PROJECT TITLE

Caring for pregnant women with diabetes who require corticosteroids in Northern NSW, are we getting it right?

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For the women and their families who access care within Northern NSW LHD I hope that this research can provide better outcomes and individualised care for the future especially for women with Diabetes in Pregnancy.

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Contents

Abstract

Introduction:

Corticosteroids are administered when a premature birth is imminent to enhance foetal lung maturity to decrease respiratory distress in the newborn, however, the rates of newborn hypoglycaemia have been found to be significantly increased especially if the woman has diabetes in pregnancy.

In 2016, the "Diabetes in Pregnancy – Management of Blood Glucose Levels (BGLS) During Corticosteroids Therapy Guideline" were developed in NNSWLHD and recommended continuous insulin infusion for women with diabetes in pregnancy receiving corticosteroid therapy for imminent pre-term birth. It was unclear the extent to which this guideline was being implemented or the impact on neonatal and maternal outcomes.

The aim of the study was to explore the impact on neonatal and maternal outcomes of the administration of corticosteroids and continuous insulin therapy for women with diabetes and imminent preterm birth, compared to corticosteroid therapy only.

Method:

A descriptive comparative study was conducted across three maternity facilities in NNSWLHD.
A clinical audit of retrospective data for the 6 years between 2013-2019 was conducted.

Results:

The medical records of 135 women and their newborns were identified and audited that matched the criteria between the years of 2013 to 2019. 59 women were identified as receiving continuous insulin and 88 women were admitted to hospital after receiving the steroids to be monitored. There was no association between receiving IV infusion and admission to the SCN for risk of/hypoglycaemia, $p = 1.00$. Whilst results show that there was no associate between the guidelines and admission to special care nursery, the guideline was followed only 48% of the time.

Discussion:

This study adds to the growing evidence that more research is required in reference to best practice of the administration of corticosteroids and continuous insulin therapy for women with diabetes and imminent preterm birth compared to corticosteroid therapy only, including the timing of corticosteroids and birth in relation to gestational age.

Significance/ implications for practice/ recommendations.

This research supports the First 2000 day's framework as it aims to evaluate current clinical treatment on maternal and newborn outcomes by examining the evidence of newborn hypoglycaemia at birth as a result of corticosteroid and continuous insulin therapy.

Keywords

Corticosteroids, Diabetes in Pregnancy, Insulin, Special Care Nursery, Neonatal outcomes, Threatened Preterm Labour, Gestation Diabetes, Threatened Pre-term Labour

Executive Summary

Background

In Northern NSW Local Health District, a guideline was developed in 2016 which recommended continuous infusion of insulin for 24- 48 hours for women with diabetes in pregnancy after the administration of corticosteroids for pre-term birth. The NNSW LHD Guideline Diabetes in Pregnancy – Management of Blood Glucose Levels (BGLS) During Corticosteroids Therapy" (referred to **DIP from** here on) was written by a multi-discipline team based on expert consensus. The new guideline recommended continuous insulin infusion for women with diabetes in pregnancy receiving corticosteroid therapy for imminent pre-term birth.

It was anticipated that a continuous insulin infusion may avoid newborn hyperglycaemia at birth preventing Special Care Nursery (SCN) admission, reducing the possibility of mothers and babies' separation in the first 24 hours after birth.

The aim of the study was to explore the impact on neonatal and maternal outcomes of the administration of corticosteroids and continuous insulin therapy for women with diabetes and imminent preterm birth compared to corticosteroid therapy only.

The research questions were.

1) What is the percentage of women with DIP receiving corticosteroid and continuous insulin therapy compared to corticosteroid therapy only?
2) What are the outcomes (admission to special care nursery) for neonates of women with DIP receiving corticosteroid and continuous insulin therapy (as per the NNSW LHD Guideline Diabetes in Pregnancy – Management of Blood Glucose Levels (BGLS) During Corticosteroids Therapy implemented in May 2016) compared to corticosteroid therapy only (pre-May 2016)?

The approach used was a comparable descriptive study auditing medical records for three years pre and post the implementation of the 2016 Continuous Infusion policy (continuous infusion of insulin for 24- 48 hours for women with DIP after the administration of corticosteroids for pre-term birth) .A population search was attended to identify women who had DIP and received corticosteroids. The comparative data was grouping the women into two data sets defined by time. The two data sets were 2013 to 31st May 2016 compared to women from beginning of June 2016 to the end of 2019.

From 2013 to the end of May 2016 across the three maternity facilities twenty-nine (29) women were identified as having DIP and receiving corticosteroids opposed to seventy-seven (77) women from the 1stJune 2016 to end of 2019.

Summary of Key Findings

From 2013 to end of May 2016

- In this data set 37.9% (11/29) women received continuous Intravenous (IV) insulin
- Admission to Special Care Nursery was 45% (13 /29) newborns.
- Newborns admitted to Special Care Nursery for risk of hypoglycaemia or hypoglycaemia treatment was 38% (5/13)

- Repeat elective caesarean sections represented 55% of mode of birth
- Corticosteroids administered after or equal to 37 weeks gestation was 52% (15/29) with 14 of these women having repeat elective caesarean sections

From 1st June to end of 2019

- In this data set 71.6 % (48/67) of women who were admitted received continuous IV insulin.
- The NNSWLHD guideline implemented in 2016 compliance rate was 48.1% (37/77).
- Admission to Special Care Nursery was 55.8% (43/77) of Newborns.
- Newborns admitted to Special Care Nursery for risk or treatment of hypoglycaemia was 40% (17/43).
- Repeat elective caesarean sections represented 45% of mode of birth
- Corticosteroids administered after or equal to 37 weeks gestation was 35% (27/77) with 20 of these women having repeat elective caesarean sections

Key Conclusion

There was no association between receiving IV insulin infusion and admission to the SCN for risk of/hypoglycaemia, p=1.00 (Fisher's Exact Test). Whilst results show that there was no associate between the guidelines and admission to special care nursery, the guideline was followed only 48% of the time.

Recommendations

The original data set acquired for 2013 to 31/05/2016 (36 women) and 1/6/2016 to the end of 2019 (97 women) before exclusion criteria for the research identified a significant rise in numbers for the later. Diabetes in pregnancy affects 10% of women with the incidence increasing 1-2% per year [1& 21]. This is significant with future and current impact for models of care and clinical practice.

Based on this statistic and data a review of models of care for diabetes in pregnancy is recommended in Northern NSW LHD.

