Rh D negative women and pregnancy

IMPORTANT: *Consider individual clinical circumstances. Consult a pharmacopeia for complete drug information. Read the full disclaimer at www.health.qld.gov.au/qcg*

Introduction

Aspect	Consideration
Context	• Early pregnancy screening, recognition of risk and timely management reduces incidence of fetal death and adverse neonatal outcomes[1] • Rh D negative women are at risk of alloimmunisation that may affect future pregnancies[2] • In Australia, approximately 15% of Australians are Rh D negative[3,4]
Definitions	• **Alloimmunisation:** immune system response of Rh D negative woman to Rh D positive fetal red cells expressing the Rh D antigen[2,5,6] • **Anti-D antibody:** circulating Rh D antibodies[6] o Passive antibodies are acquired from an external source (e.g. Rh D immunoglobulin (Ig)) o Preformed antibodies are acquired when Rh D negative woman is exposed to Rh D positive red cells and develops antibodies (sensitising event) • **Direct antiglobulin test (DAT):** determines whether there is binding of maternal immunoglobulin antibodies (Rh D antibodies) to baby's red cell antigens[7] (known historically as direct Coombs test (DCT)) • **Flow cytometry:** most accurate and method of choice for quantification of feto-maternal haemorrhage (FMH)[6] • **Haemolytic disease of the fetus and newborn (HDFN):** maternal Ig G antibodies are causing destruction of baby's red cells, and if severe can cause anaemia and hydrops • **Kleihauer-Betke test:** detects and quantifies FMH[8] • **NIPA:** non-invasive prenatal analysis for **fetal RHD gene** used to predict the baby's Rh D status[9] (also referred to as **NIPT** (non-invasive prenatal test) by National Blood Authority[6]) • **Rh D Ig:** the product administered to Rh D negative woman with no preformed anti-D antibodies[6] • **Rh D positive or negative:** blood group[6] (if positive the D antigen is present on red cells) • **Rh D (previously known as Rhesus) positive person**: carries D antigen on their red cells[10] • **Rh incompatibility:** mother and fetus incompatible for Rh D group • **RHD:** name given to the gene that encodes Rh D blood group, and used to refer to the genotype in the fetus determined by non-invasive prenatal test to analyse cell-free fetal DNA in maternal blood[6,11,12] • **Woman/women:** QCG recognise that individuals have diverse gender identities. In QCG documents, although the terms *woman* and *women* are used, these guidelines are inclusive of people who are pregnant or give birth and who do not identify as female.
Alloimmunisation	• Pathogenesis of alloimmunisation[2]: o D antigen is expressed on fetal red cells by 38 days of gestation in Rh D positive fetus o If maternal alloimmunisation occurs as a result of sensitising event, anti-D IgG antibodies cross the placenta and may result in fetal anaemia in the Rh D positive fetus in subsequent pregnancies–may also be caused by incompatible blood transfusion (rare) • Outcome from alloimmunisation: o May cause HDFN from transplacental passage of anti-D antibodies from Rh D negative woman to an Rh D positive fetus[13], resulting in potential fetal compromise or neonatal and long-term morbidity[1] o Generally no apparent adverse maternal health outcomes[6], unless severe HDFN causing hydrops when maternal mirror syndrome may develop[14] • Immunoprophylaxis occurs when injection of Rh D immunoglobulin (Rh D Ig) (to the woman) destroys fetal Rh D positive red cells in the maternal circulation before alloimmunisation can occur in the woman[15]
Clinical standards	• Refer to Queensland Clinical Guideline *Standard care*[16] for care considered 'usual' or 'standard'—includes for example: privacy, informed consent, decision making, sensitive communication, medication administration, staff education and support, culturally appropriate care and documentation • Determine the blood group (ABO Rh) and antibody status (e.g. anti-D, anti-C, Kell) for all pregnant women at booking appointment, and at approximately 28 weeks gestation[6,12,17]—can coincide with other routine tests e.g. oral glucose tolerance test (OGTT) • Offer anti-D immunoglobulin (Ig) to Rh D negative women (with no preformed antibodies) for routine prophylaxis, and for invasive procedures and other sensitising events[12]

