# NATIONAL QUALITY FORUM

#### Measure Evaluation 4.1 December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the evaluation criteria are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

**TAP/Workgroup** (if utilized): Complete all <u>yellow highlighted</u> areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).

**Steering Committee:** Complete all **pink** highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

#### Evaluation ratings of the extent to which the criteria are met

C = Completely (unquestionably demonstrated to meet the criterion)

P = Partially (demonstrated to partially meet the criterion)

M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)

N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)

NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) NQF Review #: ACP-003-10 NQF Project: Ambulatory Care - Additional Outpatient
Measures 2010

MEASURE DESCRIPTIVE INFORMATION

De.1 Measure Title: Rh immunoglobulin (Rhogam) for Rh negative pregnant women at risk of fetal blood exposure.

De.2 Brief description of measure: Percent of Rh negative pregnant women at risk of fetal blood exposure who receive Rhogam the ED.

1.1-2 Type of Measure: Process
De.3 If included in a composite or paired with another measure, please identify composite or paired measure

De.4 National Priority Partners Priority Area: Safety
De.5 IOM Quality Domain: Patient-centered, Safety
De.6 Consumer Care Need:

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	NQF Staff
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.  A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)? Yes  A.2 Indicate if Proprietary Measure (as defined in measure steward agreement): Proprietary measure  A.3 Measure Steward Agreement: Agreement will be signed and submitted prior to or at the time of measure submission  A.4 Measure Steward Agreement attached: acep agreement.doc	Z ≺ ⊳
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and	В

NQF #ACP-003-10

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update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	Y □ □	
C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement.  Purpose: Public reporting, Internal quality improvement  Accountability, Payment incentive, Accreditation	C Y□ N□	
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.  D.1Testing: No, testing will be completed within 24 months  D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?	D Y N	
(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (if submission returned):	Met Y□ N□	
Staff Notes to Reviewers (issues or questions regarding any criteria):  Staff Reviewer Name(s):		
TAP/Workgroup Reviewer Name:		
Steering Committee Reviewer Name:		
1. IMPORTANCE TO MEASURE AND REPORT		
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact	Eval Rating	Comment [KP1]: 1a. The measure focus addresses:
(for NQF staff use) Specific NPP goal:		•a specific national health goal/priority
1a.1 Demonstrated High Impact Aspect of Healthcare: Patient/societal consequences of poor quality 1a.2  1a.3 Summary of Evidence of High Impact: The potential for maternal exposure to fetal blood is a concern among pregnant patients presenting to the ED with a number of common complaints or diagnoses including abdominal pain, blunt abdominal trauma, vaginal bleeding, ectopic pregnancy, threatened or spontaneous abortion, or pelvic instrumentation. This concern increases after the first trimester as fetal RBC mass increases.  Exposure to less than 0.1 ml of fetal blood of a different rhesus (Rh) antigenicity among Rh negative has been shown to increase the risk of maternal alloimunization. Alloimmunization can result in hemolytic disease of the fetus or newborn including spontaneous abortion, fetal hemolytic anemia, hydrops fetalis and severe neonatal jaundice in subsequent pregnancies.  Anti-D-immunoglobulin reduces the likelihood of alloimmunization. Routine administration of antenatal anti-D-immunoglobulin has been demonstrated as an effective prophylaxis and is recommended by the American College of Obstetricians and Gynecologists (ACOG). Guidelines (UK) recommend administration of	1a C∏	identified by NQF's National Priorities Partners; OR  •a demonstrated high impact aspect of healthcare (e.g., affects large numbers, leading cause of morbidity/mortality, high resource use (current and/or future), sever of illness, and patient/societal consequence of poor quality).

Routine use of anti-D prophylaxis is somewhat controversial as this done to prevent so-called silent sensitization occurring in the absence of a clear hemorrhage, but this is generally performed in the UK and the US. As anti-D-immunoglobulin does cross the placenta, there are some concerns that this could cause fetal anemia, however, this was felt to be a minor concern relative to the benefits of administration.