This review of models of care should include guidelines for

- the requirement to have corticosteroids especially in reference to late gestation.
- the timing of birth from women with gestational diabetes in pregnancy especially with repeat planned elective caesarean.
- the timing of administration of corticosteroids if required for planned birth

More evidence is required such as a randomised controlled trial to determine whether benefits outweigh the risks of antenatal corticosteroids in late gestation specifically in women with gestational diabetes in pregnancy.[21]

Lastly more research and quality projects should be explored to review clinician's compliance with guidelines and take into consideration clinician, guideline, systematic and implementation characteristics. This research or quality activity should take an interdisciplinary approach with current research[24] suggesting this is essential to improve clinician's compliance with evidence -based guidelines.

Literature Review

Treatment of imminent preterm birth

If preterm birth between 23 and 34 weeks of gestation is anticipated or planned, administration of corticosteroids improves neonatal outcomes [1&3]. In a RCT of 2827 women, the administration of antenatal betamethasone in women at risk of late preterm delivery (Gestation 34 to 36^{+6}), decreased the rate of respiratory complications in newborns, however the administration of Betamethasone significantly increased the rates of neonatal hypoglycaemia [3]

Treatment of imminent preterm birth for women with diabetes

If preterm birth between 23 and 34 weeks of gestation is anticipated or planned for women with diabetes, the administration of corticosteroids to improve neonatal outcomes is usual management. Transient hyperglycaemia induced by corticosteroids can be severe in women with diabetes; even when glucose levels are controlled and treated. The hyperglycaemic effect begins approximately 12 hours after the first steroid and lasts 5 days [3]

Although administration of betamethasone has been shown to have potential benefits for preterm births between 34 to 37 weeks of gestation, in a randomised controlled trial (RCT), women with pre-gestational diabetes were excluded [3]. The neonatal benefit of antenatal corticosteroid administration in women with threatened preterm birth and Gestational diabetes or pregestational diabetes has never been specifically studied [13]. As such, the American College of Obstetricians and Gynaecologists does not have a specific position statement with regards to steroid use in this population. While the 2016 Committee Opinion of Antenatal Corticosteroid Therapy for Foetal Maturation does not comment on the use of antenatal corticosteroids in women with diabetes at any gestational age, [14] the 2017 revision clarifies that the benefit of steroids among women with GDM or pregestational diabetes is unknown in the late preterm period.[15] Similarly, the National Institute for Health and Clinical Experience (NICE) guidelines state that antenatal corticosteroids are not contraindicated in women with insulin treated diabetes [16] although there is no strong recommendation for or against use in this population. The results of a population- based study, however, show that the findings of antenatal corticosteroid trials have been extrapolated and are clinically being used in this diabetic population. [17]

If corticosteroids are administered to women with diabetes, monitoring of BGLs is recommended. However, there is no high-level evidence to identify what insulin therapy regime should be delivered in response to the BGL's to prevent hyperglycaemia[3]. There is insufficient evidence in reference to women with diabetes especially in this late preterm population as to whether they should

1) Receive the corticosteroids?

2) If they do receive the corticosteroids what BGL should be targeted and what the insulin regime should be?

Barraebee et al (2019)[7] published the results of a cross-sectional, electronic survey of actively practicing maternal-foetal medicine (MFM) providers from May 2017 to July 2017, exploring antenatal steroid use in diabetic women and the glycaemic management strategy after steroid administration.

The study identified while there are no prospective studies examining the neonatal benefit of antenatal steroids in diabetic women, expert consensus believes steroid use in this context is best practice and report they are administering steroids almost universally in this population[7]. Variations were identified in the glycaemic management strategy used after steroid administration. "While use of a standard protocol for glycaemic control was associated with practice satisfaction, routine use of a continuous insulin infusion for all women with insulin-dependent diabetes was associated with lower odds of satisfaction", although the paper did not provide explanation on why clinicians were dissatisfied. The result concluded that more research is needed to optimize care of diabetic women receiving steroids for threatened preterm labour as maternal and neonatal outcomes related to these practices remain unknown[7].

2016 NNSW LHD Guideline Diabetes in Pregnancy – Management of Blood Glucose Levels (BGLS) During Corticosteroids Therapy

In Northern NSW Local Health District, a guideline was developed in 2016 which recommended continuous infusion of insulin for 24- 48hours for women with diabetes in pregnancy after the administration of corticosteroids for pre-term birth when certain criteria were meet including blood glucose level ranges. The NNSW LHD Guideline Diabetes in Pregnancy – Management of Blood Glucose Levels (BGLS) During Corticosteroids Therapy (referred to **DIP** from here on) was written by a multi-discipline team based on expert consensus.

It was anticipated that adhering to the new clinical guideline which included specific range values of continuous insulin infusion based on blood glucose levels may avoid newborn hyperglycaemia at birth preventing Special Care Nursery (SCN) admission. This would consequently reduce the possibility of mothers and babies' separation in the first 24 hours after birth. The importance of avoiding separation is that immediate contact after birth and initiating breastfeeding early keeps an infant warm, building their immune system, promotes bonding, boosts a mother's milk supply, and increases the chances that she will be able to continue exclusively to breastfeed[9]. Mothers practicing early skin to skin contact in the first 24 hours with their newborns are more likely to breastfeed in the first one to four months of their child's life and to continue for longer durations[10]. Evidence suggests exclusive breastfeeding until 6 months may reduce the odds of type 2 diabetes, high blood pressure and childhood cancers[12]. Maternal benefits of breastfeeding include reduced risk for developing type 2 diabetes[11]. The protective effect of breastfeeding is related to breastfeeding duration and has been shown for women with gestation diabetes that resolve after birth[11]

Study Aim

The aim of the study was to explore the impact of the administration of corticosteroids and continuous insulin therapy for women with diabetes and imminent preterm birth on neonatal and maternal outcomes, compared to corticosteroid therapy only.

The research questions were.

1) What is the percentage of women with DIP's receiving corticosteroid and continuous insulin therapy compared to corticosteroid therapy only?

2) What are the outcomes (admission to special care nursery) for neonates of women with DIP receiving corticosteroid and continuous insulin therapy (as per the NNSW LHD Guideline Diabetes in Pregnancy – Management of Blood Glucose Levels (BGLS) During Corticosteroids Therapy implemented in May 2016) compared to corticosteroid therapy only (pre-May 2016)?

Methods

Study Design

The approach used was a comparable descriptive study auditing medical records. for three years pre and post the implementation of the 2016 Continuous Infusion policy (continuous infusion of insulin for 24- 48 hours for women with diabetes in pregnancy after the administration of corticosteroids for pre-term birth).

Study Setting/Location

Data was obtained from three Maternity Services Facilities across Northern NSW LHD. The sites were identified as having a role delineation where women with DIP's could be cared for as inpatients for antenatal care and birth.