Incidence and risk

Aspect	Consideration
Incidence of alloimmunisation	• If no immunoprophylaxis, the rate of alloimmunisation in Rh D incompatible pregnancy is approximately 16%[18] • Rate of alloimmunisation in Rh D negative women in Queensland due to feto-maternal haemorrhage of greater than 6 mL is approximately 4%[19]
Risk factors for D alloimmunisation	• Incompatible blood groups—occurs if Rh D negative woman has an Rh D positive fetus • Sensitising events in pregnancy [refer to Sensitising events] • Incompatible blood transfusion (including IV drug use/needle sharing)
Fetal/neonatal risk after maternal alloimmunisation	• Severe anaemia resulting from HDFN[20,21]–if anti-D level[12] o Greater than 4 international units (IU) per mL and less than 15 IU per mL, moderate risk of HDFN (unlikely to be severe) o Greater than 15 IU per mL, HDFN may be severe • If other blood group antibodies, HDFN incidence and the critical antibody titres for risk are different—if alloimmunisation suspected, consult with a specialist obstetrician • Hydrops fetalis[22] • Fetal thrombocytopenia[23]

Antenatal management

Aspect	Consideration
Information to Rh D negative woman	• Rh D status and potential risk to future babies • Blood test surveillance including indications/opportunity for NIPA • Sensitising events • Prophylaxis and other indications for Rh D Ig [refer to Sections Routine Rh D immunoglobulin prophylaxis and Sensitising events] • Provide written consumer information about Rh D Ig; discuss benefits and risks
NIPA indications	• Fetal RHD test (NIPA) available for Rh D negative pregnant women who[24]: o Are Rh D alloimmunised (have pre-formed anti-D antibodies) o Have previous obstetric indications (e.g. FMH, intra-uterine fetal death) o Are non-sensitised and have a relative contraindication to Rh D Ig (e.g. prior allergic reaction; cultural/religious beliefs)
Blood tests	• ABO Rh blood group at first appointment (if possible in first trimester)[6] • If Rh D negative woman, antibody screen for preformed anti-D antibodies[24] at first appointment and repeat at 28 weeks (prior to administration of Rh D Ig) • Fetal RHD test from 12 weeks gestation[6] o Not currently available as routine care for women in Australia[25] o If available, follow local protocols for offering Rh D negative women self-funded NIPA • Note date of administration of anti-D product on pathology request forms
Management	• Routine blood tests[6] • Identify Rh D alloimmunisation risk o Previous pregnancy history (e.g. previous baby requiring blood transfusion, or known to have HDFN)[26] • Administer prophylactic Rh D Ig at 28 and 34 weeks gestation to Rh D negative woman if[6]: o No preformed anti-D antibodies[12] [refer Anti-D immunoglobulin regimen] o Fetal RHD test (NIPA) predicts fetus to have RHD positive genotype[6] (if completed) • Identify sensitising events that may cause alloimmunisation (if antibody status not known, give Rh D Ig) [refer to Sensitising events]
Positive anti-D antibody screen[6,17]	• Check history: o Previous pregnancies o Blood transfusion o IV drug use/needle sharing o Recent Rh D Ig administration • Confirm with laboratory whether preformed antibodies present (not passive from Rh D Ig administration)—if antibodies are preformed, Rh D Ig not required • Consult with specialist obstetrician/maternal-fetal medicine specialist for management including ongoing serial monitoring of antibody titres and regular ultrasound scans[12] • Consider testing for fetal RHD by NIPA
Blood transfusion	• If woman requires transfusion use Rh D negative blood[27]

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Anti-D products

Aspect	Consideration
Context[28,29]	• Obtain informed consent before administration of anti-D product o Refer to Queensland Clinical Guideline *Standard care*[16] • Documentation–record the name of product and batch number in woman's medical record • Interactions with other medications–do not mix with medications or diluents • Observe woman for at least 20 minutes after administration • Product safety: o No fetal effects of prophylactic anti-D products o Suitable to use in breastfeeding women • Body mass index (BMI) greater than or equal to 30 kg/m^2 o No additional dose required[6] o Consider length of needle[6] and administration site (deltoid is suggested) o Consider Rhophylac®* intravenous (IV) injection[28] • No time interval required between IM (intramuscular) Rh D Ig administration and vaccination for measles, mumps, rubella and/or varicella[30] • Same dose and regimen (routine prophylaxis and sensitising events) for singleton and multiple pregnancies[6]
Rh (D) immunoglobulin-VF (single vial)[6,29]	• Human Anti-D Rh_0 immunoglobulin • Bring to room temperature before use • Administer by slow, deep intramuscular (IM) injection o Draw back to ensure not in blood vessel o Best sites are deltoid or anterolateral thigh[31] • Divide doses of more than 5 mL volume • Do **not** administer IV • If extra dose(s) for FMH round up volume to nearest full vial or vials • If more than two IM injections are required, consider IV Rhophylac®
Rhophylac® (prefilled syringe)[6,28]	• Human Anti-D (Rh_0) immunoglobulin • Usually used for large fetal maternal haemorrhage (greater than 6 mL of fetal cells) • Bring to room temperature immediately before administration • Administer IM or IV injection (if dose larger than 5 mL) • Consider IV use for woman who has haemorrhagic disorder precluding IM injection

