1-1-2016

Introduction of Routine Antenatal Anti-D Prophylaxis for all Rhesus Negative Women (RAADP) attending Cavan General Hospital.

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Citation
Reilly M. Introduction of Routine Antenatal Anti-D Prophylaxis for all Rhesus Negative Women (RAADP) attending Cavan General Hospital. [MSc Thesis]. Dublin: Royal College of Surgeons in Ireland; 2016.
Introduction of Routine Antenatal Anti-D Prophylaxis for all Rhesus Negative Women (RAADP) attending Cavan General Hospital

A Dissertation submitted in part fulfilment of the degree of MSc Healthcare Management, Institute of Leadership, Royal College of Surgeons in Ireland

2016

Student ID: 14113180
Submission Date: 12th May, 2016
Word Count: 14,681
Facilitator: Ricky Ellis
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Acknowledgements

The work for this dissertation has been enabled and sustained by the generosity and support of many individuals and institutions, and I wish to thank them here.

Firstly and most importantly I want to thank my family. To my husband Joe. Thank you for supporting and facilitating me in every way to get through this. Your easy going nature helped me to keep focus, and when I got a little bit crazy at times, you kept me well grounded. To my three beautiful girls, Sinead, Deirdre and Katie. The house would be an industrial site by now were it not for your support in all things domestic, despite all the football, camogie and music practices.

This dissertation would not have been possible without the support of my boss and friend, Margaret Mulvany. Thank you for facilitating and supporting me through this process. Your dedication to Women’s Services in the North East is why you support process improvements like this with great ease and enthusiasm. To all my work colleagues at Cavan General. I have known most of you for over 20 years and consider you all members of my extended family.

To the RCSI. Thank you so much for your help, guidance and knowledge throughout this Masters programme. You truly are an example of leadership at its best. You made a difficult journey more enjoyable. To my facilitator, Ricky Ellis. Thank you so much for your patience, guidance and expertise with this project. To Ann, Sanober, Edel, and Ceire in my ALS group, for keeping me focused and getting me unstuck when I needed it.

Finally I would like to thank my proof readers. To my sister and friend Carmel. Your common sense approach to proof reading provided clarity to my chaos. To my friend Cathy. Your
academic expertise is enviable and I feel privileged that you dedicated time to reading my dissertation and providing it with the polish that it needed.
Abstract

Aims
The aim of this process improvement was to introduce routine antenatal anti-D prophylaxis (RAADP) injection at 28 weeks gestation to all Rhesus (Rh-D) negative women attending Cavan General Maternity services. This was initially achieved by outlining objectives which gave focus to the project. These objectives facilitated the development of the subsequent business case, implementation plan and evaluation process.

Rationale
The introduction of routine antenatal anti-D prophylaxis was in order to be fully compliant with the National Guideline recommendations by the Clinical Care Programme in Obstetrics and Gynaecology.

Change Process
The writer introduced this change using the Health Service Executive Organisational Development Model as a guiding document. This provided a structured and systematic approach which informed the change process. The four stages of change included initiation, planning, implementation and mainstreaming.

Evaluation
The evaluation of the project revealed benefits from training with excellent practice and service delivery. Compliance with routine antenatal anti-D prophylaxis was successful as evidenced by the laboratory audit carried out following implementation of the project.

Results and Conclusion
All women at Cavan General Hospital are now offered routine antenatal anti-D prophylaxis (RAADP) at 28 weeks gestation. There is a need to further develop the service in order to provide RAADP as an off-site amenity.
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Chapter One: Introduction
1.1 Introduction

This dissertation proposes to guide the maternity services at Cavan General Hospital in relation to the introduction of routine antenatal anti-D prophylaxis (RAADP) injection to all Rhesus Negative (Rh-D) women attending the service. Introducing change in any organisation, but particularly a healthcare setting, requires the use of a structured process that provides clarity and engagement for all those who not only work in the service, but to those who have access to it (HSE, 2008). The writer will use the Health Service Executive (HSE) Organisational Development (OD) Change Model to provide this structure. This model is based on an organisational development approach which focuses on the people aspects of change. It also uses a project management style in order to bring structure and discipline to the process (HSE, 2008). The HSE OD Change Model adapts an action research approach which works well in a healthcare setting as it was developed to improve the experience of patient and service users, help staff and teams actively work together to improve services and provide a consistent approach to change across the system (HSE, 2008).

In order to understand why prophylactic anti-D is recommended in pregnancy it is first necessary to briefly explain the role of the placenta in pregnancy. The placenta (also known as the afterbirth) is a remarkable endocrine organ which connects the developing fetus to the uterine wall. It carries out the functions which the fetus is unable to perform for itself during intrauterine life. It plays a vital role in the transfer of oxygen and nutrients to the fetus and allows for waste elimination and gas exchange via the mother’s blood supply. It also helps fight against internal infection (Fox & Neil, 2007). The placenta also produces hormones which help support the on-going pregnancy. For the most part it also acts as a barrier to fetal blood entering the maternal circulation (Marshall & Raynor, 2014), however during pregnancy or birth, fetomaternal haemorrhage can occur. This can cause small amounts of fetal blood to
cross the placenta and enter the mothers’ blood. If the mother is Rh-D negative and the baby is Rhesus positive than this is known as a potential sensitizing event (PSE) (Appendix 1). As a result of this the maternal immune system can become sensitised against aspects of the baby’s blood group (MacDonald & Magill-Cuerden, 2011). This has implications for future pregnancies.

Currently the organisation provides anti-D immunoglobulin to all Rh-D negative women for any PSE and following delivery of a Rhesus positive baby. A total of 241 (14%) women attending Cavan General’s maternity services in 2014 were Rh-D negative.

1.2 Organisational Context

The writer works in a rural Maternity Unit that is attached to Cavan General Hospital. Approximately 2,000 births occur in this unit on a yearly basis. The unit has three Obstetric Consultants and a co-located Midwifery Led Unit. These services provide antenatal, intranatal and postnatal care for all pregnant women attending the service. Antenatal care is also provided in outreach clinics at Monaghan Hospital. The Maternity Unit delivers Level 2 (Appendix 2) services to the surrounding areas of Cavan, Monaghan, Sligo, Leitrim and parts of Meath.

In 2012 the National Clinical Care Programme in Obstetrics launched a guideline (Fitzgerald & Conneally, 2012) recommending the introduction of RAADP at 28 weeks for all Rh-D negative women. Supporting and implementing this recommendation for change will be the subject of this dissertation as the writer proposes to introduce RAADP as a quality improvement initiative in her hospital.
1.3 Rationale
The rationale for choosing this proposal evolved from the publication of this National Guideline (Fitzgerald & Conneally, 2012). Currently Rh-D negative women attending the service do not receive routine antenatal anti-D prophylactically (RAADP). There is a growing body of literature that recognises the importance of administering RAADP. The purpose of this project is to introduce RAADP to all Rh-D negative women attending Cavan General, in order to be fully compliant with the national guideline (Fitzgerald & Conneally, 2012).

1.4 Aims and Objectives
The writer aims to introduce the administration of RAADP to all non-sensitised Rh-D negative women at 28 weeks gestation at Cavan General Hospital. The following is a list of objectives to help achieve this.

1. Establish and implement procedures for the implementation of RAADP by September 2015.

2. By October 2015, all eligible Rh-D negative women will be offered RAADP at 28 weeks gestation in order to be fully compliant with the National Clinical Care Programme guideline (Fitzgerald & Conneally, 2012).

3. Design and deliver an education programme to support practitioners with implementing this service, by January 2016.

4. Produce a patient information leaflet to be given to all Rh-D negative women prior to the administration of RAADP.

5. Access the effectiveness of this initiative in January 2016 and April 2016.
1.5 Role of the Student

The writer is currently employed in Cavan General Hospital as a Clinical Midwife Manager Two (CMM2) responsible for the management and delivery of the Midwifery Led Service’s that are co-located within the main maternity unit. Introducing any process improvement within an organisation begins with an understanding of the needs of the service and the desire to provide quality to the service users (HSE, 2008). Quality within any healthcare setting can be described as a service that gives people what they need, as well as what they want, and does so at the lowest possible cost (Ovretveit, 1995). On these grounds, this project was proposed and approved by the clinical governance committee and the writer became part of the implementation team responsible for the delivery of RAADP to all Rh-D negative women at 28 weeks gestation.

1.6 Summary and Conclusion

The overall structure of this dissertation is presented in five chapters. The introductory chapter provides a brief overview of the mother and baby relationship in utero and why anti-D would be required in an antenatal context. The rationale for carrying out the project is outlined within the context of the organisation and the aim and specific objectives are set. Chapter 2 lays down the theoretical dimensions of the literature to provide a more in-depth understanding of the evidence surrounding the use of anti D immunoglobulin and its role in preventing potential Rh-D sensitisation. The themes explored will inform this process by including an explanation of what anti-D is and what is meant by prophylaxis. Further exploration of why we need to give prophylactic anti-D and the implications of both giving it, and not giving it, are considered. The writer will also explore the value of education and its role in supporting this change process. Implications for the project will be outlined and the rationale for introducing the use of prophylactic anti-D at 28 weeks gestation. Chapter 3 is
concerned with the methodology used for this project and describes its use in the implementation of RAADP. The writer will use the Health Service Executive Change Model (HSE, 2008) to provide this structure to the implementation process. A critical review of this change model, both as a tool for implementing change, and its ability to provide clarity to that change will be explored. Following delivery of the project the writer will also reflect on the experience of introducing change and using the HSE OD model as a guide to manage that change within the healthcare setting. Chapter 4 will provide a brief discussion on the importance of healthcare evaluation. The writer will look at the evidence around using audit as an evaluation tool. The design of the audit will be based around the objectives in chapter one. Three different aspects of the implementation plan will be audited that best reflect the objectives of the project. The success of the training programme will be evaluated in two separate ways. Assessment of learning will be achieved using post evaluation questionnaires following training. An audit of the documentation checklist, designed for use in the project, will reflect application of learning to practice. Three months following commencement of the project, the writer will perform an initial documentation checklist audit in order to identify if there are any training deficits withstanding. Finally the writer will carry out an audit in the laboratory to determine did all women who were eligible to receive RAADP offered it, as this will be the determinate success of the project. Chapter 5 draws together the overall findings of this project. The writer will critically discuss the implementation process and reflect on the evaluation findings. Finally the writer will discuss the impact that this process improvement has had on the organisation and the contribution it has made on delivering a quality service. Recommendations for future improvements will be suggested.
Chapter Two: Literature Review
2.1 Introduction

In pregnancy women who are Rh-D negative require specific antenatal care and monitoring (Turner et al., 2012). The use of anti-D in Rh-D negative women within a maternity setting is widely accepted and has been administered for over 40 years. The practice however mainly focuses on its administration following a potential sensitising event (PSE) (Appendix 1) and following the delivery of a Rhesus positive baby. The introduction of prophylactic anti-D to reduce the chances of unprovoked sensitisation occurring in pregnancy was first proposed in the 1970's (MacKenzie et al., 2006). The aim of prophylaxis was to further reduce the risk of Rh-D immunisation. Rhesus immunisation can have detrimental effects on the fetus and newborn.

Haemolytic disease of the newborn (HDN) due to Rh-D immunisation is an infrequent, but severe, complication of pregnancy. HDN is an alloimmune condition that develops in a fetus when anti-D IgG molecules produced by the mother pass through the placenta into the fetal circulation. The resultant anti-D allioimmunisation (Appendix 3) is a condition which can have considerable impact on the life of the unborn infant in subsequent pregnancies. There is a growing body of evidence that recognises the importance of the administration of prophylactic anti-D in pregnancies where the woman is known to be Rh-D negative to prevent this condition. The purpose of this review is to explore the theoretical dimensions of the research and review how the administration of prophylactic anti-D can improve outcomes of Rhesus positive babies born to Rh-D negative women. This review will support the writer’s process improvement initiative whereby the introduction of prophylactic anti-D in the third trimester of pregnancy is established in the organisation.
2.2 Search Strategy

Relevant papers discussing the use of prophylactic anti-D in pregnancy were identified using the sources RCSI library, Medline, Cinahl, HSElibrary, Clinical Key, Up-To-Date, Cochrane databases and Google scholar. Using Cinahl headings the following terms were used to identify suitable articles: “Rho(D) Immune Globulin”, “Rh Isoimmunization – prevention and control”, “Infant”, “Newborn”, “Pregnancy Trimester”, “First” and “Obstetric” as subject headings. The database “up-to-date” was used as the writer wanted to review articles from a user’s perspective.

The writer expanded the search using Boolean logic “and”, “or” and “not”. Limiters were used to refine the search to peer reviewed, and papers published between 2000 and 2015 were considered, with no language restrictions. From the selected articles the writer chose those whose main focuses were on the discussion of prophylactic anti-D (RAADP). Articles included guidelines, systematic reviews, meta-analyses, prospective studies and cost effectiveness analysis studies. Articles that only discussed antenatal post sensitisation administration and postnatal administration were excluded from this review and 23 articles in total were used. Five key themes emerged and informed the structure of this review. The writer begins with a background to help inform the reader as they move through the review. This is followed by an overview of anti-D and how it works, discussions around when we need to give it, the evidence on the implications for giving it and lastly the importance of the role of education.

All references obtained were entered into “Mendeley Referencing Manager” computer software system and the American Psychological Association (APA) 6th Edition referencing was utilised.
2.3 Review of Themes

2.3.1 Background

In order to better understand the relevance of anti-D it is necessary to give a brief overview of the basic physiology of the human blood system and the relationship between the maternal and fetal system in pregnancy. Human blood is classified based on two main systems. These are the ABO system and the Rhesus (Rh) system (Pilgrim et al., 2009). The Rhesus system contains several related proteins, the most relevant one being the Rhesus D (Rh-D) antigen. If a woman has this antigen she is classified as Rh-D positive and in its absence she is classified as Rh-D negative. The precise function of these antigens are unknown (Urbaniak & Greiss, 2000) but it becomes very relevant for women in pregnancy where a Rh-D negative mother carry’s a Rh-D positive baby.