Eligibility Criteria

Women ≥ 18 years with diabetes in DIP receiving corticosteroid therapy for pre-term birth and their newborns

Ineligibility Criteria

Women < than 18 years with diabetes in pregnancy receiving corticosteroid therapy for pre-term birth and their newborns.

Analysis

Data was collected from electronic maternity medical record databases. Two databases, ObstetriX and eMaternity, were required to be used due to a change in systems in 2016. Due to different types of data field requirements in the applications search criteria needed to be established for both to identify eligible women for the research project.

Once women that meet eligibility were identified through databases, hard copy medical records were requested formally to obtain all research data (See Appendix 1). A search protocol (Appendix 1) was written for the collection of data to be reliable.

Data was collected using Microsoft excel.

Ethical Considerations

The research was reviewed by the Director of Research for Northern NSW Local Health District and was supported to be exempt from the requirement for ethical and scientific review by the Human Research Ethics Committee. It was approved as a quality assurance project QA306.

Results

Pre-Guideline women identified with DIP (2013 to 31st May 2016)

From 2013 to the end of May 2016 across the three maternity facilities 35 women were identified as having DIP's and receiving corticosteroids, See Table 1.

As per Table 1 women were identified as having Type I, Type II or Gestational DIP that included if insulin was required or diet specific for the latter.

Table 1: Pre guideline implementation Women with Diabetes in Pregnancy and type who received Corticosteroids.

Diabetes in Pregnancy (DIP)	B1 Hospital	B2 Hospital	B3 Hospital
Type 1 DIP	1	3	0
Type 2 DIP		2	
Gestation DIP Insulin		9	10
Gestation DIP Diet controlled		2	8
Total	1	16	18

From the 35 women that were identified in this period six women were excluded from the results. Reason for exclusion included

- Women were transferred out of the facility for higher level care
- Medical records not able to confirm corticosteroids were administered
- Intensive Care admission for Diabetic Ketoacidosis

Data collected of the remaining 29 participants as per the research protocol in Appendix 1 were broken down into different characteristics. Women who were diagnosed with Gestational DIPs was 86% . All women with Type I & II DIP's required insulin with 18 from 25 women with Gestational DIP's requiring Insulin therapy – See Table 3

Post Implementation of Guideline Women Identified with DIP (1st June 2016 to end of 2019)

Across the three sites 97 women were identified as having DIP's and receiving corticosteroids. As per Table 2 women were identified as having Type I, Type II or Gestational DIP that included if insulin was required or diet specific for the latter.

Table 2 Post guideline Women with Diabetes In Pregnancy and type who received Corticosteroids

Diabetes in Pregnancy (DIP)	B1 Hospital	B2 Hospital	B3 Hospital
Type I DIP	3	8	1
Type II DIP	0	8	0
GDM Insulin	8	26	8
GDM Diet	7	16	12
Total	18	58	21

From the 97 women that were identified in this period 20 women were excluded from the results

Reason for exclusion included

- Women transferred out for higher level care after receiving corticosteroids
- Women received corticosteroids in facility not within Northern NSW and did not birth in that facility and returned to Northern NSW facilities to birth at a later period
- No documentation of administration of corticosteroids in medical records
- Admitted for preterm labour received steroids but birthed within 24 hours.

From the remaining 77 women 77% of these women were diagnosed with gestational DIP. There was a total of 40 or 51% of women that treatment was insulin. Twenty-four women were diet controlled and the remaining women had a combination of metformin plus or minus insulin as per Table 3

Table 3: Characteristics of Diabetes in Pregnancy Type and Therapy Pre and Post Guideline

Characteristics	**Pre Guideline N=29 (%)**	**Post-guideline N = 77 (%)**
Site		
B1 Hospital	17 (59)	15 (20)
B2 Hospital	12 (41)	47 (61)
B3 Hospital		15 (20)
Diabetes in Pregnancy Type		
GDM	25 (86)	59 (77)
Type II	2 (7)	7 (9)
Type I	2 (7)	11 (14)
Diabetes Treatment		
Insulin	22 (76)	40 (52)
Diet	7 (24)	24 (31)
Metformin		7 (9)
Insulin + Metformin		6 (8)

There was no published guideline to follow pre-June 2016 hence the documented blood glucose as per protocol is not applicable as per Table 4.

Pre guideline women with DIP who received corticosteroids 72% (21/29) were admitted to hospital for monitoring. Continuous Insulin infusion were administered in 38% (11/29) women. An insulin infusion was commenced within two hours before the first meal for 91% (10/11) women. Refer to Table 4 below.

In comparison Post Guideline administration of corticosteroids 67 or 87% of women were admitted to hospital as an inpatient as per recommendations of the new clinical guideline. This figure was 15% higher than the pre-guideline where 72% of women were admitted who had DIP following administration of corticosteroids. Of the 67 women admitted only 45 or 58% women had blood glucose documented as per guideline. Please refer to Table 4

Forty-eight or 62 % women received continuous IV insulin. Of the 48 that received continuous IV insulin 22 commenced the infusion within two hours of receiving corticosteroids. Twelve women commenced the IV insulin infusion after two hours and before ten with 14 women commencing IV insulin more than ten hours after receiving corticosteroids. Twenty-five out of the 48 women commenced insulin before their first meal. Please refer to Table 4

Table 4: Characteristics of Treatment after admission after corticosteroids for women with Diabetes in Pregnancy

Characteristics	**Pre-Guideline N =29 (%)**	**Post-Guideline N=77 (%)**
Admissions as inpatient post steroid injections		
Yes	21 (72)	67 (87)
No	8 (28)	10 (13)
Documented Blood Glucose Level (BGL) as per protocol		
Yes	0	45 (58)
No	0	22 (29)
N/A	29 (100)	10 (13)
Subcutaneous insulin therapy		
Yes	14 (48)	40 (52)
No	6 (21)	1 (1)
N/A	8 (28)	36 (47)
Yes pump	1 (3)	
Intravenous insulin therapy		
Yes	11 (38)	48 (62)
No (Includes N/A)	18 (62)	29 (38)
How long after steroids before continuous insulin commenced		
0-1	6 (21)	12 (16)
0-2	4 (14)	10 (13)
3-9	1 (3)	12 (16)
≥ 10	0	14 (18)
n/a	18 (62)	29 (38)
Was insulin commenced before first meal…		
Yes	10 (35)	25 (33)
No	1 (3	42 (54.)
N/A	18 (62)	10 (13)

The variables in Table 4 were important to determine as they were identified as key factors (as per Appendix 1) to ensure the NNSWLHD guideline was followed. As a result, if was determined that 48.1% (37/77) received care as per the clinical guideline recommendations. See Table 5

Table 5 NNSW LHD Guideline Diabetes in Pregnancy – Management of Blood Glucose Levels (BGLS) During Corticosteroids Therapy Compliance

Guideline followed	**N =77 (%)**
Yes	37 (48)
No	40 (52)

As summarised in Table 6 the following characteristics of newborn of mother with DIP who received corticosteroids pre guideline were identified

- Newborn weight between 2501 and 4000 grams was 65% (19/29)
- Gestational age at birth was greater or equal to 37 weeks was 65% (19/29)
- Repeat elective caesarean section represented 55% of mode of birth
- Corticosteroids administered after or equal to 37 weeks gestation was 52% (15/29) with 14 of these women having repeat elective caesarean sections. Nine (9) out of the fourteen (14) were admitted for monitoring after the administration of corticosteroids.
- Blood glucose monitoring was performed in 79.3% of newborns in the first twenty-four hours.