Routine Rh D immunoglobulin prophylaxis

Aspect	Consideration
Routine antenatal immune-prophylaxis[6]	• Indicated for all Rh D negative women with no pre-formed anti-D antibodies o Not required if fetal RHD test predicts fetus is Rh D negative • Administer Rh (D) immunoglobulin-VF* 625 international units (IU) IM injection at 28 weeks (after blood for group and antibody collected from the woman, but do not need to wait for results) and 34 weeks gestation • If not logistically possible to give anti-D at 28 and 34 weeks o Give as soon as practicable within two weeks of due administration date o If 28 week dose missed, give as soon as recognised and then second dose six weeks later
Routine postnatal prophylaxis[6]	• Indicated for all Rh D negative women with no preformed anti-D antibodies who give birth to an Rh D positive baby o Rh D group from cord or neonatal blood • Administer Rh (D) immunoglobulin-V* 625 international units (IU) intramuscular (IM) injection (unless baby is Rh D negative) • If baby is born at term or preterm and is Rh D positive, administer routine postnatal dose of Rh (D) immunoglobulin-VF* to woman within 72 hours of birth–regardless of when routine antenatal prophylaxis or sensitising dose given o If not given within 72 hours after birth (preferred), may be given up to 10 days postnatally

**Refer to product information*

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Sensitising events

Aspect	Consideration
First 12+6 weeks of pregnancy[6]	• Miscarriage[26] o Excludes threatened miscarriage—consider confirming gestational age by ultrasound scan • Termination of pregnancy[26] (medical or surgical) from 10+0 weeks gestation[32] • Ectopic pregnancy[26] • Molar pregnancy[26] • Chorionic villus sampling[26]

From 13+0 weeks gestation[6]	• Genetic studies[26]
	  o Chorionic villus sampling
	  o Amniocentesis
	  o Cordocentesis
	• Abdominal trauma[26]
	• Revealed or concealed antepartum haemorrhage
	  o Consider in woman with unexplained uterine pain—possible concealed antepartum haemorrhage (APH)
	• External cephalic version (successful or attempted)
	• Miscarriage or termination of pregnancy[26]
	• Birth of baby regardless of mode[26]—greatest risk

Sensitising event (or unknown maternal blood group)	• Check bloods for:
	  o Maternal blood group (if required) and anti-D antibodies
	  o Quantify FMH size by Kleihauer-Betke or flow cytometry[6,8]
	• If maternal blood group is Rh D negative, administer Rh D Ig as soon as possible after blood sample taken (most effective within 72 hours of sensitising event[6])
	  o Do not wait for test results before administering first dose[8]
	  o May be given up to 10 days from sensitising event but may have lower efficacy[6]
	  o Administer for all new sensitising events and regardless of time of routine prophylaxis
	  o Administer routine 28 and 34 week Rh D Ig regardless of extra doses for sensitising event

Measuring FMH	• If 20+1 weeks or more gestation, measure FMH size following sensitising event and at birth for all Rh D negative women[6]
	• Use method that can quantify a haemorrhage greater than or equal to 6 mL (equivalent to 12 mL of whole blood)[6]
	• Flow cytometry most useful and accurate quantitative test for FMH[6,33]
	  o If available, method of choice[6]
	  o Includes antenatal and postnatal periods[6]
	• Offer follow up testing as per laboratory or specialist obstetric advice[6]

