

Standard Operating Procedure (SOP) for the Adjustment of Insulin Doses by Paediatric Diabetes Specialist Dietitians without a supplementary prescribing qualification working with children and young people within

Please select trust

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Issue Date on CYP North West Diabetes Network Website: [insert date] Issue Date of Trust: [insert date]			Review Date: [insert date 3 years after issue date]				
Purpose and Background:			To enable the without a supp adjust insulin c	lementary pro	•		
Scope (i.e. organisational responsibility) Vital functions affected by this procedure:		dieti com SOF Med This	tians can safe petency frame is the respor icines Manag	ope of this SOP is to ensure that the paediatric diabetes specialist ns can safely and effectively adjust insulin doses within the tency framework ¹ for children and young people with diabetes. This the responsibility of the CYP diabetes medical lead and the Trust mes Management Group.			
Monitoring C	ompliance	e: <mark>Tru</mark>	<mark>st specific</mark>				
Requirement to be monitored. Must include all requirements within NHS Resolution Standards			Responsible individual/ committee for carrying out monitoring	or monitoring individual/ individual/ individual/ committee committee for committee			
Escalations (clarification r please contac	egarding					leads, clinical bing leads and	

	Committees / Group	Date
Consultation:	Paediatric Diabetes Team, MMG, NMP Lead, Trust specific	
Approval Committee:		
Ratified by Committee:		

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Standard Operating Procedure

1. Introduction

Diabetes is a chronic condition and management should be tailored to suit the individual. There is strong evidence that good glycaemic control reduces the risk of acute and chronic complications². All children with Type 1 diabetes are treated with insulin and a proportion of children with Type 2 diabetes may be treated with insulin³.

Different health care professionals, including Paediatric Diabetes Specialist Dietitians working as part of a multidisciplinary team, are required to advise individuals with diabetes on the dose adjustment of insulin based on glucose data and behavioural/lifestyle aspects of diabetes management, e.g. diet and exercise. It is noted that not all dietitians have a supplementary prescribing qualification.

This SOP allows Paediatric Diabetes Specialist Dietitians to be authorised to adjust the dose of insulin in children and young people, aged from 2 years to 18 years of age.

The SOP is designed as a guide to the safe limits within which the dietitian can adjust insulin. The dietitian should be aware of the Royal Pharmaceutical Society prescribing competencies and the BDA practical prescribing guidance

2. Who Will Recommend Dose Adjustment?

This SOP is intended for use by Paediatric Diabetes Specialist Dietitians employed by Please select trust

Before adjusting insulin doses, the dietitian must have read this SOP and understand the context in which insulin dose adjustment is allowed by dietitians within Please select trust

3. Characteristics of Staff

- Be a qualified Paediatric Diabetes Specialist Dietitian, (Band 6 or above)
- Registered with the HCPC
- Member of the BDA
- A minimum of 2 years post registration experience and have worked in diabetes for a minimum of 2 years
- Have evidence of continuous CPD within diabetes clinical practice and be able to demonstrate competence in accordance with the BDA "A training, education and competency framework for Paediatric Dietitians working in paediatric diabetes (2019) at Band 6/enhanced level or above and demonstrates evidence of core skills identified in the BDA Core Skills Training Guide for paediatric diabetes dietitians for their appropriate band
- Have completed the <u>Safe use of Insulin Module</u> available through ESR

In addition, the following requirements are necessary, staff must:

- Agree to be professionally accountable for their work.
- Be competent to assess the capacity of the patient/carer/parent/person with parental responsibility to understand the nature and purpose of the alteration in dose in order for them to give or refuse consent, as per HCPC (2019) high level Principles of Good Practice in Remote consultations and Prescribing.
- Be aware of current treatment recommendations and be competent to discuss issues concerning insulin with the patient/carer/parent or person with parental responsibility.