In Comparison as per Table 6 the following characteristics of newborn of mother with DIP who received corticosteroids post guideline were identified

- Newborn) weight was between 2501 and 4000 grams was 81% (62/77)
- Gestation age at birth was greater than 37 weeks was 59% (46/77).
- Repeat elective caesarean section represented 45% of mode of births.
- Corticosteroids administered after or equal to 37 weeks gestation was 35% (27/77) with 20 of these women having repeat elective caesarean sections. Nineteen out of the twenty women were admitted as an inpatient after receiving corticosteroids.
- Blood glucose monitoring was performed on 100% of newborns in the first twenty-four hours.

Table 6 Characteristics of newborn whose mother identified as having Diabetes in Pregnancy and received corticosteroids pre and post guideline comparison.

Characteristics of newborn	**Pre-Guideline N = 29 (%)**	**Post-Guideline N = 77 (%)**
Ethnicity		
Aboriginal	0	16 (21)
Caucasian	29 (100)	57 (74)
Other	0	4 (5)
Weight		
1500-2000	0	2 (3))
2001-2500	10 (34)	9 (12)
2501-3000	4 (14)	15 (20)
3001-3500	11 (38)	31 (40)
3501-4000	4 (14)	16 (21)
4001-4500	0	3 (4
4501-5000	0	1 (1)
Sex		
Female	13 (45)	29 (38)
Male	16 (55)	48 (62)
Gestation at Birth		
32-33.6	0	1 (1)
34-36.6	10 (35)	30 (39)
37-38.6	18 (62)	44 (57)
39-42	1 (3)	2 (3)
Mode of Birth		
Normal Vaginal Birth	4 (14)	19 (25)

Repeat caesarean – elective	16 (55)	35 (45)
Emergency caesarean	8 (28)	12 (16)
Instrumental	1 (3)	2 (3)
Elective caesarean section other than repeat		9 (12)
Blood Glucose Level monitoring attended first 24 hours		
Yes	23 (79)	77 (100)
No	6 (21)	

As summarised in Table 7 the characteristics of the newborn admitted to Special Care Nursery whose mother identified as having DIP and receiving corticosteroids were

1) Pre-Guideline
   - Admission to Special Care Nursery was 45% (13 /29) newborns.
   - Newborns admitted to Special Care Nursery for risk of hypoglycaemia or hypoglycaemia treatment was 38% (5/13).
   - Other reasons for admission included prematurity, respiratory distress, or nutritional support. IV therapy was required for 4 of the 13 admissions.
2) Post-Guideline
   - Admission to Special Care Nursery was 56% (43/77)
   - Newborns admitted to Special Care Nursery for risk or treatment of hypoglycaemia was 40% (17/43).
   - Newborns admitted within two hours of birth represented 93% of all admissions
   - Other reasons for admission included prematurity, respiratory distress, or nutritional support.
   - Twenty- eight out of the forty -three required IV therapy.
   - Eight of the seventeen that were admitted for hypoglycaemia or monitoring of hypoglycaemia received IV therapy.

Table 7 Characteristics of newborn admitted to Special Care Nursery whose mother identified as having Diabetes in Pregnancy and received corticosteroids

Characteristic	**N = 29 (%)**	**N= 77 (%)**
Admitted to Special Care Nursery (SCN)		
Yes	13 (45)	43 (56)
No	16 (55)	34 (44)
Time after birth admitted to SCN	**N = 13 (%)**	**N = 43 (%)**
0-1	5 (38)	31 (72)
0-2	8 (62)	9 (21)
0-3	0	1 (2)
≥ 10	0	2 (5)
Reason		
Risk of/hypoglycaemia	5 (38)	17 (40)
Other reason	8 (62)	26 (60)
Intravenous therapy		
Yes	4 (31)	28 (65)
No (includes N/A)	9 (69)	15 (35)
Glucose Concentration		
10%	4 (31)	26 (61)
> 10%	0	1 (2)

Glucagon infusion	0	1 (2)
N/A	9 (69)	15 (35)

Data of corticosteroids greater than 37 weeks and repeat elective caesarean sections

Another incidental finding occurred when reviewing the data for women who had repeat caesarean section and received corticosteroids after 37 weeks gestation.

There were 15 women of 29 in the period of 2013 to 31/5/2016 who received corticosteroids at a gestation greater than 37 (51%). From the group of 15 women, 14 had a repeat elective caesarean section. The 14 who had the repeat elective caesarean section nine were admitted for monitoring.

In the post June 2016 to 2019, 27 women from 77 received corticosteroids after 37 weeks gestation (35%).

From this group of 27 women, 20 had a repeat elective caesarean section with 19 of the 20 being admitted for 48 hours for monitoring before birth after receiving the corticosteroids.

Table 8 Corticosteroids administered greater or equal to 37 weeks and repeat caesarean sections.

Variables	Pre-guideline	Post-guideline
Steroids administered ≥ 37 weeks	15	27
Women who had repeat elective LSCS and steroids ≥ 37 weeks	14	20
Women who were admitted for monitoring after steroids greater than 37 weeks and had a repeat elective caser	9	19

Findings

To answer the research question, a flow chart (Appendix two) was designed to be able to analyse the results and identify

1) if the woman received continuous IV insulin or not (Before 31st May 2016)
2) If the guideline was followed or not (Post 1st June 2016)
3) if the neonate was then admitted to Special Care Nursery or not
4) If admitted, the reason. If it was any reason other than risk or treatment for hypoglycaemia they would be excluded from the statistical calculation. See Appendix 2 and Figure 1.