Follow up testing	• If large FMH (≥ 6 mL) repeat flow cytometry after Rh D Ig administration at[6]:
	  o 48 hours post IV administration
	  o 72 hours post IM injection administration

Postnatally	• If baby tests Rh D positive at birth [refer to Neonatal care]
	  o Obtain maternal bloods to detect and quantify FMH after 45 minutes and within 2–72 hours of birth[8,17]
	  o Collect blood specimen before administering Rh D Ig[8]

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Rh D immunoglobulin for sensitising event

Aspect	Consideration
Context[6]	• Indicated for Rh D negative women with no pre-formed anti-D antibodies o If test for fetal RHD predicts fetus is Rh D negative—Rh D Ig is not required • Administer dose as soon as practical within 72 hours of sensitising event • If dose not given within 72 hours, may be administered up to 10 days from event o May have lower efficacy • Quantify size of FMH after 20 weeks gestation and after birth
Sensitising event first 12+6 weeks gestation[6]	• If bleeding is repeated, heavy, or associated with abdominal pain or significant pelvic trauma administer Rh D immunoglobulin • Administer Rh (D) immunoglobulin-VF* 250 IU IM injection • If maternal bleeding is ongoing, further dose may be given after interval of six weeks–if less than 13+0 weeks gestation administer Rh (D) immunoglobulin-VF* 250 IU IM injection[29] • Insufficient evidence to support *routine* use of Rh D Ig following threatened miscarriage
Sensitising event from 13+0 weeks gestation[6]	• Administer Rh (D) immunoglobulin-VF* 625 IU IM injection[29] • If ongoing uterine bleeding further doses may be given at intervals of 6 weeks • If gestation unknown and possibly greater than or equal to 13 weeks administer Rh (D) immunoglobulin-VF* 625 IU IM injection[29]
FMH greater than or equal to 6 mL of fetal cells[6]	• Administer Rh (D) immunoglobulin-VF* 625 IU IM injection • Additional doses following laboratory or specialist obstetric advice o If required, usually an additional dose of Rh (D) immunoglobulin-VF* 100 IU IM injection per 1 mL fetal red cells greater than or equal to 6 mL • If IM injection not practical (e.g. volume of Rh D immunoglobulin to be injected is greater than 5 mL) or is contraindicated (e.g. woman has haemorrhagic disorder) o Administer Rhophylac®* 1500 IU IV injection or as advised by laboratory or specialist obstetrician/feto-maternal specialist[29]
Blood transfusion	• If woman requires blood transfusion—use red cells of the same ABO Rh D group, and K negative[12] • If Rh D negative woman receives Rh D positive blood transfusion, consult with a haematologist for specialist advice regarding individual woman's situation o Rhophylac®* 1500 IU IV injection[28] may be considered *or* other interventions

**Refer to product information*

Neonatal care

Aspect	Consideration
Screening of baby at birth	• Check Rh D group and DAT of **all** babies born to women who are Rh D negative regardless of immunoprophylaxis or alloimmunisation history[17] o Including if woman had fetal RHD test performed and result predicted baby to be Rh D negative[6] • If clinically significant antibodies in woman or increased risk of haemolysis–also test cord blood for haemoglobin and bilirubin[12,17]
Management	• Usual newborn baby care and observations • If alloimmunised mother (risk of HDFN), assessment of neurobehavioral state, jaundice and/or anaemia[12] • If weak positive DAT: o May be due to maternal antenatal immunoprophylaxis o Usually no adverse effects on newborn baby o If in doubt about significance of DAT result discuss with testing laboratory or neonatologist/paediatrician • Refer to Queensland Clinical Guidelines: *Routine newborn assessment*[34] and *Jaundice-neonatal*[35]