During intrauterine life, the fetal placental circulation operates as a single unit, providing a low resistance, high-capacity reservoir in the vascular bed of the placenta (MacDonald & Magill-Cuerden, 2011). The maternal blood circulates through the placenta enabling the absorption of food and oxygen and the absorption of waste products (Marshall et al., 2014). In the event that there is mixing of mothers’ blood with baby’s, the mother develops anti-D IgG antibodies in response. While this has little impact on the first pregnancy, the development of anti-D antibodies may result in potentially life threatening conditions in subsequent pregnancies where the mother carries a Rh-D positive baby.

2.3.2 What is Anti-D and How Does it Work?

Anti-D immunoglobulin is a freeze dried concentration of Anti-D Immunoglobulin made from a pooled source of human plasma of males and post-menopausal women who are Rh-D negative (Crowther et al., 2013). The resultant sterile solution protects against Rh-sensitisation or allioimmunisation. It is manufactured by a multistep chromatographic
procedure. This removes 98% of contaminated proteins leaving only enriched IgG (Stucki et al., 2000). This product is stable for three years and is comparable to other anti-D products on the market (Stucki et al., 2000). Development of Rh-D immunisation in the 1960’s was based on the well-recognised phenomenon of antibody-mediated immune suppression (AIMS). This process facilitates specific antibodies to be passively administered that are known to prevent active immunisation (Urbaniak & Greiss, 2000). In order to protect against immunisation of Rh-D positive cells in the maternal circulation, they must be removed within 5 days of administration of anti-D (Kumpel, 2006).

For treatment, anti-D can be administered by intravenous (IV) or intramuscular (IM) injection. When injected into the maternal system anti-D immunoglobulin will “mop up” the circulating Rh-D positive red blood cells (Figure 1). This prevents the usual immune response in the mother by preventing the development of harmful anti-D antibodies (Koelewijn et al., 2009). As a result of this the potential sensitising event (PSE) goes unnoticed by the maternal system.

![Image of how Anti-D works](image-url)
2.3.2 Why is Anti-D Given?

Haemolytic disease of the newborn (HDN) is a disease caused by maternal IgG antibodies crossing the placenta, binding to the fetal antigen-positive red blood cells (RBC), and initiating their destruction, thereby causing anaemia (Avent & Reid, 2000). Prior to 1970, HDN was a significant cause of perinatal mortality and morbidity due to the development of these anti-D antibodies secondary to feto-maternal haemorrhage (FMH) occurring in Rh-D negative women carrying an Rh-D positive baby. This led to the introduction of post-natal immunoprophylaxis and prophylaxis for other potential sensitising events (PSE), with anti-D IgG immunoglobulin (Koelewijn et al., 2009). This decreased the incidence of post pregnancy Rh-D immunisation from 12-13% to 1-2% (Hartwell, 1998). There is currently sufficient evidence demonstrating that by also providing antenatal prophylaxis, the risk of Rh-D immunisation in the subsequent pregnancy can drop to a level of below 0.4% (Liumbruno et al., 2010). Fyfe et al. (2014) in their scoping review found that despite this the delivery of anti-D to Rh-D negative pregnant women was suboptimal.

While haemolytic disease of the newborn (HDN) due to Rh-D immunisation has become an infrequent complication of pregnancy, all women who become sensitised can, on all subsequent pregnancies with a Rhesus positive baby, be effected (Tiblad et al., 2013). Once anti-D antibodies are produced by the mother they remain in the system forever. Tiblad et al., (2013) in a retrospective cohort study analysed the timing of Rh-D immunisation in pregnancy and the consequences for the existing, and subsequent pregnancies. The objective was to design an optimum antenatal screening and prevention program. The reliability of this study is in question due to the fact that only 290 Rh-D immunised women were included. All women in the study had access to antenatal anti-D following a PSE and received postnatal anti-D following the birth of a Rh-D positive baby. Although the study had small numbers it found that
at least half of the cases of Rh-D allioimmunisation could potentially have being avoided by
the administration of routine antenatal anti-D prophylaxis (RAADP) at the beginning of the
third trimester. These findings give us valuable insight into the potential benefits of RAADP.
This was further supported by the BCSH guideline (Qureshi et al., 2014) who recommended
that routine RAADP should be regarded as a separate entity and administered regardless of,
and in addition to, any anti-D that may have been given previously for a PSE.

2.3.3 Implications for the Administration of Prophylactic Anti-D.
There is strong evidence that RAADP prevents sensitisation in pregnant Rh-D negative
women (Turner et al., 2012). Different prospective studies and clinical trials explore the use of
a prophylactic one or two dose regimes (MacKenzie et al., 1999; MacKenzie et al., 2004).
These studies exhibited a reduction in the incidence of maternal sensitisation using RAADP
but there is no direct comparative data available that evaluates the efficacy of the single dose
versus the two-dose regime (Qureshi et al., 2014). The choice of the one or two dose regime
may have significant impact on the planning of antenatal visits and the local budgets
(MacKenzie, 2004). A primary concern is weighing up the risks and costs of administration of
anti-D against the benefits and morbidity associated with non-administration. MacKenzie et
al. (2004) in a prospective study evaluated the two dose regime. This study acknowledged the
effective period following anti-D administration is 42 days. In theory, to justify the use of a
second RAADP at 34 weeks, is in order to cover the post-mature babies. Laboratory studies
did not confirm any clear advantage to this practice (Fyfe et al., 2014). MacKenzie (2004)
supported this when he found no data that provided any evidence of differences in clinical
efficacy between the different dose regimes. Indeed there is no internationally agreed policy
on the correct dosage regimens to follow. MacKenzie did note that the rate of compliance with
a one dose regime was greater. This led to the recommendation of a single-dose regimen as
it was likely to be simpler and lead to fewer errors in administration. Tiblad et al. (2013) in a retrospective study recommended from its findings to also use a one dose regime in gestational week 28-30 selectively to all Rh-D negative women. In England, the one dose regime is given as part of routine practice across the NHS (RCOG, 2011).

It is also not enough to understand that we need to administer anti-D, we also need to ensure that we are providing a therapeutic dose in order to be successful (Koelewijn et al., 2009). In this study the authors found that there was merit in performing a Kleihauer test. This is a blood test used to measure the amount of fetal haemoglobin transferred from the fetus to the maternal bloodstream. Koelewijn et al., (2009) concluded that following a PSE, it was unlikely that the fetal blood loss that would extend beyond 1ml. Urbaniak & Greiss (2000) suggests that the general principle is that 100iu of anti-D will provide protection against 1ml of Rh-D positive fetal red cells. Currently in practice the dose administered is 1500 IU which protects against 15mls of fetal Rh-D positive cells. If the Kleihauer test results show a fetal blood loss exceeding 12mls than an additional “flow cytometry test” (Appendix 4) is performed in order to accurately determine the amount of extra anti-D that is required. The Kleihauer test is only required in such events that it is considered that potentially more than 15mls of fetal Rh-D positive cells will enter the maternal system. Examples of such events are following delivery and a large antepartum haemorrhage. The use of the Kleihauer test is not recommended in the administration of RAADP as it seems highly improbable that an unprovoked transplacental haemorrhage during the antenatal period is likely to exceed 15mls (MacKenzie et al., 2006).

It would appear prudent to examine the economic aspects of introducing RAADP. Failure to prevent Rh-D sensitisation and manage neonatal HDN resulted in 114,100 avoidable neonatal deaths and many others growing up with disabilities on a global scale (Bhutani et al., 2013). Chilcott et al. (2004) in a cost effectiveness analysis found that routine antenatal anti-D
prophylaxis provides a cost effective intervention to women who are Rh-D negative in preventing HDN. Further literature recommends that prophylaxis worldwide should be achieved as a matter of priority (Zipursky & Paul, 2011).

Anti-D is recognised as a blood product and so requires the same traceability measures as with any other blood products. By the late 1990’s there was growing anxiety among people in England in relation to possible infection from the administration of blood products. Some preparations previously used for Rh-D prophylaxis were withdrawn due to concerns relating to Creutzfeldt-Jakob disease (CJD) transmission (MacKenzie et al., 2006). This led to an increase in refusals among women when receiving RAADP from 0.8% to 3.5% (Qureshi et al., 2014). In acknowledgement of the benefits of RAADP work remains ongoing in the development of recombinant antibodies in order to continue to protect against Rh-D sensitisation (Urbaniak & Greiss, 2000).

The implications of administering RAADP on the neonate were also considered in a study (Dillon et al., 2011). This retrospective review aimed to look at the effect RAADP had on the Direct Coombs Test (Appendix 5) in the neonate and the subsequent requirement for phototherapy. The study concluded that there was an increase in direct coombs test (DCT) positive results from 1.5% to 2.3% following the introduction of RAADP which subsequently may result in an increase number of unnecessary bilirubin levels and phototherapy commenced in the neonate. The need for phototherapy only seemed to be significant in those neonates with high DCT levels. This paper is worth considering in an organisational context following the introduction of RAADP as a potential addition to the admission rate of the neonate to the special care baby unit for invasive monitoring and potential phototherapy. The causative factors for hyperbilirubinemia in the neonate is multifactorial and cannot always be
associated with high DCT levels. Others factors include ABO/Rh Group, ethnicity, and breastfeeding.

2.3.4 The Importance of Education

Despite the fact that the value for using anti-D has been acknowledged since 1969 more recent figures highlight the rise in errors occurring in the administration of anti-D (Hurrell, 2014). In a UK-wide report it was acknowledged that the risk in errors occurring form transfusions had dramatically increased from 67 events in 2004 to 354 events in 2013 (Bolton-Maggs & Cohen, 2013). Some of these findings were associated with the unsafe use of anti-D. Lack of knowledge among healthcare providers in relation to when and how anti-D should be administered seems to be the main problem (Hurrell, 2014).

Bolton-Maggs et al. (2013) carried out a retrospective review of cumulative reporting to the UK haemovigilance scheme (Serious Hazards of Transfusion (SHOT)). This retrospective review reviewed the SHOT database from 1996 to 2011 in order to highlight the errors associated with the use of anti-D immunoglobulin in Rh-D negative women. The authors concluded that women and babies continue to remain at risk of sensitisation due to unavoidable user errors. This was further supported by a paper written by Hurrell (2014) who suggested that confusion remains around when and how it should be administered which continues to put women and babies at risk. As a result of this further education and training is an absolute necessity. This education also needs to be on-going (Hurrell, 2014). Bolton-Maggs & Cohen, (2013) further recommend the use of a local checklist to help further reduce errors. The writer considered this when developing the project plan for this initiative. Finally to consolidate education around the administration of anti-D RCOG, (2011) recommends that information leaflets should also be made available to pregnant women to help with the informed consent process.
2.4 Implications for the Project

The studies have shown the value of administering prophylactic anti-D to Rh-D negative women in pregnancy (Chilcott et al., 2004; Crowther et al., 2013; Fyfe et al., 2014; Hurrell, 2014; Kumpel, 2006; Liumbruno et al., 2010; Pilgrim et al., 2009; Turner et al., 2012; Urbaniak & Greiss, 2000). These studies suggest offering RAADP to women in the third trimester at around gestational week 28-30. Education programs are required prior to implementation to increase knowledge and understanding of anti-D administration. The writer considered the introduction of an anti-D documentation checklist to further support staff with implementation. The practicalities of implementation need to be considered in chapter 3 to ensure success of the project with minimal disruption to existing services.

2.5 Summary and Conclusion

The purpose of this literature review was to develop a greater understanding and examine the role of prophylactic anti-D in pregnancy. Following an extensive review of the literature the writer acquired the theoretical understanding that was required to direct the organisation development project. Rh-D allioimmunisation in pregnancy continues to create a risk. The writer believes that there is sufficient evidence to support the use of RAADP as it has been shown to reduce the incidence of sensitisation and hence the risk of HDN. The introduction of prophylactic anti-D into a healthcare setting requires clear guidance for practice and in the writer’s opinion, and a structured educational programmes to ensure compliance. Chapter 3 provides an in-depth analysis of the methods and methodology used to inform and deliver this project. The writer will apply the HSE OD Model to help describe a consistent approach to the change management project.
Chapter Three: Organisational Development Process
3.1 Introduction

This organisational change project involves the introduction of RAADP to all Rh-D negative women at 28 weeks gestation at Cavan General Hospital. While this project has a relatively small scope Jacobs et al. (2013) warns that even small projects are also prone to poor planning, disappointing results and unintended consequences that divert resources from operational tasks, disrupt well established routines, and “shatter the trust” of employees and businesses alike. It is therefore important to apply the same rigor to the development, initiation, implementation and mainstreaming of this organisational change as would be required in a larger project in order to ensure success (Jacobs et al., 2013). Change management is becoming an increasingly significant topic for project management research and practice (Pollack, 2015). There are many different organisational approaches that can be used to help drive this project. The writer will critically review some of these approaches in order to help determine which one will be most suitable for use in this project.

3.2 Critical Review of Approaches to Organisational Development

It is important to define change management. Creasey (2009) describes it as the process, tools and techniques used to manage the people-side of change to achieve a required business outcome. Over the years many people have developed change models to help understand the change process and undertake change management. One of the earliest models was developed by Lewin in the late 1940’s. He used a reductionist approach. He described a three phase planned organisational change that helped move people from the old state to a new state. The phases were unfreeze, change and refreeze. This was further developed by Kotter (1995) who described the eight steps of change (Figure 2). This model consists of eight steps which commence with creating a sense of urgency, building and guiding a team, creating a vision, communicating the vision and removing the obstacles to the
vision, creating short term wins, declaring victories and finally anchoring changes in the organisational culture.

![Kotter's Eight Steps of Change](image)

**Figure 2: Kotter’s Eight Steps of Change**

Kotter’s model takes on a more structured approach making the assumption that there is a correct way of doing things. However, while useful it is very scientific and tends to overlook the human relations element to change management, the writer feels that the human relations are an important factor in the process improvement proposed.

As organisational development models evolved over the years they took on a more action research approach and Senior (2002) described an organisational development model of change that incorporates every part of the organisation and the people that work there (Figure 3). This model focuses on creating a vision for the future state, with emphasis placed on the change agent. The change agent is seen to be responsible for the driving the change forward.