Pre -Guideline 2013 to 31st May 2016

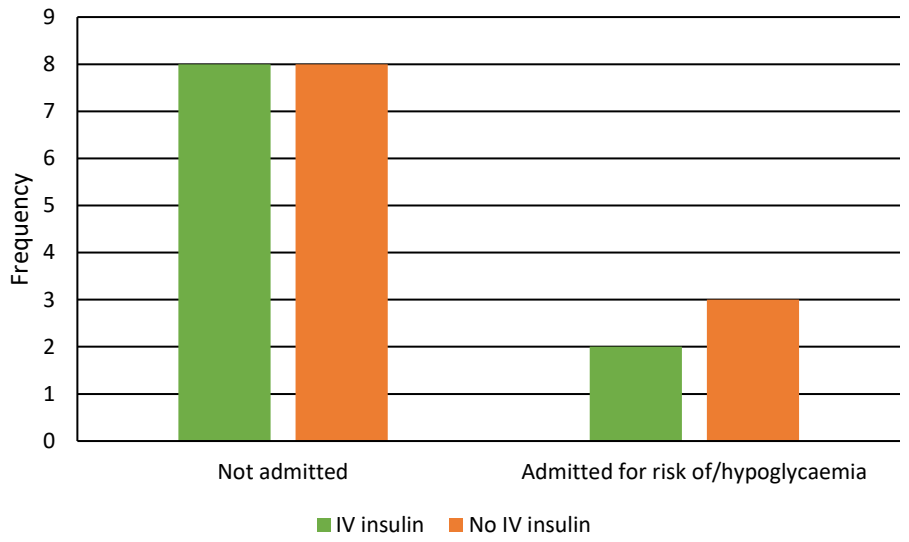
In this data 37.9% (11 out of 29) of women with DiPs received corticosteroids and IV insulin.

A total of 44.8% (13 out of 29) neonates were admitted to the Special Care Nursery (SCN). Neonates that were admitted to SCN 38.5% (5 out of 13) admissions were for risk of/hypoglycaemia and 61.5% for other reasons. Refer to Figure 1.

To determine if there was an association between women receiving IV insulin and admission to the SCN for risk of/hypoglycaemia a chi-square test was performed.

As the risk of/ or hypoglycaemia numbers had expected counts of less than 5 an Exact Fisher's Chi Square test was used. There was no association between receiving IV infusion and admission to the SCN for risk of/ or hypoglycaemia, p = 1.00 (Figure 1).

Figure 1. 2013 to 31st May 2016 (Pre-Guideline) - Association between continuous intravenous insulin and neonate outcomes with admission to Special Care Nursery



Implementation of New Guideline (1st June 2016 to end of 2019)

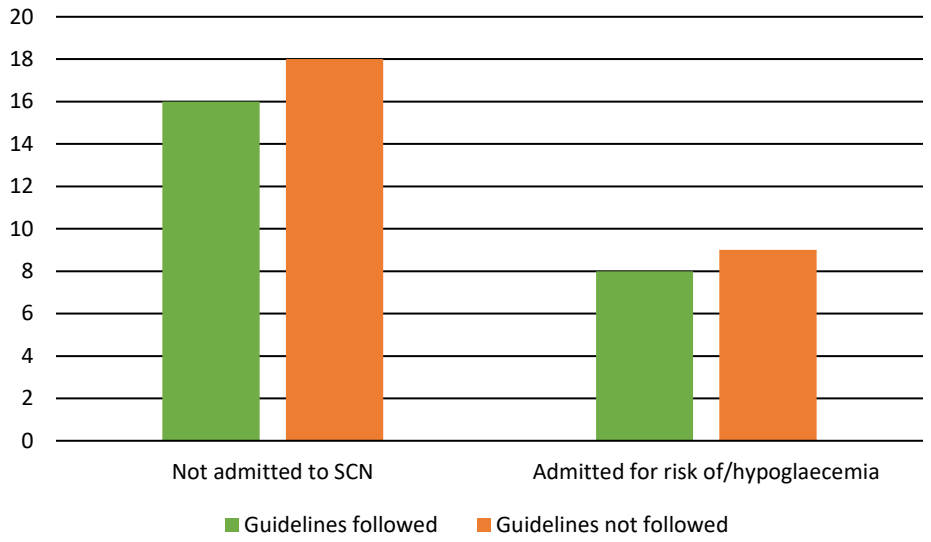
In this data set 72% (48/67) of women who were admitted received continuous IV insulin. Ten women were discharged home after receiving the corticosteroids. Of the 77 women who received corticosteroids the guideline was followed 48% (37/ 77) of the time (See Appendix 1 for guideline compliance).

A total of 56% (43/77) of Newborns were admitted to special care nursery. The criteria for admission was identified with 40% (17/43) admitted for risk or treatment for hypoglycaemia oppose to the 60% (26/43) for other reasons. – See Figure 2

To determine if there was an association between following the guideline and admission to the SCN for risk of/hypoglycaemia a chi-square test was performed.

There was no association between the following of guidelines and admission to SCN for risk of/hypoglycaemia, X2(1)=0.000, p=1.00

Figure 2. Post Implementation of Guideline, association between compliance with guidelines and neonate outcomes with admission to Special Care Nursery (N = 51).



Relationship between IV insulin and admission to SCN after 31st May irrespective if the new guideline was followed.

To consider if continuous IV insulin made a difference alone irrespective of compliance with the guideline the following was analysed.

Of the 34 Newborns that were not admitted to the Special Care Nursery 59% (20) of their mothers received continuous IV insulin opposed to 14 who did not. See Figure 3.