- **1a.4 Citations for Evidence of High Impact:** 1. Royal College of Obstetricians and Gynaecologists (RCOG). The management of early pregnancy loss. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Oct. 18 p. (Green-top guideline; no. 25). [75 references]
- 2. Parker J, Wray J, Gooch A, Robson S, Qureshi H. Guidelines for the use of prophylactic anti-D immunoglobulin. London (UK): British Committee for Standards in Haematology (BCSH); 2006. 13 p. [21 references]
- 3. ACOG practice bulletin. Prevention of Rh D alloimmunization. Number 4, May 1999 (replaces educational bulletin Number 147, October 1990). Clinical management guidelines for obstetrician-gynecologists. American College of Obstetrics and Gynecology. Int J Gynaecol Obstet 1999; 66: 63-70. (There are no new American College of Obstetrics and Gynecology guidelines since 1999)

### 1b. Opportunity for Improvement

- 1b.1 Benefits (improvements in quality) envisioned by use of this measure: The management of early pregnancy loss, and the prevention of Rh alloimmunization.
- 1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across

Recent studies suggest that recommendations for antenatal anti-D immunoglobulin administration were not closely followed, and closer adherence might further reduce the incidence of Rhesus D immunisation.

"If there is no evidence of anti-D alloimmunization in the RhD-negative woman, 300 micrograms of rhesus immune globulin should be administered intramuscularly at 28 weeks of gestation. This practice has been reported to reduce the incidence of antenatal alloimmunization from 2% to 0.1%....Evidence for the use of rhesus immune globulin in other scenarios that breach the fetoplacental barrier is lacking."

Source: Management of Rhesus Alloimmunization in Pregnancy, Obstetrics & Gynecology. Volume 112(1), July 2008, pp 164-176

"Over the years, many reports have documented a lack of adherence to guidelines regarding anti-RhD administration, although there are no data specific to the US situation. In Canada, a retrospective chart review of pregnant women presenting to the emergency department with a risk factor for Rh sensitization found significant underutilization of anti-RhD. Patients who were admitted to hospital did have their Rh status determined, but there was more than one instance when a patient was not given anti-RhD when it was indicated. Of the patients who were not hospitalized, the vast majority (86%) were not Rh typed. Although some of these mothers may well have known their blood types or their clinicians may have had access to their prenatal records including blood type, this high percentage of untyped trauma victims may indicate a lack of awareness on the part of physicians. None of the women was administered anti-RhD, whether or not it was indicated."

"The lack of awareness for anti-RhD requirement in the United Kingdom was confirmed by a telephone survey of senior house officers working in accident and emergency departments: the doctors were given a clinical scenario of a patient who presented to the department at 18 weeks' gestation following closed abdominal trauma from domestic violence and asked what their management would be. Only 20 of the 62 doctors surveyed (31%) recognized the possibility of Rh sensitization. Of these, 3 said they would request a KB test and the remainder said they would check Rh status. In the case of an Rh-negative result, 9 of the doctors reported that they would administer anti-RhD in the emergency department, whereas the remainder answered that they would refer the patient to the on-call obstetricians. More worryingly, 23 of the 44 doctors (52%) who did not recognize the 114 Obstetrical and Gynecological Survey possibility of Rh sensitization in the first instance still did not appreciate the risk when informed of the Rh-negative status of the patient in question."

Source: Thorp JM. Utilization of anti-RhD in the emergency department after blunt trauma. Obstetrical & Gynecological Survey. 63(2):112-5, 2008 Feb.

Comment [KP2]: 1b. Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating considerable variation, or overall poor performance, in the quality of care across providers and/or population groups (disparities in care)

Comment [k3]: 1 Examples of data on opportunity for improvement include, but are not limited to: prior studies, epidemiologic data, measure data from pilot testing or implementation. If data are not available, the measure focus is systematically assessed (e.g., expert panel rating) and judged to be a quality problem.

N

### 1b.3 Citations for data on performance gap:

- Moise KJ. Red blood cell alloimmunization in pregnancy. Semin Hematol 2005;42:169-178. 1.
- Eager R, Sutton J, Spedding R, et al. Use of anti-D immunoglobulin 2.
- a. in maternal trauma. Emerg Med J 2003;20:498.
- Howard HL, Martlew VJ, McFadyn IR and Clarke CA. Preventing Rhesus D hemolytic disease of the newborn by giving anti-D immunoglobulin: are the guidelines being adequately followed? Br J Obstet Gynaecol 1997; 194: 37-41.
- Herman M, Kjellman H, Ljungggren C. Antenatal prophylaxis of Rh isoimmunisation with 250microg anti-D immunoglobulin. Acta Obstet Gynecol Scand 1984; 124: 1-15.
- Ghosh S, Murphy WG. Implementation of the rhesus prevention programme: a prospective study. Scott Med J 1994; 39: 147- 49.
- Bowman JM. Controversies in Rh prophylaxis. Who needs Rh immunoglobulin and when should it be given? Am J Obstet Gynecol 1985; 151: 289-294.
- Stewart FH, Burnhill MS, Bozorgi N. Reduced dose of Rh immunoglobulin following 1st trimester pregnancy termination. Obstet Gynecol 1978; 51:318-322.
- Bhat R, Venkatesh KS. Obstetric Practice Related Severe Neonatal Jaundice. JK Science Research Letter. Vol 10 (1), Jan-Mar 2008, p 46-7.