![Senior and Swailles Organisational Development Model](image)

**Figure 3: Senior and Swailles Organisational Development Model**
In 2009 the HSE published “A Users’ Guide for Managing Change in the Health Service Executive” (HSE OD Model). While this also adapted an action-research approach, its base was grounded in an organisational approach, which placed a strong focus on the people aspects of change. It is combined with project management which helps bring structure and discipline to the process. The aim of this model is to provide a consistent approach to effective change that can be applied by leaders and managers across the whole system and at all levels. It outlines four stages of the project management lifecycle (Figure 4). The stages include initiation, planning, implementation and mainstreaming.

![Figure 4: HSE OD Change Model](image)

The writer has chosen the HSE OD Change Model to support the implementation of her project because it was felt to be the most suitable approach to use given that the health service constantly needs to react to both internal and external factors which help to govern its existence.
3.3 Rationale for using the HSE OD Change Model

The rationale for using the HSE OD change model is that this model acknowledges the complexities associated within healthcare. Change is constant with new initiatives required on a daily basis. In fact Abrahamson (2000) suggests that organisations have to change in order to stay alive. The changes currently being experienced by the Irish Healthcare system include the establishment of new services and the reconfiguration of existing services in order to improve outcomes for the service user and the wider population (HSE, 2008). The HSE OD Model recognises how different elements of change are interrelated and are dependent on people changing. While resistance to change is inevitable Stroller (2010) acknowledged that despite our aversion to change, our lives depend on progress and innovation, which is at the core of change. Using this model addresses ways of managing change in an attempt to bring people along during the “Initiation phase”.

3.4 The HSE OD Model

3.4.1 Initiation

The key component of organisational change is to have clarity and be specific about the process improvement initiative. The clarity and specifics of the project are established in the initiation phase. The initiation stage is important to the success of the project as it helps lay down the foundations for the initiative. The HSE OD Model (2008) describes the purpose of the initiation phase as being necessary in order to establish a sense of shared responsibility and helps scope out a solid foundation for successful change. Performing a GAP analysis (Appendix 6) helps to assist in the journey of change. Kotter (2008) further suggests that it is also necessary to inspire a strong sense of urgency to the project. This supports a concept of readiness that is intended to provide change agents with a perspective of what they need to do in order to convince change recipients to buy into the organisational change (Armenakis &
It is important to understand the need for change in order to be able to offer appropriate communication support, dealing with employees concerns, and actively involving staff in the process. These key factors help reduce employee resistance (Gerwing, 2015). Ford et al. (2008) further acknowledges that the key to overcoming resistance is rather than suppressing contributions to change, we should ensure to engage in all of it. A power/impact matrix chart was developed in order to identify the stakeholders that were to be involved in the project (Appendix 7). A stakeholder is anyone who is likely to be affected, directly or indirectly by organizational change or a programme of change (Huczinski & Buchanan, 2001). A stakeholder analysis chart (Appendix 8) was drawn up to help determine the level of involvement that was required by the relevant stakeholders. The list of stakeholders were identified through the use of a “responsible, accountable, consulted and informed” (RACI) chart (Appendix 9) and the roles and levels of communication that would be required by the various stakeholders were acknowledged. The more important the stakeholder is to the success of the project, the more time and resources were devoted to maintaining their involvement.

The purpose of the initiation phase is to build the foundations for effective change and to mobilise support across the organisation (HSE, 2008). The project began by drawing up a business case to present to the stakeholders (Appendix 10). The purpose of the business case was to outline the project in order to obtain approval for proceeding with the change effort (HSE, 2008). This is a high level plan and provides clarity about the purpose of the change, while also providing an understanding of why change is required. In context it is considered with the end in mind rather than as a process in its own right (Covey, 1989). The initial business case also included a summary of key risks to delivering the project. These are also at a high level but were further developed in the implantation plan with control measures.
identified as the detail of the project unfolded. The information outlined in the business case informed the subsequent development of the implementation plan.

### 3.4.2 Planning

The planning stage involves the specific detail in relation to the change and helps to create support for the change process (HSE, 2008). This involved bringing the key stakeholders together to present the business case and communicate the change initiative proposed. The purpose of the planning phase is to increase participation and engagement of the change process. Building an increased understanding of what the change is intending to accomplish and what it means to all those personally involved is vital to the success of the project. The business case was presented to the key stakeholders and approval for the project was given and commitment secured.

#### 3.4.2.1 Building Commitment

Once commitment for the project is secured it is important to ensure that the whole organisation understands the vision, and is committed and supported in making the project delivery a reality (HSE, 2008). At this stage the focus is on engaging staff and raising awareness for the project, while affording them an opportunity to explore the implications the project will have on their day to day operations (HSE, 2008). Blackman et al. (2013) highlights that there needs to be a readiness in the capacity of the organisation to work together, both within and across the organisation.

The importance of choosing a team leader for the project was highlighted by Sirkin et al. (2005) where they suggest that a good team leader has good problem-solving skills, are results orientated, methodical in their approach, are organisational savvy, willing to accept responsibility for decisions, and while being highly motivated don’t crave the limelight. On
analysing the stakeholders and to ensure success for this project it was decided to allocate the chair of the steering committee to the Haemovigilance officer as she was the embodiment of these traits and was known and respected by all other members of the team. The change agent will have the commitment, drive and time to bring the change to its successful completion (Stonehouse, 2013).

3.4.2.2 Determining the Detail of Change

During the initiation phase it is important to identify the processes existing within the service that has to change while also holding on to what’s good. Involving key stakeholders in order to provide input was identified as being integral to determining the detail of change. Focus groups were set up to discuss the new initiative and an observation study was carried out to look at the patient journey through the maternity outpatient clinics. The manager of the outpatient department identified that the clinic in its existing form would need to be amended as the time required to administer anti-D to all Rh-D negative women at 28 weeks was undeliverable in the current context due to time restrictions. A solution to this problem was the development of a separate antenatal clinic dedicated specifically to the administration of RAADP. Discussions in relation to the project helped to identify to all that change was on now inevitable.

Prior to the undertaking of this project all anti-D injections for use in the hospital were sourced through the Pharmacy. It became apparent at the outset that this was inappropriate as anti-D is a blood product and as such should go through the same traceability and governance as for all blood products. This was to be achieved by transferring all dispensing responsibilities of the product to the laboratory with clear guidelines to access, dispensing and traceability records of the product. However this caused initial concern to the senior medical scientist on the team as he felt that distribution of anti-D through the laboratory may be beyond the
training for on-call medical scientists who only have limited knowledge and training. The consultant haematologist agreed to further discuss this with a fellow colleague who had governance over the blood bank. Other issues arose in relation to the administration of anti D in general but they will only be discussed in this paper if it directly impacts on the administration of RAADP.

3.4.2.3 Developing the Implementation Plan

The purpose of this step is to provide a more detailed plan of how the vision will be achieved. This helps to further prepare the organisation for change (HSE, 2008). The implementation plan was developed (Appendix 11) in order to provide a more comprehensive outline of the project. The Plan, Do, See, Act (PDSA) cycle (Langley et al, 2009) was used as a guideline for completing the implementation plan (Appendix 12). The execution of a “strength, weaknesses, opportunities and threats” (SWOT) analysis (Appendix 13) further informed the development of the implementation plan by giving credibility to the chosen improvement project. A SWOT analysis gives the project purpose by providing relevance to the initiative while considering both internal and external influences. The implementation plan provided a brief overview of the purpose of the project. The what, who, when and where of the project was identified and proposed delivery dates attached. The resultant implementation plan described all the critical requirements that were to be in place at project start and remain so for project success. A detailed description of the risks identified and the control actions that may affect the project success or progress, were listed (Appendix 14). An impact analysis supports better decision making through a deep understanding of risk (RCSI, 2015). It also is continually referred to over the life of the project to ensure that the objectives are being met. Any issues that were identified helped towards making amendments to the process. A
detailed list of resource requirements were also added to give focus to exactly where the money was required, and for what purpose.

The need for guidelines and supporting documentation was identified and a working group was set up to work on this. Their task was to develop the guidelines, create and design an anti-D checklist (Appendix 15), and finally a patient information leaflet that would provide supportive information to the woman prior to administration of RAADP.

All communication in relation to the project was agreed to be through emails and regular structured meetings where agenda items, actions, responsibilities, and time limits were discussed and agreed under the guidance of the chairperson. An example of the minutes are shown in appendix 16. Having a structured communication plan is important to the project as it gives consistent information over several different stages of the project and provides clarity on what the issues are and who is responsible for actioning them with realistic timelines towards achieving them. It is important to establish from the outset that change is underway.

During the implementation planning it was identified that there was a need to move the dispensing of anti-D from the pharmacy to the laboratory. The logistics of transferring the dispensing of anti-D from the pharmacy to the laboratory was discussed and a team set up, primarily made up of the laboratory staff, to work on this. The managers in the relevant departments would be allocated the task of organising the clinics to facilitate the delivery of RAADP. These were included as the initial tasks on the project plan.

The need for a training programme was identified and the haemovigilance officer and the project manager were allocated to design presentations to roll out the training programmes in the implementation phase. These were to be used to provide training to all relevant staff. During this phase it is important to support those who will be responsible for the role out of the
project. This was to be done by developing their skills, knowledge and competencies to help facilitate them in the role out phase. The creation of a guideline and supporting documentation to inform their practice would further provide that support. Once the detail of the implementation plan was developed it was important that it was then communicated to all key staff in order to test some of the design details. Introductory education sessions were given to all healthcare professionals to whom the role out of RAADP had an impact on. This was to help prepare the teams that change was on the way.

Any potential industrial relation (IR) issues were to be explored at this stage. Due to the fact that the provision of this service was perceived to be in the client’s best interest and also to be well within each health care professional’s scope of practice, no IR issues were anticipated. A decision was made by the project manager not to involve the trade unions as she did not anticipate a need. Armenakis & Harris (2009) discuss the importance of involving all change recipients in the diagnosis, interpretation, and remediation of change facing the organisation. The writer reflects that by not involving everyone in the course of this project was an oversight, with a potential flashpoint being avoided by chance, rather than a good communication plan.

A detailed GANTT chart was completed which included details about roll out and go live dates (Appendix 17). Due to the nature of the project the process improvement element was not piloted. However the anti-D checklist was piloted for approximately 2 months prior to go-live to help determine reliability and efficacy of the document design.

3.4.3 Implementation

This stage is the implementation of the project plan. This is monitored constantly to ensure that it is adhering to the timelines.
The developed guidelines and supporting documentation to support the administration of anti-D were ratified by the organisation. Patient information leaflets were drafted for approval by the key stakeholders before being ratified by the organisation and sent for printing. These information leaflets were also sent out to the “National Adult Literacy Agency” (NALA) for proof reading.

In order to be ready for the go-live date of 5/10/2015 the main training of the maternity staff began of 22/09/2015. This was advertised through the use of a colourful poster which was displayed in all key service areas (Appendix 18). It was also sent out on email to all those who had access. Training was provided alongside the acute service areas to facilitate the dropping in of staff while on duty. Priority was given to staff working in the out-patient department and the midwifery led unit followed by staff in the antenatal wards. Staff working in out-patients were also given direction on the administration of IM injections using the deltoid muscle as this was not part of their routine practice to date. Not all staff were in a position to attend the allocated study days so remaining staff were trained on an adhoc basis by the writer who was on duty on a daily basis and was in a position to do one to one sessions. By 22/12/2015 95% of maternity staff were trained. Reasons for incomplete training was due to staff maternity and sick leave.

While it is important to follow the implementation plan not all the roll out dates were achieved and amendments had to be made. While it was desirable that the guideline was signed off prior to go-live and that was what was intended, unfortunately the Quality and Risk committee (Q&R) meeting due on the 01/09/2015 was postponed until later in the year making it impossible to get the guideline ratified and signed off before the go-live date. As the result the project went live with a working draft document to support staff. A ratified document
completes the governance process and without this there was an increased risk to the project (Quality Function Office of Quality and Risk, 2011).

By late August the manager on the maternity ward agreed to pilot the anti-D checklist to help determine its value and user friendliness. The instruction on the use of this document was done initially at ward level and further consolidated in training. Although the chart looks “busy” the staff found it a valuable tool in helping to inform their practice particularly in relation to the administration of anti-D following a potential sensitising event (PSE). Issues that arose following consultation with staff was duplication of double signature sign off. This was proving to not only be labour intensive but its value to practice was questionable. The reasoning for the duplication was that staff were not only required to double sign the drug kardex but the checklist also. As a result of this it was decided to see if the new checklist with minor amendments could also have the ability to accommodate prescription and therefore remove the need for a drug kardex. This was amended but is still awaiting approval and sign off from the drug and therapeutics committee (D&T). A working copy of the checklist remains in use.

In preparation for the roll-out both the CMM2 in the out-patient department (OPD) and the midwifery led units (MLU) undertook various procedures to identify women eligible for RAADP. As both the OPD and MLU were different departments the operational piece was to become slightly different. To reduce the risk of error all women at the first consultants visit in OPD, highlighted as rhesus negative, were given an appointment for the 28 week midwives clinic. This was accompanied by a patient information leaflet. A follow up appointment letter was also sent out to them approximately 2 weeks before their scheduled appointment. While the MLU took a similar approach the 28 week appointment was run as normal with the new added feature of administering RAADP. Prior to the go-live date both the CMM’s went through all the existing charts and identified all those who were around 28 weeks after the 05/10/2015.
These were then contacted and informed about the new initiative with an accompanying copy of the patient information leaflet.

3.4.3.1 Implementing change

The administration of RAADP commenced on 05/10/2015. The first clinic commenced in OPD on the 07/10/2015 with 5 women attending for RAADP. This clinic was supported by the project manager who was in attendance to ensure that all staff were happy with the agreed process and that no issues arose in the execution of the clinic.

The women expected to the clinic had being identified and a block order for anti-D was issued to the lab the previous day. The midwife running the clinic in the afternoon collected the injections from the laboratory prior to starting the clinic. They were transported to the clinic in a freezer box. Each injection had a patient label attached. For confidentiality purposes the boxes were returned to pharmacy following administration for disposal.