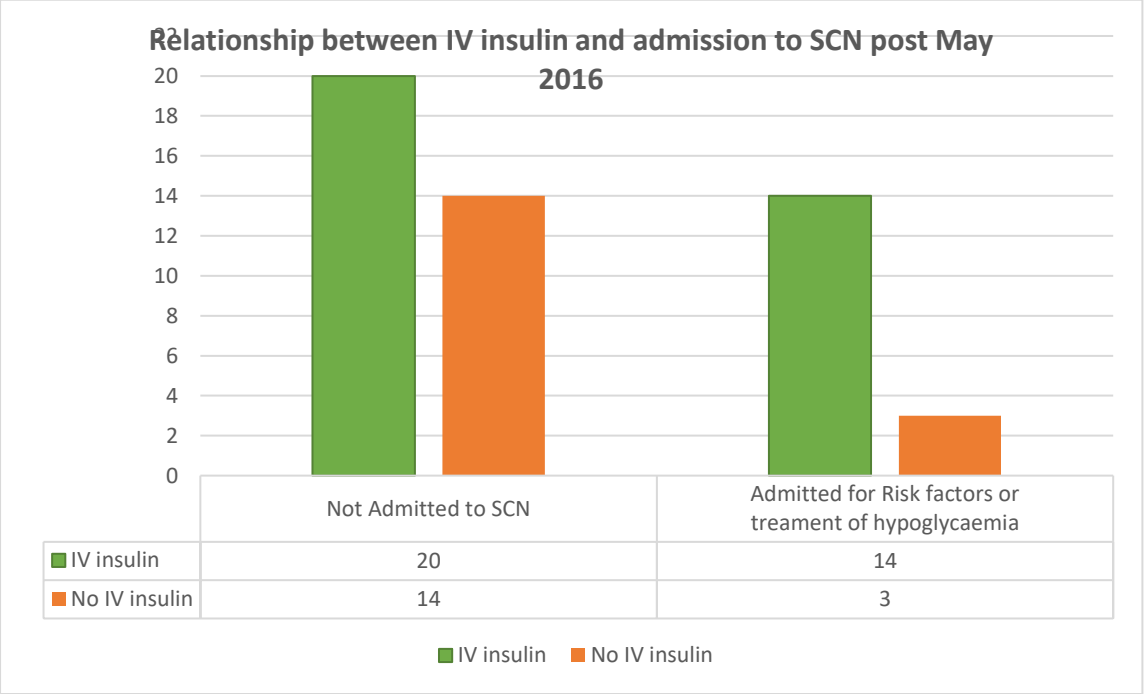
In comparison to the timeframe of post June 2016 (Figure 2) 20% (4/20) women whose newborn was not admitted to SCN (Figure 3) and received continuous IV insulin, the new clinical guideline was not followed in the provision of their care.

Admission to Special Care Nursery in the post implementation of the guideline 17 were admitted for risk or treatment of hypoglycaemia. See Figure 3
From the seventeen (17) admissions, fourteen (14) women who received continuous IV insulin, six of these women the guideline was not followed in the provision of their care.

To determine if there was an association between continuous IV insulin infusion post 1st June 2016 and admission to the SCN for risk of/hypoglycaemia a chi-Square test was used. As the risk of/ or hypoglycaemia numbers had expected counts of less than 5 an Exact Fisher's Chi Square test was used.

There was no significant association between continuous IV insulin infusion and admission to the SCN for risk of/hypoglycaemia, $p = .052$. Further research with a larger sample size is required as trending suggest that compliance with the guideline may contribute to better neonatal outcomes although this cannot be proven at this stage.

Figure 3 Relationship between continuous IV insulin and admission to SCN after 31st May 2016.



A Recent retrospective study (Rowe et al 2021)[23] identified that a specific pregnancy algorithm rate for continuous insulin infusions is validated for control of maternal hyperglycaemia following the administration of corticosteroids for women who have diabetes in pregnancy oppose to an adult standard algorithm. However, no difference in neonatal hypoglycaemia was observed between the two protocols.

Tuohy et al 2021[19] identified that the risk of neonatal hypoglycaemia is more closely related to glycaemic control immediately prior to birth than to glycaemic control after the administration after corticosteroids. Since hyperglycaemia after corticosteroids administration resolves after approximately 72 hours but can be up to 5 days. Hence administration of corticosteroids more than 72 hours before birth may reduce the risk of neonatal hypoglycaemia.

Like the findings above there was no association found for either the administration of a continuous inulin infusion opposed to none in respect to the admission to SCN for the newborn if reference to the treatment of hypoglycaemia. There are however other variables to consider which is beyond the scope of this research project.

Discussion

Increase in Gestation diabetes in Pregnancy from June 2016.

The data set acquired for 2013 to 31/05/2016 (36 women) and 1/6/2016 to the end of 2019 (97 women) identified a larger number for the latter.

The reason for the difference from 36 to 97 women can be explained from a significant change of practice with screening criteria developed by Australian Diabetes in Pregnancy Society (ADIPS) that was released at the end of 2014[17].

The change of practice with screening included

1) Recommendation for early testing for hyperglycaemia in pregnancy for women with risk factors
2) Routine testing for hyperglycaemia in pregnancy with all women offered a 75gram oral glucose tolerance test at 24-28 weeks oppose to a 50gram test that was previous offered to women who did not have any risk factors for diabetes.
3) Reclassification of the diagnostic values for fasting, one hour and two-hour blood glucose levels following oral glucose tolerance test or random fasting blood glucose tests.

Although this recommendation of practice was published late 2014[17] the transition to clinical practice was delayed and impacts were being seen by 2016 hence the development of the new guideline.

Diabetes in pregnancy affects 10% of women with the incidence increasing 1-2% per year[21]. This is significant with future and current impact for models of care and clinical practice for example

- the requirement to have corticosteroids
- the timing of administration of corticosteroids
- the timing of birth especially with repeat elective caesarean.

Data of corticosteroids greater than 37 weeks and repeat elective caesarean sections

As per Table 8 there was a significant number of women in pre and post guideline frameworks that received corticosteroids greater than 37 weeks gestation.

The New Zealand and Australian Clinical Practice Guideline for Antenatal Corticosteroids (2015)[20] recommends that elective caesarean sections at term , where possible are planned for ≥ 39 weeks' gestation. For women with diabetes in pregnancy there is insufficient evidence currently to make a recommendation for the use of antenatal corticosteroids at term (≥37 weeks' gestation) [20]

The 2015 guideline [20] clinical recommendations are to offer antenatal corticosteroids 48 hours prior to caesarean birth planned beyond 34 weeks' and 6 days gestation in women with diabetes in pregnancy or with gestational diabetes only where there is known foetal lung immaturity.

However, foetal lung maturity is seldom assessed at this age.[21] Major international groups advise against the routine use of antenatal corticosteroids before caesarean section in late gestation, because the risks are now thought to outweigh the benefits.[21]

A small retrospective study in New Zealand[21] identified it may be beneficial to use antenatal corticosteroids after 37 weeks in women with GDM when delivering by caesarean section to reduce admission to NICU for respiratory admissions. Badreldin et al 2020[22] retrospective cohort study identified neonates exposed to late antenatal preterm corticosteroids experienced increased odds of hypoglycaemia without significant improvements in respiratory morbidities however women with diabetes in pregnancy were excluded in the study.

More evidence is required such as a randomised controlled trial to determine whether benefits outweigh the risks of antenatal corticosteroids in late gestation specifically in women with GDM.[21]

There is still concern that any benefits of antenatal corticosteroids are likely outweighed by risks because respiratory complications are rare and usually transient in late gestation and the impact of hyperglycaemia is not known[21.] Other risks to be consider is the admission for monitoring and glycaemic control of the woman if this is not required in respect to unnecessary procedure, financial implications, and the social strain it may place on the woman requiring admission before birth.