- Have been trained and assessed as being competent with insulin doses by an independent prescriber within the diabetes MDT
- Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct
- Have prescribing responsibilities for insulin included in their job description

Non-diabetes specialist dietitians providing clinical cover for DSD are **not** authorised under this policy and should **not** advise on dose adjustment of insulin

3.1 Responsibility of Managers

Clinical Managers will be responsible for:

- Ensuring that the current guideline is available to staff providing care under this SOP.
- Ensuring that staff have received adequate training and are deemed competent in the adjustment of insulin doses and other aspects relevant to this SOP and meet the requirements above. This includes any updates to training that may be required.
- Maintaining a current record of all staff authorised to alter insulin doses specified in this SOP and ensuring staff have these duties included in their job description
- Ensuring that adequate support and feedback is given during supervision with manager.
- Review of dose adjustment decisions are completed by a qualified medical or nonmedical prescriber at each patient's next MDT appointment.

4. Clinical Decision Making

There are many factors influencing glycaemic management in children and young people with diabetes.

- Ensure there is sufficient glucose data before making any dose adjustments to insulin:
 - If using finger-prick testing alone then blood glucose finger pricks: >4 per day
 - o Data is required before sleep and prior to breakfast to adjust overnight inulin
 - o Data is required before and after meals for bolus dose adjustments
 - Is the glucose sensor being worn for sufficient amounts of time for accurate interpretation (aim is ≥70% but as a minimum there should be data available during the time period for which the insulin is being adjusted)
- For mealtime bolus insulin, check if:
 - All insulin is being given as prescribed
 - Accurate carbohydrate counting
 - The bolus advisor and/or insulin to carbohydrate ratios (ICR) and insulin sensitivity factors (ISF) are used appropriately
 - o Bolus insulin being given appropriately prior to meals

Other considerations:

- Is hypoglycaemia being treated appropriately, i.e. ensuring hypo prevention or treatment is not causing high glucose levels?
- Is there food being given to prevent low levels, therefore possibly masking excessive insulin doses?
- Does the young person rotate their injection sites and/or are they injecting into lumps?
- Is insulin being stored appropriately?

- Is the young person taking any other medication prescribed, over the counter or from the internet that could affect their glucose levels or effect insulin?
- Is the basal bolus split appropriate?
- Consider other factors that may be affecting glucose levels (e.g., physical activity, alcohol, stress etc)
- If on an insulin pump, are the minimum and maximum doses set at appropriate levels?

5. Exclusion Criteria/Safety Netting

This document does not cover dose adjustment in the following circumstances. Unless the dietitian has alternative guidance, they will **NOT** advise on dose adjustment of insulin in the following patients/instances and should refer/request urgent (as appropriate) review by an independent prescriber if any of the below are highlighted during clinical assessment:

- If there has been a recent episode of severe hypoglycaemia requiring support or hospitalisation and has not yet been reviewed by an Independent Prescriber
- If the patient is currently in diabetic ketoacidosis (DKA)
- Has ketones over 0.6mmol/L
- Total daily dose greater than 1 unit/kg for prepubertal children
- Total daily dose greater than 2 units/kg for post pubertal children
- Has experienced adverse side effects or drug reactions e.g., contact dermatitis
- If the presenting clinical condition is deemed to be out of the area of expertise and knowledge of the specialist dietitian
- Evidence of poor injection technique
- Lipohypertrophy
- Pregnancy
- Gestational diabetes
- CYP that have not been seen by an independent prescriber for over 3 months

6. Adjustment of Current basal and bolus insulin prescription

Each dose of insulin (basal or bolus) should be adjusted based on a clinical decision during the consultation which considers all factors which may have influenced glycaemic management.

The dietitian will be authorised to adjust the dose of insulin for children and young people with diabetes with ages ranging from 2 years to 18 years of age within 10% of their current prescription.

Behavioural/lifestyle aspects of diabetes management, namely diet and exercise, may require temporary adjustments/diversion of >10% from the prescribed dose (section 7)

Ideally adjustments should be made one at a time and the effect should be monitored prior to further adjustments being made

6.1 Increasing Insulin

Where there is a repeated pattern of hyperglycaemia without ketosis, consider increasing insulin by 10% of current dose

Where there are limitations on dose adjustment, doses should be increased by the smallest increment possible

Should the dietitian feel a greater increase is required they should seek advice from the paediatric diabetes clinical lead, medical prescriber or appropriate non-medical prescriber (NMP).

6.2 Decreasing insulin

In the event of a pattern of hypoglycaemia, glucose readings below the agreed target range or other contributing factors which may result in hypoglycaemia, the insulin dose can be reduced by a maximum of 10% of the current dose.

