) of the 145 RhD negative women who had early pregnancy loss there was no evidence of anti-D Ig administration when it was indicated.

Recommendation 1: All qualifying women who undergo surgical or medical management of early pregnancy loss or who suffer pregnancy loss after 12^{+0} weeks of gestation should be administered an appropriate dose of anti-D Ig.

KEY STANDARD 2: ROUTINE ANTENATAL ANTI-D PROPHYLAXIS (RAADP)

All qualifying RhD negative pregnant women should be offered RAADP. The dose should be 1500 IU and it should be administered between 28^{+0} weeks and 31^{+0} weeks gestation.



For 16 (1.7%) of the 953 women who subsequently delivered live births there was no evidence that anti-D Ig had been given, nor was there any documented reason for omission of this blood product.

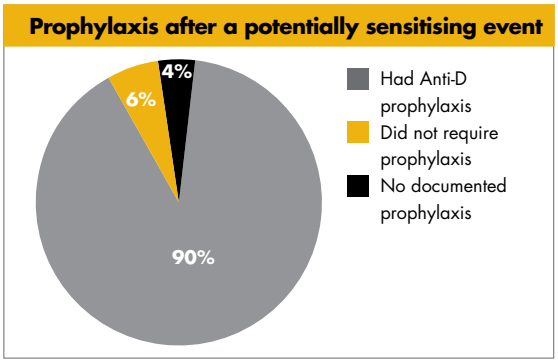
The dose of anti-D Ig administered as RAADP was too low (500 IU) in a further 5 (0.6%) cases.

RAADP was administered outside the recommended time period to 8% of women, most of whom received RAADP after 31^{+0} weeks of gestation.

Recommendation 2: 1500 IU of anti-D Ig should be offered to all qualifying RhD negative women between 28^{+0} and 31^{+0} weeks gestation.

STANDARD 3: PROPHYLAXIS AFTER A POTENTIALLY SENSITIZING EVENT

Anti-D Ig should be given as soon as possible after a potentially sensitizing event but always within 72 hours, even if the woman has recently been administered, or is due to be administered routine anti-D Ig prophylaxis. The minimum dose of anti-D Ig should be 250 IU up to 19^{+6} weeks of gestation and 500 IU thereafter during the pregnancy.



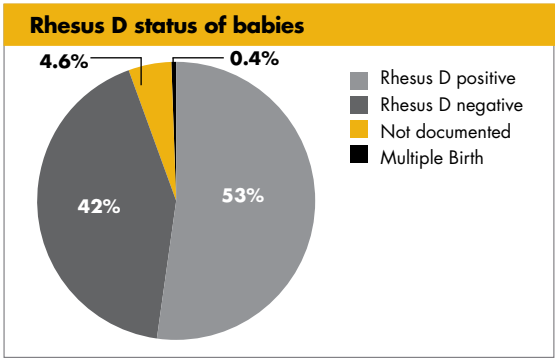
At least one potentially sensitizing event occurred in 211 (22.1%) women who had live births or stillbirths, 90% of whom were given anti-D Ig and another 6% did not require it. Of the 4% of women for which there was no documented evidence of anti-D Ig administration 4 subsequently delivered babies that were identified to be RhD positive.

Anti-D Ig was administered within 72 hours of the potentially sensitizing event in 94.2% of cases. The minimal dose requirement of 250 IU up to 19^{+6} weeks of gestation was complied with for 98.7% of these events and all women who had potentially sensitizing events at 20^{+0} weeks of gestation or later were administered the recommended minimum dose of 500 IU.

Recommendation 3: Potentially sensitizing events should be managed by prompt administration of anti-D Ig at an appropriate dose for gestational age.

STANDARD 4: ANTI-D Ig ADMINISTRATION FOLLOWING DELIVERY

All qualifying RhD negative pregnant women who deliver a RhD positive baby should receive a minimum dose of 500 IU of anti-D Ig within 72 hours of delivery.



Of 500 (53%) women who delivered RhD positive babies, 98.8% were administered anti-D Ig post delivery and in all cases the minimum recommended dose of 500 IU was given. For 96.1% of these women this dose of anti-D Ig was administered within the stipulated 72 hours of delivery.

Another 402 (42%) of mothers delivered RhD negative babies and anti-D Ig administration was documented in the clinical notes of 17 (4.2%) of these women.

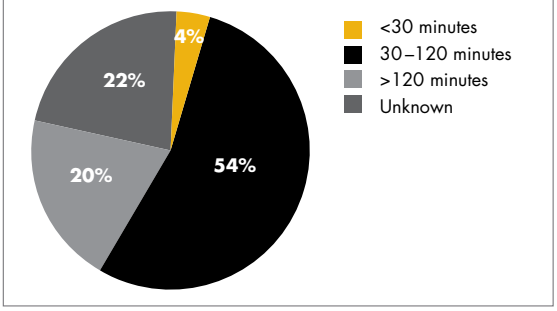
Recommendation 4: The correct dose of anti-D Ig should be given to all qualifying women within 72 hours of delivery. Anti-D Ig should not be given to RhD negative women when it is confirmed that they have delivered only RhD negative babies.

STANDARD 5: BLOOD SAMPLING FOR KLEIHAUER TEST

A Kleihauer or other screening test should be performed when anti-D Ig is given at 20^{+0} weeks of gestation or later to assess the amount of feto-maternal haemorrhage. A maternal blood sample for this test should be taken between 30 and 120 minutes after delivery to determine whether feto maternal haemorrhage greater than 4 ml has occurred.

Potentially sensitizing events occurred in 135 women at 20^{+0} weeks of gestation or more and a Kleihauer test was performed in 69.6% of these cases. There was evidence that a maternal blood sample for Kleihauer testing was taken from 96.9% of eligible women post delivery. The documented timing of this maternal sampling was correct (30-120 minutes) in only 54% of cases.

Timing of blood sampling for Kleihauer test



Recommendation 5: A Kleihauer test is required when a potentially sensitizing event has been identified in a RhD negative woman at 20^{+0} weeks of gestation or later. A maternal blood sample for this test should also be taken 30 to 120 minutes following delivery in a RhD negative woman.

STANDARD 6: CONSENT FOR ANTI-D Ig AND TRACEABILITY

There should be documentation in a woman's clinical notes to confirm that consent has been obtained prior to the administration of anti-D Ig. The dose and batch number of the product administered should also be recorded.

Indication	Anti-D Ig Administered Number of Cases	Consent Documented	% Compliance
RAADP	846	685	81.0%
1st PSE	190	53	27.9%
Delivery	551	225	40.8%
Cumulative	1587	1019	64.2%

Documented evidence of consent for RAADP administration was identified in 81% of cases but was particularly poor following potentially sensitizing events.

Indication	Anti-D Ig Administered Number of Cases	Batch Number Documented	% Compliance
RAADP	846	817	96.6%
1st PSE	190	173	91.1%
Delivery	551	526	95.5%
Cumulative	1587	1516	95.5%

PSE - Potentially Sensitizing Event

The batch number of all doses of anti-D Ig administered should be recorded in a woman's notes, to comply with traceability requirements for a human blood derived product. This documentation was incomplete for 8.9% of doses given after potentially sensitizing events and was missing for 4.5% of all administrations.

Recommendation 6: Consent must be obtained from all women for the administration of anti-D Ig and evidence of this process must be documented in the clinical notes. The batch number of all doses administered must also be recorded.