Timing of administration of corticosteroids for elective birth from women with diabetes in pregnancy

A retrospective cohort study[19] from 2006 to 2016 in a tertiary hospital in Auckland New Zealand identified that babies were more like to develop hypoglycaemia when their mothers receive corticosteroids within 24 hours of birth.

This was particularly in women birthing electively by either caesarean section or induction, for whom current recommendations are to administer corticosteroids 48 hours prior to planned birth.

This study recommended that future studies should explore whether it is possible to reduce the proportion of women with DIP giving birth while hyperglycaemic by increasing the time interval between receiving corticosteroids and birth.

Maternal hyperglycaemia within 24 hours of birth was found to be associated with increased odds for neonatal hypoglycaemia[19]. The association between maternal hyperglycaemia and neonatal hypoglycaemia observed that maternal blood glucose concentration peaked from 12 to 72 hours after corticosteroids administration. Babies of women birthing from 12 hours to 48 hours later were more likely to develop hypoglycaemia than those born before or after this period despite maternal glycaemic control management.

In the New Zealand Study[19] the use of antenatal corticosteroids prior to elective caesarean was observed to be common, increasing and cause for concern.

As per the NNSW LHD guideline women with DIP are admitted anytime from 48 hours before birth is planned for the administration of corticosteroids and monitoring of blood glucose levels. According to the New Zealand study[19] this needs to be considered around the timing of the corticosteroids if it is required for planned birth oppose to unplanned birth of threatened preterm labour.

An area for future studies is exploring whether it is possible to reduce the proportion of women with DIP giving birth while hyperglycaemic by increasing the time interval between receiving corticosteroids and birth.

Compliance with Guidelines

Of the 77 women who received corticosteroids in the group from 31/05/2016 the NNSWLHD Clinical guideline was followed 48% (37/ 77) of the time.

This does Place limitations on this small research data to be able to determine if compliance with the guideline may have indicated a different result and there in fact was an association with avoidance of special care admissions for newborns with hypoglycaemia.

There have been several studies in relation to clinician compliance with evidence-based guidelines. Gurse's et al 2010[24] identified four main categories that affected compliance with guidelines.

This included clinician, guideline, systematic and implementation characteristics. The conclusion from Gurse's et al 2010 was that an interdisciplinary approach is needed to improve clinician's compliance with evidence -based guidelines.

Similar Longman, Adams et al 2018[25] described barriers for midwives and obstetricians in the implementation of smoking cessation guidelines in pregnancy included systems that did not support implementation such as lack of knowledge, skill, and training.

These are all importance points and recommendations to consider in the implementation of new or updated clinical guidelines based on evidence-based practice.

Limitations of the study

Limitations of study included the reliance on the accuracy of data being entered correctly into medical records by clinicians. This data included administration of corticosteroids, insulin requirements and documentation of Blood Glucose Levels.
A change in maternity data base was a limitation as fields were changed with the update and the search criteria needed to be adjusted due to upgrade.
However, the above is noted as a limitation a strength was that there is specific data bases built for maternity which does provide credibility for accuracy of data required to be collected for this study.
Data was observed to be missing at times which meant exclusion from the overall results.
Further limitations included as this study was observation in nature oppose to an intervention it can establish an association however unable to establish causation. Having the admission to Special Care Nursery as an outcome also caused limitations as there were several other reasons admission was required apart from hypoglycaemia of the newborn.
Finally, being set in a rural setting research numbers were small. Hence it was important to have a well-defined research protocol (Appendix 1) to ensure data that was collected in a standardised manner.

Conclusions

In Conclusion, the study identified how many women with DIP received corticosteroids between 2013 to 2019 including identification of those that received a continual IV insulin infusion for maternal glycaemic control.

There was statistical no association identified in the study with following the NNSW LHD Guideline Diabetes in Pregnancy – Management of Blood Glucose Levels (BGLS) During Corticosteroids Therapy in preventing newborn admission to special care nursery for the monitoring or treatment of hypoglycaemia.

Further-more there was statistically no association identified in the study when women with DIP received a continual IV insulin infusion in preventing newborn admissions to special care nursery for monitoring or treatment of hypoglycaemia.

Based on limitations associated with this observational study, an interventional study would be recommended considering the timing of administration of corticosteroids and commencement of insulin and their relationship to outcomes.

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Appendix 1 Research Protocol for Collection of Data

Data Collected on Excel Spreadsheet

Column 1 (X AXIS)	**Column 2 (Y Axis)**	**Column 3**	**Column 4 (X AXIS questions – Y Axis answers)**	
Woman	**Possible Answers**	**Directions**	**Compliance with guideline keys factors (will be on excel sheet under the question it is relevant to).**	
1. Maternal Age				
2. Ethnic Origin				
3. Type of diabetes in pregnancy	Gestation, Type II, Type I			
4. Gestation age of steroids				
5. Treatment for Diabetes	Diet, oral medication, Insulin			
6. Hb1aC in past 3 months	Yes, No or Not applicable			
7. Hb1aC value				
8. Date of admission				
9. Admission after steroids	**Yes or No**	**If Yes to Admission after Steroids complete the following row, otherwise commence at row 20**		
10 Time corticosteroids administered				
11 BGL documented from time of steroids in hours for 48 hours		Need to document BGL in hours from the time of administration of steroids.		
12 Diabetes in pregnancy managed with insulin therapy	Yes or No	1. If yes Column 4 needs to be answered for determine compliance with guideline	**If yes compliance with guideline meet**	
			Monitor BGL hourly during insulin/dextrose infusion unless ordered otherwise by O&G or medical team eg. if BGLs stable, 2nd hourly overnight	
	Yes or No	1) Must be the time in hours from when the steroids where commenced	**If yes compliance with guideline meet.**	YES or NO

13. Continuous Insulin commenced from time of steroids		2) If woman on insulin compliance with guideline needs to be answered in column4	if woman is on insulin already • Continuous infusion to commence before lunch if steroids given in morning • If steroids given after lunch, does infusion start before next meal • If steroids given at night time does insulin infusion start within 2-3 hours • insulin/dextrose infusion to continue until lunch time day 3 post first steroid injection or 24 hours after the last steroid injection	
14. Continuous insulin dose		1. Document Rate of insulin in hours from when commenced 2. Column 4 needs to be answered for determine compliance with guideline	**To comply with guideline does the continuous insulin follow the "Variable rate of insulin regime"**	

Capillary BGL (mmol/L)	mL /hour (= units of Neutral Insulin (Actrapid™) per hour)
< 4.0	Stop insulin infusion & treat hypoglycaemia, refer to flowchart 1. Check BGL in 15 min. Requires clinical review[15] .
4.0 - 4.9	0.5 mL/hour
5.0 - 6.9	1.0 mL/hour
7.0 - 7.9	1.5 mL/hour
8.0 - 10.0	2.0 mL/hour
10.0	3.0 mL/hour Continue infusion Notify MO for clinical review and change to infusion rates[17]