## 1b.4 Summary of Data on disparities by population group:

None

1b.5 Citations for data on Disparities:

None

- 1c. Outcome or Evidence to Support Measure Focus
- 1c.1 Relationship to Outcomes (For non-outcome measures, briefly describe the relationship to desired outcome, For outcomes, describe why it is relevant to the target population): Decreased incidence of Rh alloimmunization and minimized practice variation with regards to immunoprophylaxis strategies.
- 1c.2-3. Type of Evidence: Evidence-based guideline
- 1c.4 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome):

Guideline Summary: Guidelines for the use of prophylactic anti-D immunoglobulin (Parker J, Wray J, Gooch A, Robson S, Qureshi H. Guidelines for the use of prophylactic anti-D immunoglobulin. London (UK): British Committee for Standards in Haematology (BCSH); 2006)

### Sensitizing episodes

- **Amniocentesis**
- Cordocentesis
- Other in-utero therapeutic intervention/surgery (e.g., intrauterine transfusion, shunting)
- Ante partum haemorrhage (APH)
- Chorionic villus sampling
- Ectopic pregnancy
- External cephalic version
- Fall/abdominal trauma
- Intrauterine death
- Miscarriage

Table: Recommendations for Antenatal and Postnatal Tests and the Prevention of Sensitization Gestation **Summary of Tests and Treatment** 

- <12 weeks No action for uncomplicated miscarriage or painless vaginal bleeding.
- In all other cases check ABO and D type to confirm D negativity. Confirm absence of anti-D.
- Issue and administer 250 iu anti-D, intramuscularly (i.m.)

Comment [k4]: 1c. The measure focus is: •an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;

•if an intermediate outcome, process structure, etc., there is **evidence** that supports the specific measure focus as follows: o<u>Intermediate outcome</u> - evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit. o<u>Process</u> - evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and if the measure focus is on one step in a multistep care process, it measures the step that has the greatest effect on improving the specified desired outcome(s). o<u>Structure</u> - evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.

oPatient experience - evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public. oAccess - evidence that an association exists

between access to a health service and the outcomes of, or experience with, care. oEfficiency - demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.

Comment [k5]: 4 Clinical care processes typically include multiple steps: assess -> identify problem/potential problem choose/plan intervention (with patient input)

→ provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome

1c

C | P | N |

12 weeks to 20 weeks • For all potentially sensitising episodes ABO and D type to confirm D negativity. Confirm absence of immune anti-D.

Issue and administer 250 iu anti-D, i.m.

20 weeks • For all potentially sensitising episodes ABO and D type to confirm D negativity. Confirm absence of immune anti-D. Assess FMH.

Issue and administer at least 500 iu anti-D, i.m., depending on the size of FMH.

Guideline Summary: The management of early pregnancy loss

Royal College of Obstetricians and Gynaecologists (RCOG). The management of early pregnancy loss. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Oct. 18.

Grade B - Non-sensitised rhesus (Rh) negative women should receive anti-D immunoglobulin in the following situations: ectopic pregnancy, all miscarriages over 12 weeks of gestation (including threatened), and all miscarriages where the uterus is evacuated (whether medically or surgically).

Grade C - Anti-D immunoglobulin should only be given for threatened miscarriage under 12 weeks gestation when bleeding is heavy or associated with pain. It is not required for cases of complete miscarriage under 12 weeks of gestation when there has been no formal intervention to evacuate the uterus.