On the initial go-live date the third client seen had her booking bloods done by the GP. This meant that the blood group report did not have the hospital number included. BSCH guidelines state that the group report for authentication purposes requires 3 patient identifiers. As this blood report only contained 2 identifiers (name and date of birth) the lab could not issue the anti-D until the woman had her blood group retaken. This was done but caused a delay to the clinic. As a result of this incident the staff relooked at attendees at subsequent clinics and identified those who had similar blood reports. Any women who was identified that would require a repeat blood test on the day was contacted and asked to attend for bloods prior to commencement of the clinic. This was to help reduce interruptions to the flow of the clinic.
3.4.3.2 Sustain momentum

Within healthcare improvements and change are continuous with new initiatives constantly being introduced or updated. It is a challenge for all healthcare professionals to sustain momentum and enthusiasm for all new initiatives being developed. In order to ensure that this project rolled out successfully and became part of routine practice it was important to regularly keep contact with front line staff and continue to have committee meetings in the initial post implementation phase. At the post go-live meeting the midwife who was responsible for running the anti-D clinic was invited to attend. Doing this allowed her a forum to discuss issues that arose at frontline while also meeting with people who had the ability to sort out these issues should they be outside her remit.

The implementation of RAADP revealed a lot of positive behaviours within the workplace. The midwifery staffs at frontline services embraced the new role, and not only actively participated in the rolling out of this initiative but with minimal supervision were capable of troubleshooting a lot of the minor issues that arose post go-live. As the clinic was held in a remote area of the out-patient department the staff, and in consultation with the ward manager, it was decided in the interest of safety, all women at increased risk would be administered RAADP at ward level. Women with a factor 8 deficiency and those who were at risk of anaphylaxis were given appointments to attend the maternity ward for injection administration. An anaphylaxis box was also kept in the outpatient clinic for emergencies and all staff received anaphylaxis training.

Following the identification of the original cohort of women who were to require RAADP the CMM2 in outpatients in an attempt to reduce the risk of women being overlooked, considered different processes to reduce the risk of this occurring. All women were identified at the first consultants visit and an appointment was booked for them at this point. The RAADP
information leaflet was also given to the women at this point. Reminder letters were also sent out to them 2 weeks in advance of that scheduled appointment. The introduction of reminder letters was something that was not covered in the guideline but the CMM2 felt that this was an important additive to the process in order to ensure that no women were missed. Implementation of the project was now complete.

3.4.4 Mainstreaming

The purpose of this next stage is to focus on the success of the change effort (HSE, 2008). When introducing any change within an organisation the development team will help drive the project and ensure that what needs to be done gets done in order for the project to succeed. The true measure of success of a project is that on completion it becomes “the way we do our business”, and does so independent of the project team.

3.4.4.1 Making it “the way we do our business”

Al-Haddad & Kotnour,(2015) identify the importance of choosing an integrated approach to drive systematic, constructive change as well as addressing the consequences of making the change. These are important factors to consider when integrating the new behaviour, skill and work practices. The development of a separate clinic whose sole purpose was the administration of RAADP helped to re-inforce and support the new behaviour. Creating a separate clinic made it easier to transit to a new mindset that was required in order to execute a new way of doing business.

The concept of this process improvement was such that decision making processes were very clear. This was enabled by the guideline and supporting documentation that was developed while also providing flexibility to staff to develop further practices that were of interest to the project. An example of this was when the manager of the out patients
department developed a diary that contained the name of all Rhesus negative women that were identified after the initial blood group. This diary was used to schedule their 28 week appointment and also served as a trigger to staff to send out the two week reminder letter prior to their appointment. Although this was not covered in the supporting guideline the manager seen these further practices as a way to improve efficiency and effectiveness of the service.

This stage also identifies the need to acknowledge success and to take time to celebrate achievements (HSE, 2008). On an annual basis, our hospital runs a “Quality and Safety Awards” ceremony that celebrate initiatives that have being achieved within the organisation in various categories. The writer plans to submit this project as part of the “Quality Initiative” awards category in order to celebrate all the work that went in to achieving this project.

3.4.4.2 Evaluating and Learning

The purpose of this stage is to look back at the project and critically review its design and implementation (HSE, 2008). It is important to acknowledge if we have achieved what we set out to achieve and to prepare for the future by making it part of the way we do our business. Flexibility and openness to change is critical for the organisation to remain relevant and responsive (HSE, 2008). The writer critically looked at the process and the eventual end result and reflects on some aspects of the project that led her to question whether we were indeed relevant and responsive to the needs of the service user. As described previously, all women receiving antenatal care at out-reach clinics had to attend the main hospital at 28 weeks as we could not provide anti-D injections off-site. The writer questions how user friendly this was to our clients as it meant they had an added burden of travelling for an extra clinic to the main hospital. The new national maternity strategy launched this year (DOH, 2016) aims to deliver a large amount of the maternity services in the community over the next
ten years. It was remiss of this project team not to look at ways on how we as an organisation would be able to adopt to this when anti-D will be required for administration at community level.

It is also important to discontinue any activity that no longer serves the need of the new organisational reality (HSE, 2008). Therefore on the 22\textsuperscript{nd} April 2016, the anti-D team held their last meeting at which they formally handed over to the maternity practice development team for on-going review and responsibility. It was the recommendation of this committee that a repeat audit would be carried out in a year to determine was there any new cases of women who became Rh-D sensitised.

In order to measure success of the project we need to evaluate the aims that were laid down in chapter 1. The methods and process of evaluation will be covered more in depth in chapter 4.

3.5 Summary and Conclusion

The aim of this project was to introduce the administration of RAADP to all Rh negative women at 28 weeks gestation in a rural maternity hospital in Ireland. The writer followed the HSE OD Model to help provide structure to the project but also because this model places a strong focus on the people aspects of change. This process improvement was heavily reliant on people not only to buy in to the initiative but also be willing to change the way they do things and provide a service that would be beneficial to this cohort of women.

The writer included the use of various analytical tools to help inform the process. These included the use of SWOT analysis, stakeholder analysis, RACI chart, PDSA cycle, GAP analysis, impact analysis and risk controls charts. These tools helped to identify the key stakeholders that needed to be involved in the project while also providing data to those
stakeholders to help inform the need for change. They were also used to develop the implementation plan which was used to deliver the project successfully and within the specified timeframe.

This chapter concluded with a brief overview on the evaluation of the change. This will be discussed in more detail in chapter 4.
Chapter Four: Evaluation
4.1 Introduction

The project went live on 05/10/2015 and all Rh negative women attending the hospital now receive RAADP at 28 weeks. Evaluation of change is fundamental to the change process in order to assess whether the change is working in practice or not (Cork, 2005). How successful this project was can only be determined through evaluation. We need to specify the outcomes of care, by formulating the appropriate criteria and standards, and finally obtaining the necessary information in order to assess quality (Donabedian, 1988). Choosing what to evaluate in order to determine success is vital. De la Harpe & Kavanagh (2007) highlight that if we measure the wrong things in the wrong way, then wrong things may get done.

Firstly we will look at some definitions that best describe what evaluation is in the healthcare setting. Lazenbatt (2002) describes it as:

“A method of measuring the extent to which an intervention achieves its stated objectives.”

Another valuable definition used by (Green & South, 2006) defines it as:

“Determining the value or worth of a healthcare initiative against a standard of acceptability. To examine or judge.”

The challenge for healthcare professionals is not only to identify what quality is but also to be able to apply some sort of measurement tool in order to evaluate whether we achieved that quality. Research provides healthcare professionals with standards that achieve quality, whereas evaluation is the tool to assess whether we achieved these defined goals. Health managers have a responsibility to ensure access of quality services to all of the population served by a service (Ovretveit, 2002).
The writer will firstly look at the significance of healthcare evaluation followed by a critique of some evaluation models that will be considered for use in this project. This will be followed by publishing the results found using the chosen model for evaluation and a plan of how these results will be disseminated to the wider team involved in the project.

4.2 Significance of Healthcare Evaluation

It is important as health managers that we are able to improve the performance of health services in order to deliver a quality service (De la Harpe & Kavanagh, 2007). Green & South (2006) outline the benefits of evaluating. They describe it as being necessary to help improve health programme implementation, establish whether healthcare interventions have worked, and provide accountability to funders. It also helps to increase support for sustaining or expanding an intervention, contributes to the scientific base for interventions, and has an impact on policy decisions. Evaluation helps to provide information that is important to the service provider to ascertain these benefits.

It is also important to be clear on what we need to evaluate. De la Harpe & Kavanagh (2007) highlight that it is important that the right things must get measured in the right way if they are to underpin the right management decisions in order to improve healthcare performance. Ovretveit (1998) looks at further breaking down evaluation into interventions that we can evaluate. Interventions are treatments, services, policies, and change to an organisation.

4.3 Evaluation

It is important to understand what we need to evaluate in order to ensure that we can determine whether this project was a success or not. Finding out what has worked and what has not is essential for human performance improvement and organisational success
(Kaufman et al., 1995). The easiest way to do this is to link back to the aims and objectives of this project.

4.3.1 Aims

Aim 2 states that by October 2015 all Rh negative women attending Cavan General Hospital will receive RAADP as recommended by the national guidelines. The writer reflected on the best way of evaluating this and concluded that a single before and after design outcome was the best approach. This was to take place in the form of an audit. The measurable outcome was that all women received RAADP post go-live. It was identified that a way to do this was to go to the laboratory records. The laboratory staff have access to records that identify all Rh negative women attending the hospital. They could also track all dispensing of anti-D injections.

Aim 3 was to design and deliver the education programme to support practitioners with knowledge. Program evaluation is the use of social research procedures to systematically investigate the effectiveness of social intervention programmes such as education and training (McNamara, et al., 2010). The writer looked at different models for evaluation. The CIPP (“context, input, process and product”) model (Zhang et al., 2011) is a popular evaluation tool in educational settings. Its core concepts are context, input process, and product evaluation, with the intention of not to prove, but rather improve the programme itself (Stufflebeam, 2003). However this model requires a lot of careful planning and multiple sets of data collection are required to use it successfully. Due to the time constraints attached to this project the writer concluded that the Kirkpatrick model was the one that best suited this form of evaluation (Figure 5). It also provided clear evaluation questions that suited the type of evaluation required for this project.
Figure 5: Kirkpatrick’s Model

This model focuses on 4 keys outcomes through its clear focus on learner behaviour in relation to the training. The four outcomes are reaction, learning, behaviour, and results. The writer will use these as a guide to discuss the evaluation used for this project.

Finally, Aim 4 was to produce a patient information leaflet to be given to all Rh negative women prior to the administration of RAADP. The checklist contains the question “Patient received Anti-D information booklet prior to anti-D administration”. This question will be included in the documentation audit and a yes response will be interpreted as success to this aim.

4.3.2 Methods and Measures

Aim Two: By October 2015 the unit will administer routine RAADP to all Rh negative women at 28 weeks gestation in order to be fully compliant with the National Clinical Care Programme guideline.

It is important to decide how quality is to be defined. Specifying the outcomes of care, formulating the appropriate criteria and standards, and obtaining the necessary information are the necessary steps in the process (Donabedian, 1988). The writer reflected on how best to obtain data that would verify that all women received RAADP following delivery of the
implementation plan. The laboratory technician generated a report from the computer software system used in their department. A sample population was chosen between 05/11/2015 and 09/02/2016. This population was all those who had received anti-D during the specified timeframe. The writer acknowledges that this information is driven by demand and does not specifically reflect the distribution of anti-D injection for the purpose of RAADP. In order to refine the search, the technician then added filters to the report. The filters removed administration by ward which excluded surgical and accident and emergency departments. This left the out-patient department (OPD) and the midwifery led unit (MLU). The maternity was included in order to capture those high risk women who received RAADP at ward level.

**Aim Three: Design and deliver an education programme to support practitioners with knowledge in relation to the use and administration of RAADP by January 2016.**

This evaluation was also done in two parts. Firstly the writer used an evaluation form that was given out to every member of staff that attended for training. This would help to identify the reaction and learning behaviours of the attendees. A total of 66 evaluation forms were returned for use in the evaluation. This evaluation form established the “reaction and “learning” component of the Kirkpatrick model. Outcomes are presented in Figure 3.

In order to assess the impact and the outcome of the training (Kirkpatrick Model), the writer choose to review the documentation checklist that was designed for use in the healthcare setting. Compliance with using the document and its completeness was determined to be the measure of success of the training. The document was assessed in relation to completeness and application in practice. Compliance with the administration of RAADP, when required, was also assessed using an audit.
Aim Four: Produce a patient information leaflet to be given to all Rh negative women prior to the administration of RAADP

The distribution of the anti-D information leaflet prior to administration was chosen as a measure to determine that the learner did training to practice, and a determination that the training investment did, in fact, pay off and the learners did deploy learnings to the job.

4.3.3 Results

Aim 2: In order to confirm that all women who were eligible for RAADP were offered it, the writer had to carry out two separate checking systems. Firstly, the numbers of pregnant Rh-D negative women were identified using the clinic diary that was developed by the ward manager. Once a woman was identified as Rh-D negative, a chart sticker belonging to her was placed in the diary. The writer counted the number of Rh-D women using this diary. Secondly, an audit of the dispensing of anti-D from the laboratory was carried out. A total of 133 anti-D injections were dispensed by the laboratory. 52 of them were distributed to OPD which accounted for RAADP as anti-D is not administered in OPD for PSE. Two more injections were documented as being destroyed. This was accounted for by two maternal refusals who did not consent to the administration of RAADP. A total of 19 RAADP were administered to the MLU. The resultant two figures were matched confirming that all eligible Rh-D negative women were offered RAADP demonstrating compliance with the national guideline.

Aim 3: The following questions and responses from the training day evaluation form were entered on to an excel spreadsheet and presented as below (Figure 6).
The evaluation findings showed that staff were satisfied with the training and felt that it helped develop their skills and knowledge.

**Aim 4:** The writer evaluated the compliance of the completion of the checklist to ensure that it was documented in the chart that the anti-D was given when required. This audit was performed by the writer supported by the maternity clinical placement coordinator in January 2016. It consisted of reviewing ten charts that were randomly chosen for audit purposes. These charts were identified from the clinic diary in the MLU and the new anti-D diary that was now in use in the out-patients department (OPD). Once identified the charts were accessed from the chart room in the medical records and the new anti-D checklist was used to source the following data collected (Figure 7). The information was collected and entered into an excel spreadsheet for analysis.

**Figure 6: Education Evaluation Outcomes**

The programme was well organised  
The learning outcomes were clearly defined  
The programme content was relevant to my area of practice  
Class discussion was a valuable part of the programme  
The programme was helpful in developing my skills and knowledge  
The time allotted to the programme was sufficient

[Bar chart showing the distribution of responses to the evaluation questions.]