Where there are limitations on dose adjustment, doses should be decreased by the smallest possible increment.

Should the dietitian feel a greater reduction is required they should seek advice from the Consultant or appropriate non-medical prescriber.

6.3 Children and Young People dose adjusting using ratios

For CYP using insulin to carbohydrate ratios and insulin sensitivity factors, increase or decrease insulin dosing by 10% in a stepwise approach. Any adjustment to ratios needs to be done with consideration of the change this would make to the dose delivered. Table in Appendix 1 is provided for guidance.

7. Deviation from current prescription for behavioural/lifestyle aspects of diabetes management - Diet and Exercise

Deviations from usual prescription should be sensible and done in a stepwise approach.

7.1 Adjustment of Insulin for Exercise

Insulin adjustment for exercise is based on glucose level, the delivery method of insulin, site of delivery, timing of dose, duration and type of activity, and timing and amount of carbohydrates consumed.

The recommendations below are only starting guidelines. Glucose levels should be monitored, regularly and the appropriate adjustments for the individual made accordingly.

Adjustments on hybrid closed loop pumps would begin with using an exercise target or equivalent setting and/or reductions in carbohydrate amount entered into the pump, to result in reduced bolus dose, if exercising near mealtime. Evidence is continuously emerging therefore refer to most up to date guidelines and guides for specific systems.

Table 4 in Appendix 1 gives a carb reduction table for reference.

Bolus adjustment for activity lasting	ng at least 30 minutes
---------------------------------------	------------------------

MDI and CSII	If exercise is within 2 hours of last meal	Meal after exercise
Aerobic Exercise	-50% Bolus reduction	- 50% Bolus
		reduction
Mixed Activity	-50% Bolus reduction	-25% Bolus
		reduction
Anaerobic	-25% Bolus reduction	-25% Bolus
		reduction

- Glucose levels should be checked before and during activity to inform timing and quantity of additional carbohydrate ingestion
- Ideally, the exercise would be performed within 90 minutes of the meal if reducing mealtime bolus before exercise
- If meal is consumed more than 2 hours prior to exercise, then normal insulin dose should be given for that meal to prevent hyperglycaemia
- Anaerobic exercise may not require an insulin reduction if it has been associated with a significant rise in blood glucose and may require additional insulin (correction) with caution

Basal Insulin Adjustment

Mode of delivery	Before exercise	After late afternoon/evening exercise
MDI	If prolonged exercise is planned, reduce Glargine/Detemir by up to 20%	Reduce basal insulin Glargine/Detemir by up to 20%
CSII (Aerobic Exercise)	If activity is more than 120 minutes since meal, then commence TBR 90 minutes before and for the duration of exercise and longer dependant on the intensity and duration Reduce BR by 50%	20% basal reduction overnight from bedtime for 6 hours.
CSII (Mixed Exercise)	If activity is more than 120 minutes since meal, then commence TBR 90 minutes before and for the duration of exercise and longer dependant on the intensity and duration Reduce BR by 25%	20% basal reduction overnight from bedtime for 6 hours.
CSII (Anaerobic Exercise)	Normal BR	20% basal reduction overnight from bedtime for 6 hours.

Exercise using CSII if disconnected for contact sports

If safe to do so and if glucose level indicates the need, consider replacing part of the missed basal during activity by reconnecting the pump and bolusing 50% of the missed basal each hour.

7.2 Adjustment of Insulin for high fat and/or high protein meals

Foods containing large amounts of fat and/ or protein can cause delayed or prolonged hyperglycaemia with glucose levels staying high for many hours. Education should be given on which meals this applies to where there is evidence of this occurring.

Evidence is continually emerging in this field, before increasing insulin ensure that advanced bolus features are being utilized, if on insulin pump, in line with most up to date evidence.

Below are some starting suggestions for increasing insulin where required.

Stepwise Dose Adjustment - MDI

• Note: research has been done in insulin aspart (Novorapid[®]) not fast-acting insulin aspart (Fiasp[®])

Increase the insulin dose by 10% of the dose calculated for carbohydrate (please refer to table 3 in the appendices).