Guideline Summary: Prevention of Rh alloimmunization (Canada)

Fung Kee Fung K, Eason E, Crane J, Armson A, De La Ronde S, Farine D, Keenan-Lindsay L, Leduc L, Reid GJ, Aerde JV, Wilson RD, Davies G, Désilets VA, Summers A, Wyatt P, Young DC; Maternal-Fetal Medicine and Genetics Committees of the Society of Obstetricians and Gynaecologists of Canada (SOGC). Prevention of Rh alloimmunization.. J Obstet Gynaecol Can. 2003 Sep;25(9):765-73.

OBJECTIVE: To provide guidelines on use of anti-D prophylaxis to optimize prevention of rhesus (Rh) alloimmunization in Canadian women. OUTCOMES: Decreased incidence of Rh alloimmunization and minimized practice variation with regards to immunoprophylaxis strategies. EVIDENCE: The Cochrane Library and MEDLINE were searched for English-language articles from 1968 to 2001, relating to the prevention of Rh alloimmunization. Search terms included: Rho(D) immune globulin, Rh iso- or alloimmunization, anti-D, anti-Rh, WinRho, Rhogam, and pregnancy. Additional publications were identified from the bibliographies of these articles. All study types were reviewed. Randomized controlled trials were considered evidence of highest quality, followed by cohort studies. Key individual studies on which the principal recommendations are based are referenced. Supporting data for each recommendation is briefly summarized with evaluative comments and referenced. VALUES: The evidence collected was reviewed by the Maternal-Fetal Medicine and Genetics Committees of the Society of Obstetricians and Gynaecologists of Canada (SOGC) and quantified using the Evaluation of Evidence guidelines developed by the Canadian Task Force on the Periodic Health Exam.

### RECOMMENDATIONS:

- 1. Anti-D Ig 300 microg IM or IV should be given within 72 hours of delivery to a postpartum nonsensitized Rh-negative woman delivering an Rh-positive infant. Additional anti-D Ig may be required for fetomaternal hemorrhage (FMH) greater than 15 mL of fetal red blood cells (about 30 mL of fetal blood). Alternatively, anti-D Ig 120 microg IM or IV may be given within 72 hours of delivery, with testing and additional anti-D Ig given for FMH over 6 mL of fetal red blood cells (12 mL fetal blood). (I-A)
- 2. If anti-D is not given within 72 hours of delivery or other potentially sensitizing event, anti-D should be given as soon as the need is recognized, for up to 28 days after delivery or other potentially sensitizing event. (III-B)
- 3. There is poor evidence regarding inclusion or exclusion of routine testing for postpartum FMH, as the cost-benefit of such testing in Rh mothers at risk has not been determined. (III-C)
- 4. Anti-D Ig 300 microg should be given routinely to all Rh-negative nonsensitized women at 28 weeks' gestation when fetal blood type is unknown or known to be Rh-positive. Alternatively, 2 doses of 100-120 microg may be given (120 microg being the lowest currently available dose in Canada): one at 28 weeks and one at 34 weeks. (I-A)
- 5. All pregnant women (D-negative or D-positive) should be typed and screened for alloantibodies with an indirect antiglobulin test at the first prenatal visit and again at 28 weeks. (III-C)
- 6. When paternity is certain, Rh testing of the baby's father may be offered to all Rh-negative pregnant

women to eliminate unnecessary blood product administration. (III-C)