**Education Evaluation Outcomes 2015-2016**
This audit using the same format was repeated in April 2016 for comparative results (Figure 8).

The second audit showed an improvement with 100% of RAADP given as required. In both audits 100% of women received the RAADP information leaflet prior to drug administration.
4.3.4 Dissemination Plan

The writer presented these finding to the anti –D meeting group at a meeting on the 13th April 2016. A copy of the findings was also distributed via e-mail to all the key stakeholders involved in the project. It is further proposed that the finding will be presented at the weekly maternity audit meetings that take place in the hospital and which are attended by all members of the multi-disciplinary team.

The final project will also be submitted to the Quality and Safety awards in June 2016 as an exemplar of a Quality Initiative. It is also hoped that following submission of this dissertation to the RCSI it will be published on e-publications, allowing access at a public level.

4.4 Summary and Conclusion

The aim of this process improvement was to introduce RAADP to all Rh-D negative women at 28 weeks in a rural hospital in Ireland. In order to achieve this the writer set a number of objectives to help deliver this. They were to provide an education programme to assist practice and also introduce a new documentation checklist to provide guidance for practitioners with their decision making.

Evaluation of this project was carried out in three ways. Firstly the writer completed an audit looking at data available from the lab to determine that all women who were eligible received RAADP as that was the overall aim of the project. The results of the lab audit showed that 98% of women eligible for RAADP received it. The 2% who did not receive it were because of maternal refusal and not omissions. The writer reflects that the aim of 100% compliance may have been unrealistic when you feature in the need for woman’s consent.

The education programme was evaluated using the Kirkpatrick model and found that the staff’s evaluation response was received favourably as they scored the evaluation as either
“strongly agree” or “agree” in relation to learning and satisfaction. The Kirkpatrick model ensured that the questions asked in the evaluation form were measureable and the writer felt that using this model gave focus to the evaluation. The impact and results of the Kirkpatrick were further evaluated by the use of an audit where the completion of the checklist and the distribution of the anti-D information leaflet were used as a measure of achievement of the objectives. In the second audit carried out in April 2016 100% of women who received RAADP received the information leaflet prior to the anti-D injection. The fact that the checklist was completed 90% of the time, (an omission of date and time was the reason for non-compliance), was seen as evidence that the learners did indeed deploy learnings to the job.

Overall the evaluation findings showed a successful outcome to this project. Outcomes showed that the project was introduced successfully and delivered what it set out to achieve in its objectives at the start of the project. Chapter 5 will draw together the overall findings of this project.
Chapter Five: Discussion and Conclusions
5.1 Introduction

Change is a consistent feature of health and social care delivery (HSE, 2008). Indeed many change models acknowledge the significance of the decision that a compelling need for change exists (Fernandez & Rainey, 2006; Kotter, 1996). In order to survive and prosper in the current climate Armenakis & Harris (2009) acknowledge that we must be knowledgeable about how to implement appropriate organisational change that will be embraced by the employees.

The writer lead this process improvement using the HSE OD Model (HSE, 2008) for guidance. The motivation for using this model was clear to the writer as the process improvement that was proposed was to take place in a healthcare setting. This HSE OD Model is specifically adapted for, and culturally sensitive to, the Irish Health Service environment (HSE, 2008). It provides a consistent approach to change and is the only model that places a strong emphasis on people and staff. It is good from the prospective that it has been agreed by all public sectors, both departmental and industrial relations. Most importantly of all, the HSE OD Model shifts the focus to sustainability. When people share beliefs and values, they can coordinate their efforts and intuitively know what to do (Glouberman & Mintzberg, 2001). Having common values is a very important part of process improvement. Process improvements are not short term projects, but need to be embraced within the organisation, to becoming the new way of conducting business. Engagement is essential for overcoming barriers to quality improvements (Nembhard & Edmondson, 2006).

This was the first time that the writer used a model of any kind for the delivery of a project, despite having lead out on different projects in the past. Using the HSE OD Model for the most part was extremely helpful as it provided a step by step approach to follow when rolling out the project. Critically the writer felt that the model was very “wordy” and as a result didn’t
always provide the clarity that the process needed. There was a lot of reading required in order to get to the key points that was the overall requirement of the different stages of the process. The nature of the document secured certain rigidity to the process, which at times left no room for artistic interpretation and innovative application of new ideas. All that been said, it added validity to all stages of the project, and justified aspects of the process that were considered redundant by some members of the team, myself included.

5.2 Project Impact

Managers need to put support systems in place that allow employees the opportunity to empower themselves to flourish, thus increasing their own effectiveness as well as that of the organisation (Kane-Urrabazo, 2006). This project brought a change of practice to the organisation that relied on staff empowerment, which in turn was pivotal to the success of this project.

5.2.1 Stakeholders

The identification of key stakeholders in the Initiation Phase of the HSE OD Model (HSE, 2008) was very helpful to the writer. By performing a stakeholder analysis chart (Appendix 7), this helped to identify how involved different people needed to be, and also how reliant they were on the success of the project. In the initial stakeholder analysis the writer identified the obstetrician as “Medium” interest, “High” influence. It was felt that attendance at the anti-D meeting was required by the obstetrician. However as the project developed, the obstetrician did not attend any of the meetings, and his absence did not seem to interfere with moving the project on. Although Huczinski & Buchanan (2001) states that a stakeholder is anyone who is likely to be affected, directly or indirectly, by organisational change, once they are identified, the level of subsequent involvement in the change process needs to be given careful consideration. On reflection, once the consensus was received that RAADP would be given to
all Rh negative women, the value of having an obstetrician in attendance to discuss the practicality and logistics of the roll-out did seem wasteful.

This project facilitated teams, who don’t normally interact with each other, to come together for a common goal. For the most part the laboratory staff have little or no engagement with clinical staff except through phone communication. Initially there was hesitancy among the stakeholders to mix clinical staff with technical staff, as it was felt that the priorities among the groups would be in conflict. Kotter & Schlesinger, (2008) suggests that not involving the right people can lead to not having all the information needed to bring about change correctly. This project afforded the teams with an opportunity to come together and develop a process that was designed to be efficient, safe and all inclusive. Regular meetings provided all of the teams with an opportunity to gain a better understanding of what each other did and personally I found it a very enlightening experience where I gained new insight into the governance and workings of other departments that I had not known previously.

5.2.2 Practice

Reorganisation is usually feared, because it means disturbance of the status quo, a threat to peoples vested interest in the jobs, and an upset to the well-established way of doing things (Kotter & Schlesinger, 2008). It is important to acknowledge this when introducing a new initiative. The majority of change that was required for this project was heavily reliant on one main department. This was the out-patients department (OPD). It is important to understand the dynamic of this department. This team have worked together for many years and the manager of this department has being in her role for the over 16 years. Services ran as they had done for over a decade. Schein (1984) acknowledges that a group culture exists when people have been together for long enough to have shared significant problems and have had opportunities to solve these problems. The writer herself having worked within the
organisation for over 20 years, although in varying roles, was very cognizant of the culture that existed in this department. It was for this reason that the importance of involving the team at an early stage to help develop the process was seen as integral to the success of this project.

Prior to roll out of the project the writer was very clear in how she seen the operational element of this project working. It was understood initially that the administration of anti-D injections would be given as part of the routine antenatal clinics visits. Indeed in the MLU, where she worked, it was decided to give the injection as part of the routine visits. The development of a new clinic that was run solely for the purposes of administration of the injection posed the following problems. This clinic would become a single discipline clinic with midwives, in the current setting, unfamiliar with working in isolation. Problems identified by women at this clinic that required obstetric input would require the development of guidance for staff as to the correct pathways required to obtain obstetric input. However, following a brainstorming session with the out-patient department staff it became clear that the process of anti-D administration at the clinic was undeliverable due to cited time constraints. Real teams always find ways for each individual to contribute and thereby gain distinction. Indeed, when harnessed to a common team purpose and goals, our need to distinguish ourselves as individuals becomes a powerful engine for team performance (Katzenbach & Smith, 2003). Acknowledging the value of team participation and its value in project delivery the writer agreed to the development of a separate clinic and the development of practices that would support it. The option to develop a separate clinic dedicated to the administration of the anti-D injection was explored and agreed.

As the implementation plan rolled out, staff in the out-patients department added certain practices to the process already defined in the guideline. Their reasoning for this was cited as
providing extra failsafe measures to avoid omissions in administration. The introduction of anti-D diaries and reminder letters were developed by the out-patient team. The introduction of an RAADP stamper to be applied to the antenatal visits section of the chart was developed. This was done by the manager in the team without consultation with the project team and as a result the use of these stamps was not used initially by the MLU staff. They were added to the process once it was identified that they were in use. This was to ensure consistency in practice in both departments. Glouberman and Mintzberg (2001) identified that the most powerful way to enhance mutual adjustment is to strengthen the standardization of norms. Although the writer embraced these new changes that were implemented, she reserved judgement as to the value these multiple steps that were now added to the process, finding that they only made the process more labour intensive.

As part of this project the process of transferring the distribution of anti-D from pharmacy to the laboratory needed to be addressed. This became a large part of the project and at times slowed down the implementation plan. However the value of now receiving anti-D from the pharmacy is tenfold. The ability to track this blood product is much easier and subsequent audits performed were achieved with minimal time constraints. This has value in relation to efficiency and the ability to audit ones practice for quality and efficiency.

5.2.3 Theory

Introducing quality programs are examples of large scale interventions that are aimed at improving health care (Ovretveit & Gustafson, 2003). It is important to have a clear understanding of the project and its potential value to the organisation. This cannot be done without looking to the evidence in order to help support the change. The writer carried out a literature review of the evidence in relation to the administration of RAADP and came up with 4 main themes. It is necessary to understand what anti-D is and why it is needed in a
healthcare setting. The need identified from the literature is what informed this project (Tiblad et al., 2013; MacKenzie, 2004; Qureshi et al., 2014). The importance of timely administration, and the importance of education, were keys factors in successful compliance of administration of RAADP (Hurrell, 2014; Bolton-Maggs & Cohen, 2013; Bhutani et al., 2013; Turner et al., 2012; MacKenzie, 2004; Koelewijn, et al., 2009; Urbaniak & Greiss, 2000). The literature review is what informed the project team and was used in conjunction with the business plan as the background to delivering the project to the key stakeholders for approval.

The use of the HSE OD Model provided the writer with a structure that was to inform the life of the project. It was easy to use and provided guidance that was sequential and practical. The model was ideal for use in a healthcare setting because it places a strong emphasis on people and staff.

5.3 Strengths of the Project

There were many strengths to this project. Having working in this organisation for over 20 years it is sometimes easy to believe that change is impossible. However, this project that if there is clear guidance and hunger for change that people, for the most part, are willing to provide a service that they are proud of. The writer is reassured that the service will stand up to any scrutiny and proclaim efficiency.

The strengths of this project were that it was rolled out as part of a dissertation. This created a sense of urgency for the project and kept the things moving in a forward direction. This is essential to any change management (Kotter, 1996). The senior management team approved this initiative from the outset and never at any point in the process put any barriers or obstacles in the way of achieving completion.
The process of moving the dispensing of anti-D from the pharmacy to the laboratory was a challenging part of the project. However its successful transfer from one service to another proved highly beneficial when it came to evaluation. All dispensing of anti-D was logged on to the laboratory computer system. This allowed easy access to data when reviewing the service. Cross checking of maternal blood groups with administration of anti-D was possible using the same laboratory system.

During the lifetime of the project there were changes to the project team. In November 2015 the haemovigilance officer, who was chair of the anti-D meetings group, got a new job within the RSCI Hospital Group. The project manager took over her role as chair but in January 2016 she too left her role in the organisation and took up a new post outside of the hospital. The strength of this project was that despite these changes there was minimal disruption to the project and it subsequently achieved what it set out to do.

5.4 Limitations of the Project

For the most part the writer felt that this process improvement was highly beneficial to the organisation. The evaluation methods that were applied to this project proved that indeed it was successful and achieved what it set out to achieve. Looking at the literature the evidence suggests that the reason for introducing RAADP was to ultimately reduce the risk of haemorrhagic disease of the newborn (HDN). This is more challenging to prove. Knowing whether the introduction of RAADP would in fact reduce the incidence of HDN goes beyond the lifespan of this project. It is a rare condition and would take several years before any data of sufficient quality would be available for analysis. It was agreed at the last anti-D group meeting that an audit would be carried out in a year following commencement of RAADP in
order to determine if there were any new incidents of Rh-D allioimmunisations post implementation.

On reflection the writer never addressed the fact that the women attending out-reach clinics had to attend the parent hospital at 28 weeks in order to receive this injection as it could not be given across sites. This was a limitation of the project that came to light only after the project rolled out. The new maternity strategy document (DOH, 2016) highlights the need for more women focused maternity care, with many services moving to community settings. There will be a need to deliver services in the community and issues like the delivery of RAADP will need to be achieved at community level, if we are truly to want to deliver a woman focused service.

5.5 Recommendations
The writer recommends that the next step in this process is to look at the ability of the service to be able to provide anti-D injections off-site. Having the ability to deliver this injection outside of the main hospital is a step towards making this a more woman friendly service.

5.6 Summary and Conclusion
This organisational development was to introduce RAADP to all Rh negative women at 28 weeks, attending Cavan General Hospital. The writer used the HSE OD Model which provided structure to the project. The aims of the project were achieved and evaluated using different audits. A documentation checklist was designed to guide staff with administration of anti-D in general and an audit of this documentation showed good compliance with the document. An education programme designed to give a better understanding about anti-D was received positively by staff and helped to inform their practice. The women received an information leaflet prior to the administration of RAADP in order to help them make an
informed decision in relation to their care. The documentation audit showed 100% compliance with administration of this leaflet. Finally the laboratory showed that all women who were Rh negative were offered RAADP post project go-live and the reason for non-compliance was cited as patient refusal. This leads the writer to conclude that we must never forget that women have a right to refuse care and staff supported them in their decision to do so.