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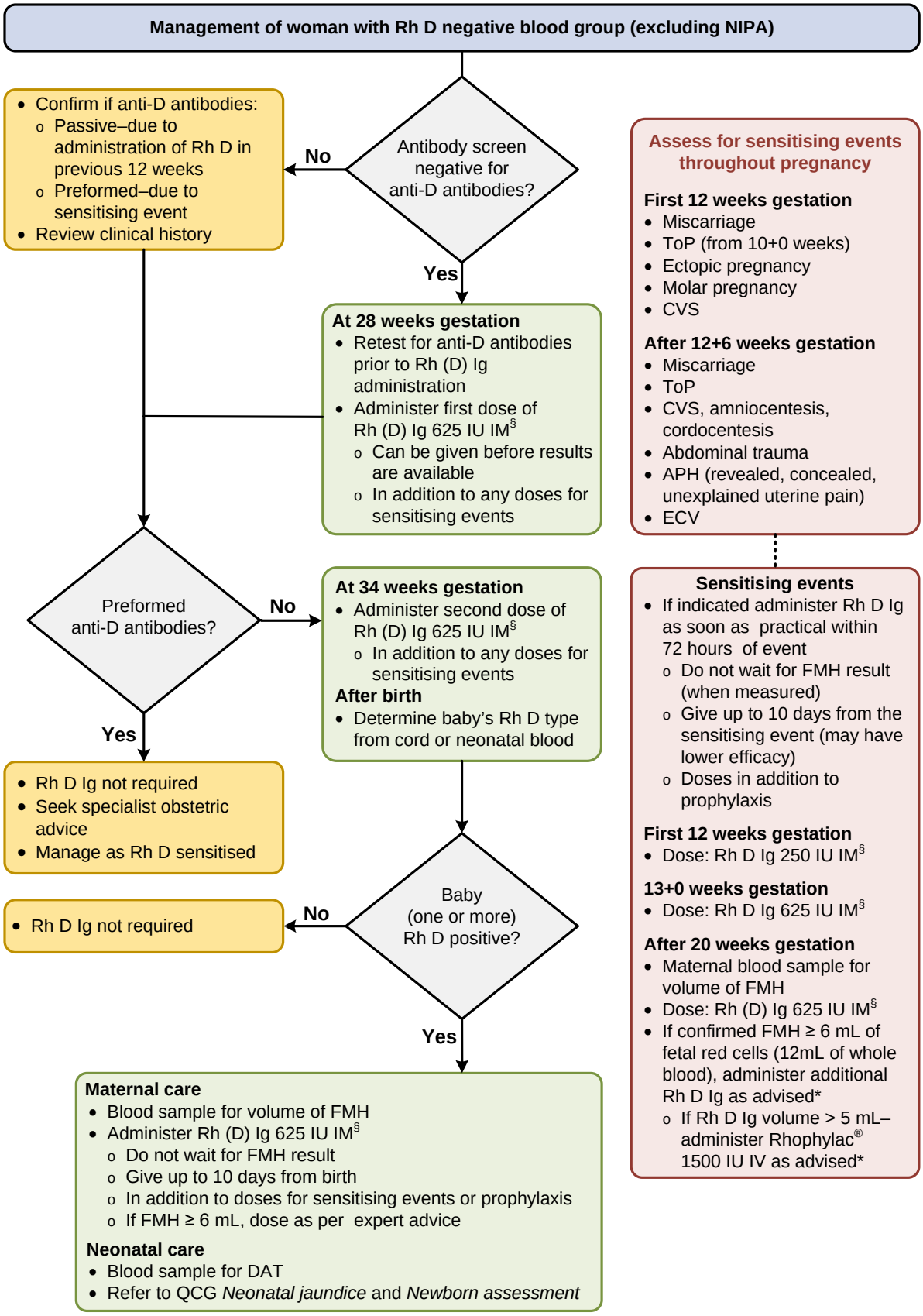
Flowchart Routine management of Rh D negative woman excluding NIPA



* as advised by laboratory or specialist obstetrician/feto-maternal specialist.
§ draw back on plunger of syringe before injection to ensure the needle is not in a blood vessel and administer by deep IM injection.

APH: antepartum haemorrhage **CVS:** chorionic villus sampling **ECV:** external cephalic version **FMH:** feto-maternal haemorrhage, **Ig:** immunoglobulin **IM:** intramuscular **IV** intravenous **NIPA:** non-invasive prenatal analysis **Rh D Ig:** Rh (D) immunoglobulin-VF **ToP:** termination of pregnancy **≥:** greater than or equal to