If the prolonged hyperglycaemia continues, increase the dose in increments of no more than 10% up to a maximum of 25%.

The adjusted dose of insulin should usually be given before eating. However, if hypoglycaemia occurs 1-2 hours after eating, then try splitting the dose so that the extra units of insulin are given 1 hour after the meal.

Advise patient/carer of the need to monitor the effect on glucose levels in the hours following the meal by reviewing glucose levels 3, 5, and 7 hours after the meal to check whether this has worked. Use these glucose levels to adjust as necessary.

Stepwise Dose Adjustment – CSII (excludes those using Hybrid Closed Loop):

Increase the insulin dose by 20% of the dose calculated for carbohydrate (please refer to table 3 in the appendices).

If the prolonged hyperglycaemia continues, increase the dose in 10% increments up to 40% (table 3 appendices).

Advise patient/ carer of the need to monitor the effect on glucose levels in the hours following the meal at 3, 5, and 7 hours to check whether this has worked. Use these glucose levels to adjust as necessary.

Hybrid Closed Loop Pumps

The above suggestions do not apply to hybrid closed loop pumps. As hybrid closed loop systems are still relatively new, evidence is currently lacking regarding the adjustments for high fat/protein meals. Therefore, an individualized approach, taking into account the particular system's algorithm is required.

8. Follow Up

At least 48 hours should be left between insulin adjustments. Any further adjustments should be made according to glucose patterns.

Verbal advice should also be provided on what to do should the patient have any major/minor reactions:

- When insulin doses are increased there is an increased risk of hypoglycaemia.
- When insulin doses are reduced there is an increased risk of hyperglycaemia.

The patient/carer/parent/person with parental responsibility should be advised on how to contact the team and what to do if they are unable to contact a member of the diabetes team for advice.

Agree appropriate time for reviewing changes +/- MDT. Patient should be reviewed by a prescriber minimally every 3 months.

9. Documenting Changes

Details of all changes carried out by the dietitian to an insulin dose must be documented contemporaneously within the patient record which can be accessed by the paediatric diabetes MDT as per local and national guidance.

Patients/carers/parents/people with parental responsibility are asked to make agreed changes to dose within their glucose monitoring equipment, pump or their appropriate Apps and repeat back changes to the dietitian prior to the end of the consultation to ensure accuracy, this is especially important in virtual consultations (HCPC, 2019). The understanding of their doses should be reviewed at every clinic appointment.

Agree and document an appropriate time for reviewing the changes by downloading the glucose devices according to the device used.

10. References

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11. Appendices

Table 1: Insulin: Carbohydrate Ratio Adjustment Table

Below demonstrates the dose change that would occur alongside an ICR change for different portions of carbs.

	Carbohydrate intake					
ICR	15	30.0	45.0	60.0	75.0	90.0
5	3.00	6.00	9.00	12.00	15.00	18.00
6	2.50	5.00	7.50	10.00	12.50	15.00
7	2.14	4.29	6.43	8.57	10.71	12.86
8	1.88	3.75	5.63	7.50	9.38	11.25
9	1.67	3.33	5.00	6.67	8.33	10.00
10	1.50	3.00	4.50	6.00	7.50	9.00
11	1.36	2.73	4.09	5.45	6.82	8.18
12	1.25	2.50	3.75	5.00	6.25	7.50
13	1.15	2.31	3.46	4.62	5.77	6.92
14	1.07	2.14	3.21	4.29	5.36	6.43
15	1.00	2.00	3.00	4.00	5.00	6.00
16	0.94	1.88	2.81	3.75	4.69	5.63
17	0.88	1.76	2.65	3.53	4.41	5.29
18	0.83	1.67	2.50	3.33	4.17	5.00
19	0.79	1.58	2.37	3.16	3.95	4.74
20	0.75	1.50	2.25	3.00	3.75	4.50
21	0.71	1.43	2.14	2.86	3.57	4.29
22	0.68	1.36	2.05	2.73	3.41	4.09
23	0.65	1.30	1.96	2.61	3.26	3.91
24	0.63	1.25	1.88	2.50	3.13	3.75
25	0.60	1.20	1.80	2.40	3.00	3.60
26	0.58	1.15	1.73	2.31	2.88	3.46
27	0.56	1.11	1.67	2.22	2.78	3.33
28	0.54	1.07	1.61	2.14	2.68	3.21
29	0.52	1.03	1.55	2.07	2.59	3.10
30	0.50	1.00	1.50	2.00	2.50	3.00
35	0.43	0.86	1.29	1.71	2.14	2.57
40	0.38	0.75	1.13	1.50	1.88	2.25
45	0.33	0.67	1.00	1.33	1.67	2.00
50	0.30	0.60	0.90	1.20	1.50	1.80
60	0.25	0.50	0.75	1.00	1.25	1.50
70	0.21	0.43	0.64	0.86	1.07	1.29