The impact that this project has had on the organisation can only be seen as a positive one. Within the organisation midwives are now running a stand-alone clinic within the main maternity services. Although midwives in the MLU have been providing clinic services, this is the first time midwives have been providing stand-alone clinics as part of the main maternity services. The writer sees this as a step closer to further developing midwives skills to support the development of “midwifery supported care” as is recommended by the maternity strategy (DOH, 2016). Finally, it is the writers view that those involved in the project have come to a better understanding of different departments and how they work, which has improved working relationships overall. The next step in this project is now to look at the ability to deliver RAADP off-site.
References


Creasey, T. (2009). Defining change management to project management and organizational change. Prosci and the Change Management Learning Centre (pp. 1–7).


Appendices
Appendix 1: Potential Sensitising Events in Pregnancy (PSE)

<table>
<thead>
<tr>
<th>Potential Sensitising Events in Pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Termination of pregnancy (medical or surgical)</td>
</tr>
<tr>
<td>• Evacuation of the uterus (medical or surgical)</td>
</tr>
<tr>
<td>• Miscarriage – threatened or complete miscarriage</td>
</tr>
<tr>
<td>• PV Bleeding in early pregnancy (depends on pain/gestation)</td>
</tr>
<tr>
<td>• Molar pregnancy</td>
</tr>
<tr>
<td>• Ectopic Pregnancy</td>
</tr>
<tr>
<td>• Antepartum Haemorrhage</td>
</tr>
<tr>
<td>• External Cephalic Version (including attempted procedure)</td>
</tr>
<tr>
<td>• Chorionic villous sampling</td>
</tr>
<tr>
<td>• Amniocentesis</td>
</tr>
<tr>
<td>• Cordocentesis</td>
</tr>
<tr>
<td>• Other in-utero therapeutic intervention/surgery (e.g. Intra Uterine transfusion/insertion of shunts etc)</td>
</tr>
<tr>
<td>• Abdominal trauma (sharp/blunt, open/closed) or fall</td>
</tr>
<tr>
<td>• Intrauterine Death</td>
</tr>
<tr>
<td>• Stillbirth</td>
</tr>
<tr>
<td>• Post Delivery – if RhD positive baby</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pregnant Less than 12 weeks Gestation Anti-D required ONLY:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Molar pregnancy (requiring surgical evacuation)</td>
</tr>
<tr>
<td>• Miscarriage (requiring surgical or medical intervention)</td>
</tr>
<tr>
<td>• Medical/surgical termination</td>
</tr>
<tr>
<td>• Ectopic pregnancy (treated surgically or medically)</td>
</tr>
<tr>
<td>• PV bleeding with moderate-severe pain</td>
</tr>
<tr>
<td><em>(If any of these are present woman eligible for Anti-D from positive pregnancy test)</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Between 12 and 20 weeks Pregnant Anti-D is required When:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Evacuation of uterus (medical/surgical)</td>
</tr>
</tbody>
</table>
- Miscarriage – threatened /complete
- Termination of pregnancy – medical/surgical
- PV Bleeding – without pain (once/recurrent)
- Molar pregnancy
- Ectopic Pregnancy
- Abdominal trauma/fall (sharp/blunt, open/closed)
- Intrauterine Death

<table>
<thead>
<tr>
<th>Between 20 and 40 Weeks Pregnant Anti-D is Required When:</th>
</tr>
</thead>
<tbody>
<tr>
<td>■ Any PSE event</td>
</tr>
<tr>
<td>■ 28-30 – RAADP offered</td>
</tr>
<tr>
<td>■ Post delivery – RhD positive baby</td>
</tr>
</tbody>
</table>
### Appendix 2: Level 2 Maternity Care

#### Level 2 (Specialty Care)

<table>
<thead>
<tr>
<th>Definition</th>
<th>Care of uncomplicated pregnancies with the ability to detect, stabilize, and initiate management of unanticipated maternal-fetal or neonatal problems that occur during the antepartum, intrapartum, or postpartum period until patient can be transferred to a facility which specialty maternal care is available. In addition to the above care of appropriate high-risk antepartum, intrapartum, or postpartum conditions, both directly admitted and transferred from another facility.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capabilities</td>
<td>Birth centre capabilities plus</td>
</tr>
<tr>
<td>Ability to begin emergency caesarean delivery within a time interval that best incorporates maternal and fetal risks and benefits with the provision of emergency care.</td>
<td></td>
</tr>
<tr>
<td>Available support services including access to obstetric ultrasonography. Laboratory testing and blood bank supplies at all times.</td>
<td></td>
</tr>
<tr>
<td>Protocols and capabilities for massive transfusion, emergency release of blood products, and management of multiple component therapy.</td>
<td></td>
</tr>
<tr>
<td>Ability to establish formal transfer plans in partnership with a higher-level receiving facility.</td>
<td></td>
</tr>
<tr>
<td>Ability to initiate education and quality improvement programs to maximize patient safety, and/or collaborate with higher-level facilities to do so.</td>
<td></td>
</tr>
<tr>
<td>Computed tomography scan and ideally magnetic resonance imaging with interpretation available.</td>
<td></td>
</tr>
<tr>
<td>Basic ultrasonographic imaging services for maternal and fetal assessment.</td>
<td></td>
</tr>
<tr>
<td>Special equipment needed to accommodate the care and services needed for obese women.</td>
<td></td>
</tr>
<tr>
<td>Types of health care providers</td>
<td>Birthing centre providers plus</td>
</tr>
<tr>
<td>Continuous availability of adequate number of midwives with competence in level 2 care criteria and ability to stabilize and transfer high-risk women and newborns who exceed level 2 care criteria.</td>
<td></td>
</tr>
<tr>
<td>Midwifery leadership and staff have formal training and experience in the provision of prenatal nursing care and should coordinate with respective neonatal care services.</td>
<td></td>
</tr>
<tr>
<td>Obs-gyn available at all times</td>
<td></td>
</tr>
</tbody>
</table>
- Director of obstetric service is a board certified obs/gyn with special interest and experience in obstetric care.
- Anaesthesia services available to provide labour analgesia and surgical anaesthesia at all times.
- Board certified anaesthesiologist with special training or experience in obstetric anaesthesia available for consultation.
- Medical and surgical consultants available to stabilize obstetric patients who have been admitted to the facility or transferred from other facilities.

<table>
<thead>
<tr>
<th>Examples of appropriate patients (not requirements)</th>
<th>Any patient appropriate for a birth centre, plus capable of managing higher-risk conditions such as</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Term twin gestation</td>
</tr>
<tr>
<td></td>
<td>- Trial of labour after caesarean section</td>
</tr>
<tr>
<td></td>
<td>- Uncomplicated caesarean delivery</td>
</tr>
<tr>
<td></td>
<td>- Severe preeclampsia</td>
</tr>
<tr>
<td></td>
<td>- Placenta praevia with no prior uterine surgery</td>
</tr>
</tbody>
</table>
Appendix 3: Allioimmunisation

**Definition:** An immune response generated by an individual in response following exposure to genetically different cells or tissues from a different individual of the same species.

Appendix 4: Flow Cytometry Test

**Flow Cytometry Test:**
In biotechnology, *flow cytometry* is a laser-based, biophysical technology employed in cell counting, cell sorting, biomarker detection and protein engineering, by suspending cells in a stream of fluid and passing them by an electronic detection apparatus. It allows simultaneous multiparametric analysis of the physical and chemical characteristics of up to thousands.

Appendix 5: Direct Coombs Test

**Direct Coombs Test Definition:** A test used to detect antibodies or complement proteins that are bound to the surface of red blood cells. A blood sample is taken and the red blood cells are washed and then incubated with anti-human globin (Coombs reagent). If this produces agglutination of red blood cells then the direct coombs test is positive as it confirms a visual indication that antibodies are bound to the surface of red blood cells.
### Appendix 6: Gap Analysis

<table>
<thead>
<tr>
<th>Current State</th>
<th>Future State</th>
<th>Gap Identified</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>No RAADP administered to Rhesus negative women at 28 weeks gestation</td>
<td>National guideline recommends the administration of RAADP</td>
<td>Non-compliant with guideline</td>
<td>All Rhesus negative to receive RAADP at 28 weeks gestation</td>
</tr>
<tr>
<td>All women attend antenatal clinic where there is high waiting times</td>
<td>A move efficient running clinic</td>
<td>Time delays unavoidable due to current clinic process</td>
<td>Run a separate clinic to administer RAADP</td>
</tr>
<tr>
<td>Anti-D is dispensed through pharmacy</td>
<td>A more robust traceability of blood products</td>
<td>Non-compliant with regulations in relation to the dispensing of a blood product</td>
<td>Anti-D is dispensed through the lab.</td>
</tr>
</tbody>
</table>
Appendix 7: Stakeholder Power/Impact Matrix

**Power Impact/Matrix**

Introduction of Routine Anti-D Prophylaxis for all Rhesus Negative Women (RAADP) attending Cavan General Hospital

<table>
<thead>
<tr>
<th>High Importance</th>
<th>Low Influence</th>
<th>High Importance</th>
<th>High Influence</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMM OPD/MLU</td>
<td></td>
<td>DOM</td>
<td></td>
</tr>
<tr>
<td>Haematologist</td>
<td></td>
<td>Obstetric Consultants</td>
<td></td>
</tr>
<tr>
<td>Project Manager</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory Staff</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemovigilance Officer</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Low Importance</th>
<th>Low Influence</th>
<th>Low Importance</th>
<th>High Influence</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCHD’s</td>
<td></td>
<td>GM</td>
<td></td>
</tr>
<tr>
<td>SHO’s</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rh Neg Women</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Midwives</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Appendix 8: Stakeholder Analysis Chart

<table>
<thead>
<tr>
<th>Name</th>
<th>Interest/Impact</th>
<th>Influence</th>
<th>Resistance</th>
<th>Responsibility</th>
<th>Dependency on the project</th>
<th>How to communicate</th>
<th>Involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>GM</td>
<td>Low</td>
<td>High</td>
<td>Budget</td>
<td>Low</td>
<td>High</td>
<td>Present business case and secure sign off. Email updates on project progress</td>
<td>Approval for project to be given.</td>
</tr>
<tr>
<td>Obstetricians</td>
<td>Medium</td>
<td>High</td>
<td>Potentially have the power not to sign off on the project</td>
<td>Low</td>
<td>High</td>
<td>Meetings and emails</td>
<td>To agree to RAADP</td>
</tr>
<tr>
<td>DOM</td>
<td>High</td>
<td>High</td>
<td>Resources</td>
<td>High</td>
<td>High</td>
<td>Meetings and emails</td>
<td>Sign off and support</td>
</tr>
<tr>
<td>CMM2</td>
<td>Medium</td>
<td>Medium</td>
<td>Labour intensive. Training requirements.</td>
<td>High</td>
<td>High</td>
<td>Meetings and emails</td>
<td>Updated regularly and involvement in the logistical roll out. Redistribution of staff as required</td>
</tr>
<tr>
<td>Midwives</td>
<td>Medium</td>
<td>Low</td>
<td>Labour intensive</td>
<td>Low</td>
<td>High</td>
<td>Through the CMM who will need to regularly update staff</td>
<td>Brainstorm with CMM to help with logistical roll out phase. Training</td>
</tr>
<tr>
<td>Lab Staff</td>
<td>Medium</td>
<td>Low</td>
<td>Labour intensive as the dispensing of Anti-D will become a new role for this group</td>
<td>Low</td>
<td>Medium</td>
<td>Meetings and emails</td>
<td>Audit responsibility and traceability of product. Dispensing of product</td>
</tr>
<tr>
<td>Haemovigilance Officer</td>
<td>Medium</td>
<td>Low</td>
<td>None anticipated</td>
<td>Medium</td>
<td>High</td>
<td>Meetings and emails</td>
<td>Become chair of the Anti-D meetings. Help deliver training</td>
</tr>
<tr>
<td>Rh Negative Women</td>
<td>Low</td>
<td>Low</td>
<td>Potential refusal of consent for treatment</td>
<td>Low</td>
<td>Low</td>
<td>Patient information leaflet and staff engagement</td>
<td>None</td>
</tr>
<tr>
<td>Haematologist</td>
<td>Low</td>
<td>Medium</td>
<td>None anticipated</td>
<td>Low</td>
<td>Low</td>
<td>Meetings and emails</td>
<td>To ensure that adherence to blood product administration requirements are fulfilled</td>
</tr>
<tr>
<td>NCHD’s</td>
<td>Low</td>
<td>Low</td>
<td>Omissions due to lack of awareness</td>
<td>Low</td>
<td>Low</td>
<td>Through training and Obs Cons</td>
<td></td>
</tr>
<tr>
<td>SHO’s</td>
<td>Low</td>
<td>Low</td>
<td>Omissions due to lack of awareness</td>
<td>Low</td>
<td>Low</td>
<td>Training and senior colleagues</td>
<td>Prescribe drug as required</td>
</tr>
</tbody>
</table>
Appendix 9: RACI Chart

- **Responsible**
  - Who is/will be doing this task?
  - Who is assigned to work on this task?

- **Accountable**
  - Who’s head will roll if this goes wrong?
  - Who has the authority to take decision?

- **Consulted**
  - Anyone who can tell me more about this task?
  - Any stakeholders already identified?

- **Informed**
  - Anyone whose work depends on this task?
  - Who has to be kept updated about the progress?
Appendix 10: Business Case

Cavan Monaghan Hospital

Business Case for Introduction of Routine Antenatal Anti-D Prophylaxis

Purpose

1. To provide an explanation for the need for introducing RAADP.
2. To inform both the consumer and Health Care Professional that RAADP is available to all relevant Rhesus negative women.
3. To educate all health care professionals in the use and administration of RAADP.

Reasons

- Prior to 1970, the development of Anti-D antibodies in pregnant women secondary to fetomaternal haemorrhage (FMH) was a leading cause of perinatal mortality and morbidity as a result of haemolytic disease of the newborn, (HDN).
- The introduction of Anti-D immunoglobulin for use in post-natal immunoprophylaxis and prophylaxis following potentially sensitising events significantly reduced deaths due to RhD alloimmunisation and significantly reduced the incidence of seroconversion with Anti-D antibodies among RhD negative women.
- Despite these advances there are still a small proportion of women who become alloimmunised either due to silent antepartum haemorrhage, or failure to administer adequate amount of Anti-D following sensitising events. Sensitisation is most common in the third trimester and during childbirth.
- In 2008 NICE (UK) recommended the introduction of Routine Anti-D Antenatal Prophylaxis, (RAADP) in an effort to prevent particularly third trimester sensitisations. It is recommended that all non-sensitised RhD negative women should be offered a dose of Anti-D immunoglobulin at 28-30 weeks gestation and this is now the gold standard of care in the UK.
- The publication of the HSE Clinical Practice Guideline on the use of Anti-D also recommended the use of RAADP at 28-30 weeks gestation for all non-sensitised women and many maternity units in Ireland are in the process of implementing a RAADP programme.
- Based on these recommendations and a request from Obstetric/Gynaecology clinicians an estimated cost for the implementation of such a project for all eligible RhD women was investigated.