- 7. A woman with "weak D" (also known as Du-positive) should not receive anti-D. (III-D)
- 8. A repeat antepartum dose of Rh immune globulin is generally not required at 40 weeks, provided that the antepartum injection was given no earlier than 28 weeks' gestation. (III-C)
- 9. After miscarriage or threatened abortion or induced abortion during the first 12 weeks of gestation, nonsensitized D-negative women should be given a minimum anti-D of 120 microg. After 12 weeks' gestation, they should be given 300 microg. (II-3B)
- 10. At abortion, blood type and antibody screen should be done unless results of blood type and antibody screen during the pregnancy are available, in which case antibody screening need not be repeated. (III-B) 11. Anti-D should be given to nonsensitized D-negative women following ectopic pregnancy. A minimum of 120 microg should be given before 12 weeks' gestation and 300 microg after 12 weeks' gestation. (III-B)
- 12. Anti-D should be given to nonsensitized D-negative women following molar pregnancy because of the possibility of partial mole. Anti-D may be withheld if the diagnosis of complete mole is certain. (III-B) 13. At amniocentesis, anti-D 300 microg should be given to nonsensitized D-negativeesis, anti-D 300 microg should be given to nonsensitized D-negative women. (II-3B)
- 14. Anti-D should be given to nonsensitized D-negative women following chorionic villous sampling, at a minimum dose of 120 microg during the first 12 weeks' gestation, and at a dose of 300 microg after 12 weeks' gestation. (II-B)
- 15. Following cordocentesis, anti-D Ig 300 microg should be given to nonsensitized D-negative women. (II-3B)
- 16. Quantitative testing for FMH may be considered following events potentially associated with placental trauma and disruption of the fetomaternal interface (e.g., placental abruption, blunt trauma to the abdomen, cordocentesis, placenta previa with bleeding). There is a substantial risk of FMH over 30 mL with such events, especially with blunt trauma to the abdomen. (III-B)
- 17. Anti-D 120 microg or 300 microg is recommended in association with testing to quantitate FMH following conditions potentially associated with placental trauma and disruption of the fetomaternal interface (e.g., placental abruption, external cephalic version, blunt trauma to the abdomen, placental previa with bleeding). If FMH is in excess of the amount covered by the dose given (6 mL or 15 mL fetal RBC), 10 microg additional anti-D should be given for every additional 0.5 mL fetal red blood cells. There is a risk of excess FMH, especially when there has been blunt trauma to the abdomen. (III-B)
- 18. Verbal or written informed consent must be obtained prior to administration of the blood product Rh immune globulin. (III-C)

VALIDATION: These guidelines have been reviewed by the Maternal-Fetal Medicine Committee and the Genetics Committee, with input from the Rh Program of Nova Scotia. Final approval has been given by the Executive and Council of the Society of Obstetricians and Gynaecologists of Canada.

# 1c.5 Rating of strength/quality of evidence (also provide narrative description of the rating and by whom):

Grade B: Non-sensitised rhesus (Rh) negative women should receive anti-D immunoglobulin in the following situations: ectopic pregnancy, all miscarriages over 12 weeks of gestation (including threatened), and all miscarriages where the uterus is evacuated (whether medically or surgically); Grade C: Anti-D immunoglobulin should only be given for threatened miscarriage under 12 weeks gestation when bleeding is heavy or associated with pain. It is not required for cases of complete miscarriage under 12 weeks of gestation when there has been no formal intervention to evacuate the uterus.

1c.6 Method for rating evidence: The Cochrane Library and MEDLINE were searched for English-language articles from 1968 to 2001, relating to the prevention of Rh alloimmunization. Search terms included: Rho(D) immune globulin, Rh iso- or allo-immunization, anti-D, anti-Rh, WinRho, Rhogam, and pregnancy. Additional publications were identified from the bibliographies of these articles. All study types were reviewed. Randomized controlled trials were considered evidence of highest quality, followed by cohort studies. Key individual studies on which the principal recommendations are based are referenced. Supporting data for each recommendation is briefly summarized with evaluative comments and referenced.

VALUES: The evidence collected was reviewed by the Maternal-Fetal Medicine and Genetics Committees of the Society of Obstetricians and Gynaecologists of Canada (SOGC) and quantified using the Evaluation of Evidence guidelines developed by the Canadian Task Force on the Periodic Health Exam.

**Comment [k6]:** 3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system

http://www.ahrq.gov/clinic/uspstf07/method s/benefit.htm). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system changes). When qualitative studies are used, appropriate qualitative research criteria are used to judge the strength of the evidence.