Flowchart F23.74-1-V2-R28

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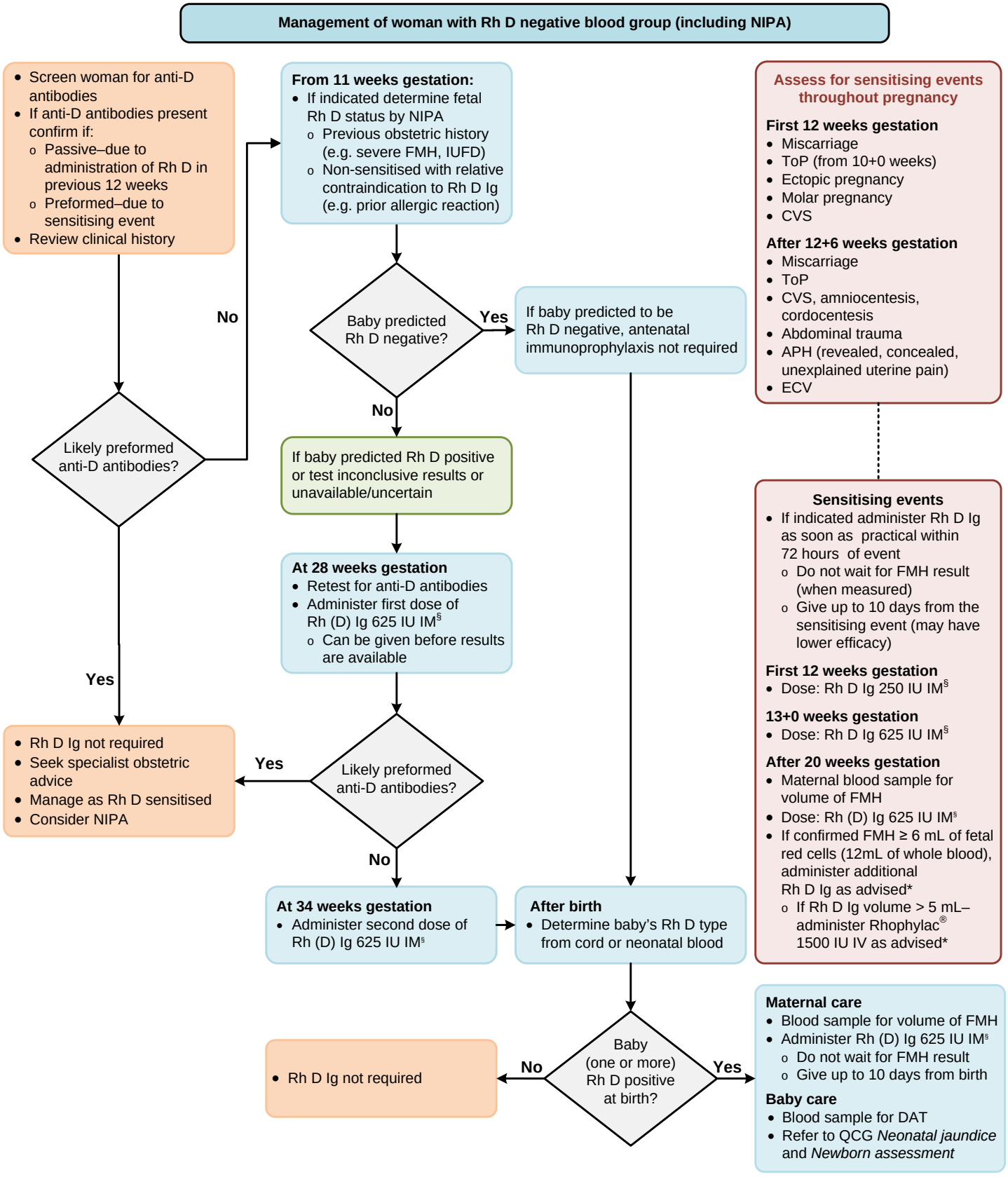
Flowchart Management of Rh D negative woman including NIPA



***** as advised by laboratory or specialist obstetrician/feto-maternal specialist
§ draw back on plunger of syringe before injection to ensure the needle is not in a blood vessel and administer by deep IM injection

APH: antepartum haemorrhage **CVS:** chorionic villus sampling **ECV:** external cephalic version **FMH:** feto-maternal haemorrhage **Ig:** immunoglobulin **IM:** intramuscular **IUFD:** intrauterine fetal death **IV** intravenous **NIPA:** non-invasive prenatal analysis **Rh D Ig:** Rh (D) immunoglobulin-VF **ToP:** termination of pregnancy **≥:** greater than or equal to

Flowchart F23.74-2-V2-R28

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