Options Considered for Project Delivery with Predicted Costs

Cavan Monaghan Hospital Figures

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of women delivered</th>
<th>Number RhD Negative women</th>
<th>Percentage of RhD Negative women delivered</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>2007</td>
<td>301</td>
<td>15%</td>
</tr>
<tr>
<td>2011</td>
<td>2015</td>
<td>323</td>
<td>16%</td>
</tr>
<tr>
<td>Year</td>
<td>No of Anti-D Ampoules Issued from Pharmacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------</td>
<td>------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>290</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>305</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>297</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>270</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>262</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Anti-D Usage 2010 – 2014** (includes administration to Maternity & Gynae patients)

- On average 14% deliveries per annum are to RhD negative mothers.
- Based on the delivery data for the last five years, there will be an approximate average of 281 women who will be eligible for Routine Antenatal Anti-D Prophylaxis per year, which is approximately 20 women per month, but this will vary depending on the amount of RhD negative are at 28-30 weeks gestation at any time and on the annual birth rate in Cavan General Hospital.

**Requirements**

**Overall**

- Anti-D immunoglobulin – per annum €20,372
- Patient Information Leaflet costs – editing by NALA €230
- Patient Information Leaflet costs – printing per annum €150
- Anti-D Checklist – printing cost per annum TBC
- Midwifery 0.25 WTE
- Clerical 30 mins per week
- Laboratory 30 mins per week

**Expected project benefits**

There is currently sufficient evidence to demonstrate that by providing RAADP, the risk of Rh-D immunisation in the subsequent pregnancy can drop to a level of below 0.4% (Liumbruno et al., 2010). This has long term benefits to both mother and future babies.
### Project Risks

<table>
<thead>
<tr>
<th>Risk ID</th>
<th>Description of Risk</th>
<th>Risk Assessment</th>
<th>Risk Rating (I x L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>As a result of lack of understanding of the value of the use of RAADP among clientele, there is a risk of poor uptake of the injection</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>As a result of lack of understanding with the use of RAADP among staff, there is a risk of inappropriate care delivery which may lead to non-compliance of administration</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>As a result of inadequate and undefined guidelines, there is a risk of key information being overlooked impacting on patient safety.</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>
Appendix 11: Implementation Plan

Implementation/Project Plan for the Introduction of RAADP to Rhesus Negative Women at 28 Weeks at Cavan General Hospital

Overview

This project proposes to guide the maternity services at Cavan General Hospital in relation to the introduction of Routine Antenatal Anti-D Prophylaxis (RAADP) injection for all Rhesus Negative women attending the service.

The vision is that “In line with best practice all eligible rhesus negative women will be provided with RAADP injection at 28 weeks gestation”.

The scope is that “All women identified at booking visit, who have no existing anti-D antibodies, will be given an appointment at 28 weeks gestation to the midwives clinic where RAADP will be administered”.

This project plan was proposed based on the recommendations outlined in publication of a National Guideline (Fitzgerald & Conneally, 2012).

The following is a list of objectives set out to help achieve this.

1. Establish and implement procedures to facilitate the implementation of RAADP by September 2015.

2. By October 2015, all eligible Rh-D negative women will be offered anti-D at 28 weeks gestation in order to be fully compliant with the National Clinical Care Programme guideline (Fitzgerald & Conneally, 2012).

3. Design and deliver an education programme to support practitioners with implementing the services by January 2016.
4. Produce a patient information leaflet to be given to all Rh-D negative women prior to the administration of RAADP.

5. Access the effectiveness of this initiative in January 2016 and April 2016.

Implementation Details

<table>
<thead>
<tr>
<th>WHAT</th>
<th>WHO</th>
<th>WHEN</th>
<th>WHERE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draw up RAADP guideline</td>
<td>MB/WG</td>
<td>01/01/2015</td>
<td>PD</td>
</tr>
<tr>
<td>Create anti-D checklist</td>
<td>MB/WG</td>
<td>1/03/2015</td>
<td>PD</td>
</tr>
<tr>
<td>Patient Information leaflet</td>
<td>MB/WG</td>
<td>30/05/2015</td>
<td>PD</td>
</tr>
<tr>
<td>Move dispensing of anti-D from pharmacy to lab</td>
<td>EH/WG</td>
<td>05/10/2015</td>
<td>Lab</td>
</tr>
<tr>
<td>Set up anti-D clinic for OPD and MLU</td>
<td>MF+MR/WG</td>
<td>16/09/2015</td>
<td>OPD/MLU</td>
</tr>
<tr>
<td>Provide training session for all staff to include midwives, doctors, and laboratory staff.</td>
<td>MR/MB/WG</td>
<td>22/09/2015-20/12/2015</td>
<td>All depts</td>
</tr>
<tr>
<td>Go-live with RAADP</td>
<td>MR</td>
<td>05/10/2015</td>
<td>OPD/MLU</td>
</tr>
<tr>
<td>Post go-live audit</td>
<td>MR</td>
<td>01/03/2016</td>
<td>PD</td>
</tr>
</tbody>
</table>

Performance and Quality Measures

The quality measure to assess outcome will be through the use of audit. The checklist will be audited for compliance and the lab will perform an audit to ensure that all eligible women attended the service within the specified timeframe received RAADP.

Resource Requirements

**Anti-D Costs**

- Approx 281 ampoules Anti-D immunoglobulin €20,372
- Patient Information Leaflet costs – editing by NALA €230
- Patient Information Leaflet costs – printing per annum €150
- Anti-D Checklist – printing cost per annum TBC

Anti-D Clinic
- Weekly clinic held in OPD every Wednesday afternoon.
- Approx 5 women per week to attend

Preparation for Clinic

Clerical
- Clerical support to obtain approx 5 Maternity notes 30 mins

Midwifery
- Check notes and complete first page Anti-D Checklist 1 hour
- Pre-order Anti-D from laboratory 15 mins
  Required 1hr 15 mins

Laboratory
- Issue approx 5 doses of Anti-D & package for dispatch 30 mins

Clinic

Midwifery
- HCA or midwife to collect Anti-D from laboratory 10 mins
- HCA or midwife to return transport box to laboratory 5 mins
  Required 15 mins

Required per woman:
- Ensure woman eligible to receive 5 mins
- Two person check pre-administration 5 mins
- Preparation, administration & documentation 5 mins
- Woman to stay in OPD for 15 mins post administration 15 mins
  Required 5 x 30 mins = 2hr 30 min

Total Midwifery Requirement
- Pre Clinic Preparation 1hr 15 mins
- Clinic Time 2hr 45 min
  Total 4 hours

85
Total Clerical Requirement

- Pull 5 maternity charts 30 mins

*Total*

30 mins

Laboratory

- Issue approx 5 doses of Anti-D & package for dispatch 30 mins

*Total*

30 mins

Overall

- Anti-D immunoglobulin €20,372
- Patient Information Leaflet costs – editing by NALA €230
- Patient Information Leaflet costs – printing per annum €150
- Anti-D Checklist – printing cost per annum TBC
- Midwifery 0.25 WTE
- Clerical 30 mins per week
- Laboratory 30 mins per week

Impact Analysis and Risk Control

See Appendix 14

Communication and Engagement Plan

All communication for this project will be through anti-D meetings and email with the relevant stakeholders.
Appendix 12: PDSA Cycle

- **PLAN**
  - **INVESTIGATE**
    - Not providing RAADP currently
    - Anti-D dispensed from pharmacy
    - Look at options
    - Meet with lab staff

- **DO**
  - **ENLIGHTEN & IMPLEMENT**
    - Move dispensing of anti-D to the lab
    - Provide RAADP to all Rh Neg pregnant women
    - Logistics of administration to women

- **STUDY**
  - **EVALUATE & VALIDATE**
    - Carry out an audit on compliance with RAADP
    - Carry out an audit on compliance with new documentation to support the use of RAADP
    - Make improvements as necessary
    - Present findings to key stakeholders

- **ACT**
  - **CORRECT & STANDARDISE**
    - Standardise practice
    - Look for ways to make the process more efficient

Appendix 13: SWOT Analysis

SWOT Analysis

Introduction of Routine Anti-D Prophylaxis for all Rhesus Negative Women (RAADP) attending Cavan General Hospital

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>- National Clinical Care Programme guideline recommendation&lt;br&gt;- Strong evidence to support RAADP in the literature review</td>
<td>- Requires involvement and changes across numerous disciplines&lt;br&gt;- Initiative potentially labour intensive&lt;br&gt;- Administration of the injection is single site only</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Opportunities</th>
<th>Threats</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Improve patient outcomes among this client cohort&lt;br&gt;- National recommendation&lt;br&gt;- Strengthen multi-disciplinary relationships</td>
<td>- Limited staff resources&lt;br&gt;- Added cost to the service</td>
</tr>
</tbody>
</table>
## Appendix 14: Impact Analysis and Risk Control

<table>
<thead>
<tr>
<th>Risk ID</th>
<th>Description of Risk</th>
<th>Risk Assessment</th>
<th>Risk Rating (I x L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>As a result of lack of understanding of the value of the use of RAADP among clientele, there is a risk of poor uptake of the injection</td>
<td>3 4</td>
<td>12</td>
</tr>
<tr>
<td>2</td>
<td>As a result of lack of understanding with the use of RAADP among staff, there is a risk of inappropriate care delivery which may lead to non-compliance of administration</td>
<td>4 3</td>
<td>12</td>
</tr>
<tr>
<td>3</td>
<td>As a result of inadequate and undefined guidelines, there is a risk of key information being overlooked impacting on patient safety.</td>
<td>4 4</td>
<td>16</td>
</tr>
<tr>
<td>Risk ID</td>
<td>Before risk rating</td>
<td>Control action</td>
<td>After risk assessment</td>
</tr>
<tr>
<td>---------</td>
<td>--------------------</td>
<td>----------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>1.1</td>
<td>12</td>
<td>Design and distribute patient information leaflet on the use of RAADP to clientele</td>
<td>4</td>
</tr>
<tr>
<td>1.2</td>
<td>12</td>
<td>Provide verbal explanation of the value of RAADP to support leaflet</td>
<td>4</td>
</tr>
<tr>
<td>2.1</td>
<td>12</td>
<td>Provide education and training to all key personnel</td>
<td>4</td>
</tr>
<tr>
<td>2.2</td>
<td>12</td>
<td>Provide initial go-live support to staff</td>
<td>4</td>
</tr>
<tr>
<td>3.1</td>
<td>16</td>
<td>Draw up a set of guidelines to support and direct practice in the administration of anti-D</td>
<td>4</td>
</tr>
<tr>
<td>3.2</td>
<td>16</td>
<td>Introduction of an anti-D multidisciplinary checklist at ward level to support standardisation and improve patient safety.</td>
<td>4</td>
</tr>
</tbody>
</table>
Appendix 15: Anti-D Checklist

Patient Name: ___________________
Date of Birth: ___________________
MRN: ___________________

Cavan Monaghan Hospital

Anti-D Administration Checklist Ed 00

Checklist No……………………

Complete form for every RhD Negative woman who is pregnant or post-delivery

<table>
<thead>
<tr>
<th>Date:</th>
<th>Event date</th>
<th>Event date</th>
<th>Event date</th>
<th>Event date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Record date form commenced</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. **Gestational Age or Post-delivery (PD)**
   - /40 PD □

2. **What is the woman’s blood group?**
   - (Check most recent group and antibody screen result on the Laboratory 'Ward Look-up')
   - Result: [Result]
   - Date of test: [Date]
   - Checked by [Signature]

   **If woman is not RhD negative Anti-D is not required**

3. **Has group and antibody screen been taken in this pregnancy?**
   - (if no, G&A sample must be taken to confirm blood & RhD group and antibody status)
   - Yes □ No □
   - Checked by [Signature]

4. **Does the woman have an immune Anti-D already?**
   - (Check latest & previous group & antibody screen results.)
   - Yes □ No □
   - Checked by [Signature]

Patient Name: ___________________
Date of Birth: ___________________
MRN: ___________________
### Potentially Sensitising Events (PSEs) <12 weeks - delivery

<table>
<thead>
<tr>
<th>Gestation LESS than 12 Weeks</th>
<th>Required Actions</th>
</tr>
</thead>
</table>
| If any of the following present – see ‘Required Actions’: | 1. Work through checklist 1-6 above to ensure woman is eligible for Anti-D  
2. Administer 1500iu Anti-D within 72hrs of the PSE  
3. No Kleihauer Test is required |
| - Vaginal bleeding associated with severe pain  
- Ectopic or Molar Pregnancy  
- ERPC/Instrumentation of uterus  
- Medical or surgical termination | |

<table>
<thead>
<tr>
<th>Gestation 12-20 Weeks</th>
<th>Required Actions</th>
</tr>
</thead>
</table>
| For any potentially sensitising events: | 1. Work through checklist 1-6 above to ensure woman is eligible for Anti-D  
2. Administer 1500iu Anti-D within 72hrs of the PSE  
3. No Kleihauer Test is required |
| - Termination of pregnancy  
- Evacuation of uterus  
- Miscarriage (threatened/complete)  
- PV bleeding  
- Ectopic pregnancy  
- Abdominal trauma/fall | |

<table>
<thead>
<tr>
<th>Gestation 20 Weeks to term</th>
<th>Required Actions</th>
</tr>
</thead>
</table>
| For any potential sensitising events (irrespective of whether RAADP has been given): | 1. Work through checklist 1-6 above to ensure woman is eligible for Anti-D  
2. Take a Kleihauer test and group and antibody screen (do not wait for the result)  
3. Administer Anti-D immediately or within 72hrs of PSE  
3. Administer additional Anti-D if required (Contact Consultant Haematologist for advice) |
| As above plus: | |
| - Chorionic villous sampling  
- Amniocentesis  
- Cordocentesis  
- External cephalic version (including attempted procedure)  
- Intra-uterine therapeutic intervention (IUT etc)  
- Abdominal trauma (sharp/blunt, open/ closed)  
- Intrauterine death  
- Stillborn | |