Table 2: Insulin Sensitivity Ratio Adjustment

Below demonstrates the dose change that would occur alongside an ISF change for different glucose levels with a target glucose level of 6mmol/l.

ISE	Glucose (mmol/L)							
ISF	10	12.0	14.0	16.0	18.0	20.0	22.0	24.0
1	4.00	6.00	8.00	10.00	12.00	14.00	16.00	18.00
2	2.00	3.00	4.00	5.00	6.00	7.00	8.00	9.00
3	1.33	2.00	2.67	3.33	4.00	4.67	5.33	6.00
4	1.00	1.50	2.00	2.50	3.00	3.50	4.00	4.50
5	0.80	1.20	1.60	2.00	2.40	2.80	3.20	3.60
6	0.67	1.00	1.33	1.67	2.00	2.33	2.67	3.00
7	0.57	0.86	1.14	1.43	1.71	2.00	2.29	2.57
8	0.50	0.75	1.00	1.25	1.50	1.75	2.00	2.25
9	0.44	0.67	0.89	1.11	1.33	1.56	1.78	2.00
10	0.40	0.60	0.80	1.00	1.20	1.40	1.60	1.80
11	0.36	0.55	0.73	0.91	1.09	1.27	1.45	1.64
12	0.33	0.50	0.67	0.83	1.00	1.17	1.33	1.50
13	0.31	0.46	0.62	0.77	0.92	1.08	1.23	1.38
14	0.29	0.43	0.57	0.71	0.86	1.00	1.14	1.29
15	0.27	0.40	0.53	0.67	0.80	0.93	1.07	1.20

Table 3: Table of Carbohydrate Amounts to use for calculating % increase for carbohydrate bolus. This could be used for fat / protein.

Carbohydrates in Meal (g)	10% extra carbohydrates for calculation	20% extra carbohydrates for calculation	30% extra carbohydrates for calculation	40% extra carbohydrates for calculation
15	17	18	20	21
20	22	24	26	28
30	33	36	39	42
40	44	48	52	56
50	55	60	65	70
60	66	72	78	84
70	77	84	91	98
80	88	96	104	112
90	99	108	117	126
100	110	120	130	140

Table 4: Table of carbohydrate amounts for calculating % decrease pre or post exercise

Carbohydrates in Meal (g)	25% carb reduction	50% carb reduction	75% carb reduction
15	11	7.5	4
20	15	10	5
30	22.5	15	7.5
40	30	20	10
50	37.5	25	12.5
60	45	30	15
70	52.5	35	17.5
80	60	40	20
90	67.5	45	22.5
100	75	50	25

12. Glossary

Carb – Carbohydrate SOP – Standard Operating Procedure MMG – Medicines Management Group NMP – Non-Medical Prescriber Apps – Software Applications for iOS and android devices MDT – Multi Disciplinary Team ICR – Insulin to Carbohydrate Ratio ISF – Insulin Sensitivity Factor BR – Basal Rate DSD – Diabetes Specialist Dietitians MDI – Multiple Daily Injections CSII - Continuous Subcutaneous Insulin Infusion TBR – Temporary Basal Rate CGMS – Continuous Glucose Monitoring System BG – Blood Glucose

13. Acknowledgements

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14. Disclaimer

The 'Children and Young People's North West Diabetes Network' is not a statutory body and therefore cannot be held accountable for this generic document or be involved with an individual Trust's consultation and ratification process of the document.

If a Trust decides to use the generic template it must be adapted to ensure that it is 'Trust specific' and follows the Trust's individual consultation and ratification processes.