Evidence does not support the measure for

all instances of vaginal bleeding  • Patients who have "received appropriate Rh immunoglobulin previously" are not necessarily protected from current risk of feto-maternal transfusion  • The evidence is not strong for first trimester use, but it may be considered "standard of care."	
1c.8 Citations for Evidence (other than guidelines): Royal College of Obstetricians and Gynaecologists	
1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number):  Administration of Anti-D Immunoglobulin  1. Documentation accompanying the injection must include a report containing the following details:	
<ul> <li>Identity of the patient to include surname, forename, date of birth and a unique ID number with the date when the injection is to be given. (Level IIa, Grade B).</li> <li>Identity and address of the general practice (GP) surgery/antenatal clinic administering the injection. (Level IIa, Grade B).</li> </ul>	
Details of the injection will include batch number and strength of dose and route of administration.  The details of the administration of anti-D must be recorded in the antenatal record. It is also important that these details are centrally recorded in the hospital blood bank computer so that this information is readily available should pre-transfusion testing be required.	
1c.10 Clinical Practice Guideline Citation: Parker J, Wray J, Gooch A, Robson S, Qureshi H. Guidelines for the use of prophylactic anti-D immunoglobulin. London (UK): British Committee for Standards in Haematology (BCSH); 2006 1c.11 National Guideline Clearinghouse or other URL: National Guideline Clearinghouse: http://www.guideline.gov/summary/summary.aspx?doc_id=12011.	
1c.12 Rating of strength of recommendation (also provide narrative description of the rating and by whom):  Level II.a, Grade B - Level IIa Evidence, means evidence obtained from at least one well-designed controlled study without randomization; Grade B Recommendation (evidence levels IIa, IIb, III) requires availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendation	
1c.13 Method for rating strength of recommendation (If different from USPSTF system, also describe rating and how it relates to USPSTF): Please see above.	
1c.14 Rationale for using this guideline over others: Strength of Evidence	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance</i> to Measure and Report?	1
Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i> , met? Rationale:	1 Y N
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, <u>as specified</u> , produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	Eval Rating
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL:	2a- specs
2a. Precisely Specified	C □ P □
2a.1 Numerator Statement (Brief, text description of the numerator - what is being measured about the	M
Deting C. Completely, D. Doutielly, M. Minimelly, M. Met et all, MA. Met englishly	_

1c.7 Summary of Controversy/Contradictory Evidence: •

Comment [k7]: USPSTF grading system http://www.ahrq.gov/clinic/uspstf/grades.ht m: A - The USPSTF recommends the service. There is high certainty that the net benefit is substantial. B - The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. C - The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. Offer or provide this service only if other considerations support the offering or providing the service in an individual patient. D - The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. I - The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance

of benefits and harms cannot be determined.

Comment [KP8]: 2a. The measure is well defined and precisely specified so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NQF's Health Information Technology Expert Panel (HITEP).

N

target population, e.g. target condition, event, or outcome): Number of appropriate patients who receive Rhogam in the ED.

**2a.2 Numerator Time Window** (The time period in which cases are eligible for inclusion in the numerator):

None

2a.3 Numerator Details (All information required to collect/calculate the numerator, including all codes, logic, and definitions):

- CPT E/M Service Codes: 99281, 99282, 99283, 99284, 99285, 99291 and
- Chart review evidence of Rh-immunoglobulin administered (Recommend new CPT2 or G codes be created)

2a.4 Denominator Statement (Brief, text description of the denominator - target population being

measured):
All women, confirmed pregnant, who are at significant risk of fetal blood exposure, including:

- 1. those diagnosed with an ectopic pregnancy
- 2. those in the second or third trimester:
  - a: with a threatened abortion (threatened, partial, complete, or spontaneous)
  - b. those who report or are found to have significant vaginal bleeding (not just spotting)
  - c. those who have sustained blunt abdominal trauma
- 3. those who undergo an invasive obstetric procedure in the ED (genetic amniocentesis; chorion villus sampling; fetal blood sampling, D&C).
- 2a.5 Target population gender: Female 2a.6 Target population age range: 14 to 50
- 2a.7 Denominator Time Window (The time period in which cases are eligible for inclusion in the denominator):

None

2a.8 Denominator Details (All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions):

CPT E/M Service Codes: 99281, 99282, 99283, 99284, 99285, 99291

- 2a.9 Denominator Exclusions (Brief text description of exclusions from the target population): 1.
- Patient refusal
  . Patients who have received appropriate Rh immunoglobulin previously
- 3. OB/GYN consultation documenting Rh immunoglobulin not recommended
- 2a.10 Denominator Exclusion Details (All information required to collect exclusions to the denominator, including all codes, logic, and definitions):

Chart review evidence of Rh immunoglobulin administered.

2a.11 Stratification Details/Variables (All information required to stratify the measure including the stratification variables, all codes, logic, and definitions):

2a.12-13 Risk Adjustment Type: No risk adjustment necessary

2a.14 Risk Adjustment Methodology/Variables (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method):
N/A

2a.15-17 Detailed risk model available Web page URL or attachment:

2a.18-19 Type of Score: Count

2a.20 Interpretation of Score:

2a.21 Calculation Algorithm (Describe the calculation of the measure as a flowchart or series of steps): N/A

**Comment [k9]:** 11 Risk factors that influence outcomes should not be specified as exclusions.

12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

2a.22 Describe the method for discriminating performance (e.g., significance testing): N/A

2a.23 Sampling (Survey) Methodology If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate): N/A

2a.24 Data Source (Check the source(s) for which the measure is specified and tested)
Paper medical record/flow-sheet, Electronic administrative data/claims, Electronic Health/Medical
Record, Electronic clinical data

2a.25 Data source/data collection instrument (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.):

Data will be collected from the medical record. These can be easily recorded either electronically or on paper using institution-specific instruments.