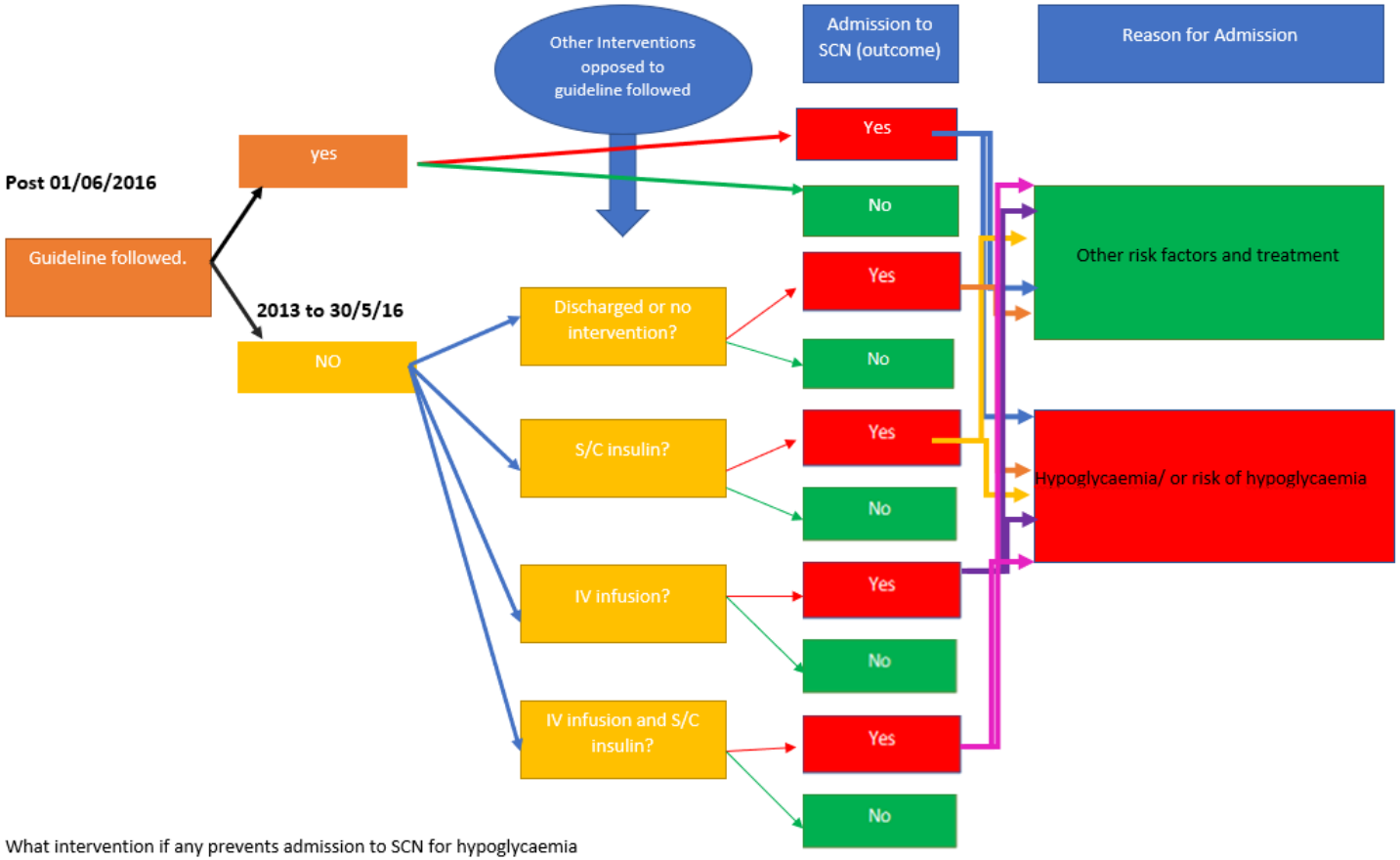
15. Insulin s/c doses as per medication chart		1. Document when s/c insulin given from time of infusion commenced as well as actually time of day.	**If yes compliance with guideline meet.** Document amount of s/c insulin given. Does it match the prescribed dose?

		2. Column 4 needs to be answered for determine compliance with guideline		
16. Was a maintenance dose of IV dextrose accompanying the IV insulin infusion	Yes or No	1. Column 4 needs to be answered for determine compliance with guideline	**If yes compliance with guideline meet.**	
17. Diabetes in pregnancy managed with diet alone or Metformin	Yes or No	1. If yes Column 4 needs to be answered for determine compliance with guideline	**If yes compliance with guideline.**	
			Monitor BGLs pre and 2 hours post commencement of meals, 12 midnight and 3am	
			If BGLs are > 5.0mmol/L fasting and/or > 7.0mmol/L at any other time on 2 occasions has an insulin/dextrose infusion been commenced	

Column 1	Column 2	Column 3	Column 4
19. Newborn	Answers	Directions	Compliance (NA)
20. Date of Birth			
21. Ethnic Origin			
22. Weight			
23. Sex			
24. Gestation at birth			
25. Mode of Birth	Vaginal Birth / Instrumental/ LSCS	If instrumental or LSCS state in Column 4 reason as per medical records	
26. Ethnic origin			
27. BGL frequency and Levels		Document BGL recorded from time of birth for 24 hour period by the hour since birth.	
28. Type of Feeds	Breast feeding/ Formula Feeding or Both		
29. Frequency of Feeds.		Document time of feed for 24 hours since birth.	

30. Feeding concerns	Yes/No	Refer to notes and in column 8 document what concerns are	
31. Treatment of hypoglycaemia	Oral glucose, feed, IV therapy, IV Glucose	Details in column 4.	
32. Admission to Special Care Nursery	Yes/ No	If the newborn is not admitted to Special Care Nursery – to not complete any further rows.	
33. Time after birth of admission			
34. Length of admission		In hours	
35. Reason for Admission	Sepsis, respiratory distress, hypoglycaemia, prematurity, congenital abnormality	Details in column 4.	
36. Blood Glucose Level during admission		Document BGL recorded from time of birth for 24 hour period by the hour since birth.	
37. IV therapy required	Yes/No		
38. Type of IV Therapy	Glucose – what concentration.		

Appendix 2 Flow Chart to Determine Percentage of Women admitted for corticosteroids and IV insulin infusion and Special Care Nursery Admissions and Outcomes.



What intervention if any prevents admission to SCN for hypoglycaemia

For women with Type 1, Type 2 of Gestational Diabetes Mellitus