**For continuous vaginal bleeding 1500iu Anti-D should be administered at a minimum of 6-weekly intervals, (irrespective of detectable Anti-D) and a Kleihauer should be taken every two weeks to monitor if additional Anti-D is required**

---

### Potentially Sensitising Events (PSEs) ≥12 weeks - delivery

<table>
<thead>
<tr>
<th>5. Does the woman require Anti-D?</th>
<th>Yes ☐ No ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Checked by</td>
<td>Checked by</td>
</tr>
<tr>
<td>Signature:</td>
<td>Signature:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6. Has informed consent been obtained for administration of Anti-D?</th>
<th>Yes ☐ No ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obtained by</td>
<td>Obtained by</td>
</tr>
<tr>
<td>Signature:</td>
<td>Signature:</td>
</tr>
</tbody>
</table>

---

**Gestation LESS than 12 Weeks**

- Vaginal bleeding associated with severe pain
- Ectopic or Molar Pregnancy
- ERPC/Instrumentation of uterus
- Medical or surgical termination

**Gestation ≥12 Weeks**

- Termination of pregnancy
- Evacuation of uterus
- Miscarriage (threatened/complete)
- PV bleeding
- Ectopic pregnancy
- Abdominal trauma/fall

**Gestation 20 Weeks to term**

- Chorionic villous sampling
- Amniocentesis
- Cordocentesis
- External cephalic version (including attempted procedure)
- Intra-uterine therapeutic intervention (IUT etc)
- Abdominal trauma (sharp/blunt, open/ closed)
- Intrauterine death
- Stillborn

---

**For continuous vaginal bleeding 1500iu Anti-D should be administered at a minimum of 6-weekly intervals, (irrespective of detectable Anti-D) and a Kleihauer should be taken every two weeks to monitor if additional Anti-D is required**
### Routine Antenatal Anti-D Prophylaxis (RAADP) 28-30 weeks

<table>
<thead>
<tr>
<th>Required Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>RAADP to be administered between 28-30 weeks gestation (irrespective of whether Anti-D has been administered already for a previous PSE)</td>
</tr>
<tr>
<td>- Work through checklist 1-6 above to check if woman is eligible for Anti-D</td>
</tr>
<tr>
<td>1. Work through checklist 1-6 on page 1 to ensure woman is eligible for Anti-D</td>
</tr>
<tr>
<td>2. If eligible - take group and antibody screen prior to Anti-D administration (do not wait for the result)</td>
</tr>
<tr>
<td>3. Administer 1500iu Anti-D</td>
</tr>
</tbody>
</table>

### Intrauterine Death (IUD) > 20 weeks

<table>
<thead>
<tr>
<th>Required Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>IUDs</td>
</tr>
<tr>
<td>1. Give Anti-D immediately following the diagnosis of an IUD</td>
</tr>
<tr>
<td>2. Give further dose of 1500IU Anti-D post delivery</td>
</tr>
<tr>
<td>1. Work through checklist 1-6 on page 1 to ensure woman is eligible for Anti-D</td>
</tr>
<tr>
<td>2. Take G&amp;A screen &amp; review result prior to administration of Anti-D.</td>
</tr>
<tr>
<td>3. Take Kleihauer test prior to the Anti-D administration</td>
</tr>
<tr>
<td>4. Administer 1500IU Anti-D prior to delivery</td>
</tr>
<tr>
<td>5. If no cord blood result available administer a further 1500IU Anti-D within 72hr of delivery</td>
</tr>
</tbody>
</table>

### Does Kleihauer test/flow cytometry indicate that further Anti-D is required?

<table>
<thead>
<tr>
<th>Required Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Work through checklist 1-6 on page 1 to ensure woman is eligible for Anti-D</td>
</tr>
<tr>
<td>2. Administer more Anti-D (1500IU covers a 12ml bleed) Additional Anti-D dosage based on 125iu/ml</td>
</tr>
</tbody>
</table>

### AT DELIVERY

<table>
<thead>
<tr>
<th>Required Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cord blood &amp; Kleihauer must be taken at every RhD negative mother’s delivery</td>
</tr>
<tr>
<td>Either:</td>
</tr>
<tr>
<td>- Cord blood group of baby confirms baby blood group as RhD positive</td>
</tr>
<tr>
<td>Or</td>
</tr>
<tr>
<td>- No cord blood sample available</td>
</tr>
<tr>
<td>1. Work through checklist 1-6 on page 1 to ensure woman is eligible for Anti-D</td>
</tr>
<tr>
<td>2. Take Kleihauer test ideally within 40-60 mins of delivery, (max 2hrs)</td>
</tr>
<tr>
<td>3. Take cord bloods for group and antibody screen.</td>
</tr>
<tr>
<td>4. Administer 1500iu Anti-D within 72hr delivery</td>
</tr>
</tbody>
</table>

### Does Kleihauer test/flow cytometry indicate that further Anti-D is required?

<table>
<thead>
<tr>
<th>Required Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Work through checklist 1-6 on page 1 to ensure woman is eligible for Anti-D</td>
</tr>
<tr>
<td>2. Administer more Anti-D (1500IU covers a 12ml bleed) Additional Anti-D dosage based on 125iu/ml (Consultant Haematologist can be contacted for advice).</td>
</tr>
</tbody>
</table>
# RECORD OF ANTI-D ADMINISTRATION

## ROUTINE ANTENATAL ANTI-D PROPHYLAXIS 28-30 WEEKS

<table>
<thead>
<tr>
<th>Date:</th>
<th>Gestation:</th>
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Patient Received Anti-D Information Booklet prior to Anti-D administration

- Yes □ No □

Patient gives verbal consent to Anti-D administration

- Yes □ No □

Group and Antibody screen taken prior to Anti-D administration

- Yes □ No □

Anti-D prescribed on Medication Chart

- Yes □ No □

Details on ID band match details on front of form, box label & Lab issue form

- Yes □ No □

<table>
<thead>
<tr>
<th>Anti-D Batch No</th>
<th>1. Administered</th>
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<th>Date of Administration</th>
<th>Time of Administration</th>
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<td><em>Signatures</em></td>
<td><em>Printed Name</em></td>
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</table>

If Anti-D not given at 28-30 weeks, please state reason/s:

## ANTI-D FOR A POTENTIALLY SENSITISING EVENT (<12 weeks – delivery)

### 1. Date: | Gestation: |

Start of sensitising event: Date: | Time: |

Reason for Anti-D: 
- Miscarriage □
- Bleeding during pregnancy □
- Trauma □
- Other Reason (please specify) ______________________

Group and Antibody screen taken prior to Anti-D administration

- Yes □ No □

<20 weeks gestation – no Kleihauer Test required

- Yes □ No □

>20 weeks gestation – take Kleihauer Test prior to Anti-D administration

- Yes □ No □

Patient Received Anti-D Information Booklet prior to Anti-D administration

- Yes □ No □

Patient gives verbal consent to Anti-D administration

- Yes □ No □

Anti-D prescribed on Medication Chart

- Yes □ No □
### ANTI-D FOR A POTENTIALLY SENSITISING EVENT (<12 weeks – delivery)

1. Date: [ ]
   Gestation: [ ]/40

2. Start of sensitising event:
   - Date: [ ]
   - Time: [ ]

3. Reason for Anti-D:
   - Miscarriage [ ]
   - Bleeding during pregnancy [ ]
   - Trauma [ ]
   - Other Reason (please specify): [ ]

4. Group and Antibody screen taken prior to Anti-D administration
   - Yes [ ]
   - No [ ]

5. <20 weeks gestation – no Kleihauer Test required
   - Yes [ ]
   - No [ ]

6. >20 weeks gestation – take Kleihauer Test prior to Anti-D administration
   - Yes [ ]
   - No [ ]

7. Patient Received Anti-D Information Booklet prior to Anti-D administration
   - Yes [ ]
   - No [ ]

8. Patient gives verbal consent to Anti-D administration
   - Yes [ ]
   - No [ ]

9. Anti-D prescribed on Medication Chart
   - Yes [ ]
   - No [ ]

10. Details on ID band match details on front of form, box label & Lab issue form
    - Yes [ ]
    - No [ ]

### Details on ID band match details on front of form, box label & Lab issue form

<table>
<thead>
<tr>
<th>Anti-D Batch No</th>
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<th>1. Administrator</th>
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<td>2. Checked by:</td>
<td>2. Checker</td>
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3. Kleihauer Result: _____ mls

4. Repeat Sample taken
   - Yes [ ]
   - No [ ]

5. Result: _____ mls

---

*If Kleihauer result ≥ 8mls may require flow cytometry +/- additional Anti-D refer to SOP CP-HV-0015

*If Kleihauer result ≥ 8mls repeat Kleihauer test at 72hr/48hr post admin IM/IV Anti-D
**POST DELIVERY**

1. **Date of Birth:** [ ]  **Time of Birth:** [ ]  **Yes** [ ]  **No** [ ]  **Sample taken by:**

   1. Cord bloods taken
   2. Kleihauer taken 45-60 mins post delivery (max 2hrs)

2. **Cord blood result:** [ ]  **Signature:** [ ]  **Date:** [ ]

   *If baby’s cord blood result is RhD positive give mother Anti-D (if she does not already have an immune Anti-D)*

3. **Kleihauer Result:** [ ]  **mls**  **Is Kleihauer ≥ 8mls?** Yes [ ]  No [ ]

   *If Kleihauer result ≥ 8mls may require flow cytometry +/- additional Anti-D refer to SOP CP-HV-0015
   *If Kleihauer result ≥ 8mls repeat Kleihauer test at 72hr/48hr post admin IM/IV Anti-D*

4. **Repeat Sample taken** Yes [ ]  No [ ]  **Result:** [ ]  **mls**  **Result checked by:**

5. **Patient received information about Anti-D prior to Anti-D administration** Yes [ ]  No [ ]

   - Patient gives verbal consent to Anti-D administration Yes [ ]  No [ ]
   - Anti-D prescribed on Medication Chart Yes [ ]  No [ ]

   **Details on ID band match details on front of form, box label & Lab issue form** Yes [ ]  No [ ]

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<th>1. Administered: [ ]  <strong>Signature:</strong> [ ]  2. Checked by [ ]  <strong>Checkered:</strong> [ ]  2. Checker [ ]  <strong>Printed Name:</strong> [ ]</th>
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*If more than 4 doses of Anti-D are required during a pregnancy then please use an additional checklist. (Ensure each checklist is numbered)*

**ANTI-D LABORATORY ISSUE FORM**

(AFFIX BELOW)
Appendix 16: Anti-D Meeting Minutes Agenda

ATTENDEES:

APOLOGIES:

<table>
<thead>
<tr>
<th>Chairperson</th>
<th>MB</th>
<th>Gatekeeper</th>
<th>MR</th>
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<tr>
<td>Timekeeper</td>
<td>MR</td>
<td>Minute taker</td>
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<td>Anti-D guideline</td>
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<td>3</td>
<td>Roll out date</td>
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### Appendix 18: GANTT Chart

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HAVE YOU HEARD ABOUT THE NEW CAVAN MONAGHAN HOSPITAL ANTI-D GUIDELINE & THE INTRODUCTION OF ROUTINE ANTE-NATAL ANTI-D PROPHYLAXIS?

THERE IS A NEW ANTI GUIDELINE & WE WILL BE GIVING PREGNANT RhD NEGATIVE WOMEN ANTI-D ROUTINELY

To prepare everyone for the new changes & the introduction of the new
Anti-D Checklist Mary Reilly will be holding education sessions as follows:

<table>
<thead>
<tr>
<th>DATE</th>
<th>TIME</th>
<th>VENUE</th>
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<td>15.00-15.45</td>
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<td>15.45-16.30</td>
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<td>23/09/15</td>
<td>14.00-14.45</td>
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<tr>
<td>28/09/15</td>
<td>15.00-15.45</td>
<td>SCBU Seminar Room</td>
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Appendix 19: Anti-D Poster

Introducing Routine Antenatal Anti-D Prophylaxis for Rhesus Negative Women

Mary Reilly

Introduction & Background
Since 2012 the HSE practice guideline in Ireland recommends the use of prophylactic anti-D (RAADP). It’s introduction into a rural hospital was in order to be compliant with this guideline. The reason for providing RAADP was to reduce the number of babies born affected by Haemolytic Disease of the Newborn (HDN). Anti-D injection is administered to women to prevent the maternal system developing antibodies against a rhesus positive baby, the cause of HDN.

The importance of developing an education programme to support the administration of RAADP was identified and rolled out as part of this process improvement.

Aims & Objectives

The aims of this project was to introduce RAADP in a rural hospital using the following objectives:

1. Establish and implement procedures to facilitate the implementation of RAADP by September, 2015.
2. By October 2015, all eligible rhesus negative women will be offered anti-D at 28 weeks gestation in order to be fully compliant with the national guideline.
3. Design and deliver an education programme to support practitioners with implementing the service by January, 2016.
4. Produce a patient information leaflet to be given to all rhesus negative women prior to the administration of RAADP.
5. Assess the effectiveness of this initiative in January, and April, 2016.

Methodology

The HSE OD Model was chosen to support the implementation of this project as it acknowledges the complexities associated with healthcare. It recognises how different elements of change are interrelated and are dependant on people changing.

The Kirkpatrick model was used to help design the evaluation questionnaire in order to assess the effectiveness programme that was developed for this initiative.

Evaluation 1

The writer evaluated the training programme.

Evaluation 2

The documentation checklist that was designed to support practice was audited in order to evaluate was the learning identified, translated into practice.

Organisational Impact

The impact that this had on the organisation that processes were designed to support the administration of RAADP. An audit of the laboratory records showed that ALL women who were eligible between October 2015 and February 2016 were offered RAADP.

Conclusion

With the correct motivation and guidance, it is indeed possible to introduce change to a healthcare organisation. People working within the profession have a keen interest in putting patients at the centre of their service once they are supported with clear direction and leadership.

References