2a.26-28 Data source/data collection instrument reference web page URL or attachment:

2a.29-31 Data dictionary/code table web page URL or attachment;

2a.32-35 Level of Measurement/Analysis (Check the level(s) for which the measure is specified and tested)

Clinicians: Individual, Clinicians: Group, Can be measured at all levels

2a.36-37 Care Settings (Check the setting(s) for which the measure is specified and tested)
Ambulatory Care: Emergency Dept

2a.38-41 Clinical Services (Healthcare services being measured, check all that apply) Clinicians: Physicians (MD/DO)

### **TESTING/ANALYSIS** 2b. Reliability testing 2b.1 Data/sample (description of data/sample and size): ACEP has not conducted testing. 2b.2 Analytic Method (type of reliability & rationale, method for testing): 2b C | | P | | 2b.3 Testing Results (reliability statistics, assessment of adequacy in the context of norms for the test M N conducted): N/A 2c. Validity testing 2c.1 Data/sample (description of data/sample and size): N/A 2c.2 Analytic Method (type of validity & rationale, method for testing): N/A 2c C | P | M | N | 2c.3 Testing Results (statistical results, assessment of adequacy in the context of norms for the test conducted): 2d. Exclusions Justified 2d C | P | M | N | 2d.1 Summary of Evidence supporting exclusion(s): N/A 2d.2 Citations for Evidence: N/A NA 🗌

Comment [KP10]: 2b. Reliability testing demonstrates the measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period.

Comment [k11]: 8 Examples of reliability testing include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing may address the data items or final measure score.

Comment [KP12]: 2c. Validity testing demonstrates that the measure reflects the quality of care provided, adequately distinguishing good and poor quality. If face validity is the only validity addressed, it is systematically assessed.

Comment [k13]: 9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method: correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic

Comment [KP14]: 2d. Clinically necessary measure exclusions are identified and must be: 
•supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;

- •a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
- precisely defined and specified:
- —if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);

if patient preference (e.g., informed decisionmaking) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category

Comment [k15]: 10 Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyses with and without the exclusion, and variability of exclusions across providers.

2d.3 Data/sample (description of data/sample and size): N/A	
2d.4 Analytic Method (type analysis & rationale): N/A	
2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses): N/A	
2e. Risk Adjustment for Outcomes/ Resource Use Measures	
2e.1 Data/sample (description of data/sample and size): N/A	
2e.2 Analytic Method (type of risk adjustment, analysis, & rationale): N/A	2 <u>e</u>
2e.3 Testing Results (risk model performance metrics): N/A	C
2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: N/A	NA 🗆
2f. Identification of Meaningful Differences in Performance	
2f.1 Data/sample from Testing or Current Use (description of data/sample and size): N/A	
2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (type of analysis & rationale): N/A	
2f.3 Provide Measure Scores from Testing or Current Use (description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance):  N/A	2f C   P   M   N
2g. Comparability of Multiple Data Sources/Methods	
2g.1 Data/sample (description of data/sample and size): N/A	20
2g.2 Analytic Method (type of analysis & rationale): N/A	C   P
2g.3 Testing Results (e.g., correlation statistics, comparison of rankings): N/A	N   NA
2h. Disparities in Care	21
2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts): N/A	2h C□ P□
2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans: N/A	M NO
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Scientific Acceptability of Measure Properties?	2
Steering Committee: Overall, to what extent was the criterion, Scientific Acceptability of Measure	2
Properties, met? Rationale:	C □ P □
	M□   N□
3. USABILITY	

**Comment [KP16]:** 2e. For outcome measures and other measures (e.g., resource use) when indicated:

•an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outcome (but not disparities in care) and are present at start of care; Error! Bookmark not defined. OR rationale/data support no risk adjustment.

Comment [k17]: 13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women). It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.

Comment [KP18]: 2f. Data analysis demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance.

Comment [k19]: 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of \$25 in cost for an episode of care (e.g., \$5,000 v. \$5,025) is practically meaningful. Measures with overall poor performance may not demonstrate much variability across providers.

Comment [KP20]: 2g. If multiple data sources/methods are allowed, there is demonstration they produce comparable results.

Comment [KP21]: 2h. If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender);OR rationale/data justifies why stratification is not necessary or not feasible.

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Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	Eval Rating
3a. Meaningful, Understandable, and Useful Information	
3a.1 Current Use: Testing not yet completed	
3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years):  This measure is not in use.	
3a.3 If used in other programs/initiatives (If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years):  N/A	
Testing of Interpretability (Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement)  3a.4 Data/sample (description of data/sample and size): N/A	
3a.5 Methods (e.g., focus group, survey, QI project): N/A	3a C□ P□
3a.6 Results (qualitative and/or quantitative results and conclusions): N/A	M D
3b/3c. Relation to other NQF-endorsed measures	
3b.1 NQF # and Title of similar or related measures:	
(for NQF staff use) Notes on similar/related endorsed or submitted measures:	
3b. Harmonization	3b
If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source <u>or</u> different topic but same target population):  3b.2 Are the measure specifications harmonized? If not, why?	C □ P □ M □
· · · · · · · · · · · · · · · · · · ·	N_ NA_
3c. Distinctive or Additive Value	
3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:	3c C□
5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:	P
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Usability?</i>	3
Steering Committee: Overall, to what extent was the criterion, <i>Usability</i> , met? Rationale:	3 C   P   M   N
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be	Eval

Comment [KP22]: 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.

Comment [KP23]: 3b. The measure specifications are harmonized with other measures, and are applicable to multiple levels and settings.

Comment [k24]: 16 Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., influenza immunization of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for patients with diabetes), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

Comment [KP25]: 3c. Review of existing endorsed measures and measure sets demonstrates that the measure provides a distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare, is a more valid or efficient way to measure).

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implemented for performance measurement. (evaluation criteria)	Rating
4a. Data Generated as a Byproduct of Care Processes	4a
4a.1-2 How are the data elements that are needed to compute measure scores generated?  Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)	C P M
4b. Electronic Sources	
4b.1 Are all the data elements available electronically? (elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims) No	4b C□
4b.2 If not, specify the near-term path to achieve electronic capture by most providers.  In EDs where EMR is present, data elements will be available electronically. As adoption improves, electronic capture will improve.	P N
4c. Exclusions	
4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?	4c C   P   M   N
4c.2 If yes, provide justification.	NA.
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences	4d
4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.  None	C   P   M   N
4e. Data Collection Strategy/Implementation	
4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:  This measure has not been tested by ACEP.	
4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures):	
The cost to implement this measure will depend on the method used to collect data. Personnel time will be needed if paper medical records are to be reviewed in order to determine whether Rh-immunoglobulin was administered in the ED.	
4e.3 Evidence for costs: Not available.	4e C   P   M
4e.4 Business case documentation; Not available.	Ν□
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Feasibility?	4
Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i> , met? Rationale:	4 C□ P□ M□ N□
RECOMMENDATION	

Comment [KP26]: 4a. For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. (e.g., BP recorded in the electronic record, not abstracted from the record later by other personnel; patient self-assessment tools, e.g., depression scale; lab values, meds, etc.)

Comment [KP27]: 4b. The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record.

Comment [KP28]: 4c. Exclusions should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.

Comment [KP29]: 4d. Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.

Comment [KP30]: 4e. Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).

(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.	Time- limited
Steering Committee: Do you recommend for endorsement? Comments:	Y
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Measure Developer If different from Measure Steward	
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Co.6 Additional organizations that sponsored/participated in measure development	
ADDITIONAL INFORMATION	
Workgroup/Expert Panel involved in measure development Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations Describe the members' role in measure development. The following workgroup developed this measure.	i•
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Ad.2 If adapted, provide name of original measure: N/A Ad.3-5 If adapted, provide original specifications URL or attachment

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.6 Year the measure was first released:

Ad.7 Month and Year of most recent revision:

Ad.8 What is your frequency for review/update of this measure? This is a newly developed measure by the College, however we expect to review at least every 3 years

Ad.9 When is the next scheduled review/update for this measure? 10, 2012

Ad.10 Copyright statement/disclaimers: None

Ad.11 -13 Additional Information web page URL or attachment:

Date of Submission (MM/DD/YY): 07/19/2010