



Model of Care for the Provision of Continuous Subcutaneous Insulin Infusion for the treatment of Type 1 Diabetes in the Under Five Age Group

National Paediatric Clinical Programme

National Diabetes Clinical Programme

Clinical Strategy and Programmes Division

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Foreword

In 2011 the National Paediatric and National Diabetes Clinical Programmes, under the supervision of Dr Barry White, National Lead of the HSE Clinical Strategy and Programmes Directorate, established a subgroup to examine the delivery of diabetes care in Ireland to all children under 16 years of age. From an early stage it became clear to the subgroup that there are significant deficits in clinical personnel and resource in the field of paediatric diabetes in Ireland. At the same time it also became clear to the group that due to the dire financial situation of the country any new resource in paediatric diabetes had to be delivered as cost neutral as possible.

In 2010 the HSE started a procurement process in relation to CSII therapy. This process led to a reduction in the price of CSII pumps and their consumables and a limited cost saving to the health service. The National Paediatric and Diabetes Clinical Programmes identified this cost saving and developed a business case to use this cost saving to develop new CSII centres across the country, to increase the clinical personnel in existing CSII centres and to develop a national model of care for children with type 1 diabetes under five years of age so that all clinically appropriate children under five years in Ireland will be offered CSII therapy.

The business case was developed, submitted to the Clinical Strategy and Programmes Directorate for inclusion in the 2012 HSE National Service Plan. The business case was approved by the Clinical Strategy and Programmes Directorate in the HSE and Department of Health and is a line item in the National Service Plan for 2012.

In early 2012 Dr Barry White nominated a 'National Clinical Lead in Paediatric Diabetes', Dr Stephen O'Riordan, with a new Programme Manager, Grace Turner, to implement the project. This was also supported by Dr Diarmuid Smith and Ms Mairead Gleeson, Clinical Lead and Programme Manager for the Diabetes National Clinical Programme and Prof Alf Nicholson National Paediatric Clinical Lead. Since this date, Dr Ronan Canavan and Ms Marie Tighe have taken up their roles as clinical lead and programme manager in the National Clinical Programme for Diabetes and continue to support this initiative.

The aim of the project is to improve access to CSII in the under five age group. This was Phase 1, i.e. the first step in a stepwise progression of the evolution of a National Paediatric Diabetes Model of Care. The timeline for implementation of Phase 1 was 2014. The additional 4.2 posts that had been requested to implement Phase 1 have been in place since early 2014. These staffing levels were essential to establish the first five pump centres. Additional staffing has been secured through the 2015 national service plan to allow these pump centres to continue to grow and meet patient needs.

1.0 Executive Summary

The National Institute for Health and Clinical Excellence (NICE) Guidelines (2008) state that “insulin pump therapy should be recommended for children younger than 12 years with type 1 diabetes as a treatment where clinically appropriate”. This model of care has been developed in order to provide this service to children with type 1 diabetes under five years old (<5.99years old).

The key objectives in this model of care are to:

- Provide CSII therapy to children under five, where appropriate.
- Ensure that diabetes services and staffing levels are equitable in the pump centres nationwide
- Reduce acute and chronic complications of type 1 diabetes
- Improve the quality of life of children and their families living with diabetes

This Model of Care is focused **ONLY** on the provision of Continuous Subcutaneous Insulin Infusion (CSII) for the Treatment of Type 1 Diabetes in **children under five years of age**.

KEY POINTS IN THIS MODEL OF CARE (MOC) INCLUDE:

1. Continuous Subcutaneous Insulin Infusion (pump therapy) should be the primary treatment option in children with type 1 diabetes
2. That patients attend a pump centre led by a Consultant Paediatric Endocrinologist (Consultant Paediatrician with a special interest in diabetes) on a quarterly basis for diabetes control and stabilisation (more frequently if necessary)
3. A pump centre is defined as a hospital which treats ≥ 150 children with type 1 diabetes and is staffed with a Paediatric Endocrinologist, a Paediatric Diabetes Nurse Specialist, and a Dietitian as a minimum.
4. The newly developed national guidelines for the management of type 1 diabetes in the under five age group are adapted from the ISPAD and BSPED guidelines.
5. Children under five years of age at diagnosis **MAY** be referred to one of the designated pump centres for assessment of suitability for CSII therapy. An initial period of multiple dose injection (MDI) education is vital so that all families have a fall-back strategy in the event of pump malfunction.
6. Patients and their carers must be assessed for suitability for CSII therapy using the Kaufman Competency Scale (an objective assessment tool)
7. In some instances patients and families may not be suitable for CSII therapy.
8. Patients not deemed suitable and wishing to use CSII therapy must have the negating factors identified so that they can work towards the required standard.
9. Patients undergoing CSII therapy will remain under the care of the pump centre while the therapy is being established. This period of time will be assessed on a case by case basis; however 6 to 12 months is suggested to consolidate the education and CSII initiation prior to transfer back to a local hospital. In some cases patients may remain under the care of the pump centre or shared care between the local and regional centre may be considered.

10. Patients / carers are to receive appropriate diabetes and nutrition education in the regional centres. This may be in the form of a structured education programme and will vary from centre to centre. Carbohydrate counting education must be established in the pump centres as often a specialist dietitian is not available at the local hospital.
11. The established patients receiving CSII therapy under five years may be transferred to a more accessible pump centre. This will also be done on a phased basis (over 6-12months) in agreement between the two centres. For example, a patient currently cared for by a Dublin hospital would be transferred to Cork as it is now a pump centre.

2.0 Background

This document reflects the proposed model of care for paediatric diabetes care in Ireland with respect to children under five years with type 1 diabetes. The aim of this model is to improve diabetes care for children with type 1 diabetes 5 years of age and under, and to ensure that all clinically appropriate children with type 1 diabetes in this age group are offered continuous subcutaneous insulin infusion (CSII), which is recognised as the “gold standard” diabetes treatment in this age group. The document is based on previous documents such as the EAG pump subgroup report and the 2011 business case submission for Continuous Subcutaneous Insulin Infusion (CSII) usage in younger children with diabetes.

2.1 Definition of Age

This Model of Care is focused solely on the provision of CSII for the **treatment of Type 1 Diabetes in children under five years of age**. This is defined as an age of 0 to 5.99years.

2.2 Purpose of the Model of Care

The aim of the project is to improve access to CSII in the under five age group.

Type 1 diabetes is one of the most common chronic diseases in childhood. It is an auto-immune condition resulting in destruction of insulin-producing pancreatic beta cells and absolute insulin deficiency. Treatment is with insulin given subcutaneously, either as multiple injections given up to 5 times a day, or via a pump which delivers a constant infusion of insulin.

There are unique challenges in replacing the insulin deficiency in younger children. These include the differences in the size of the patients, the unpredictability of a toddler's daily intake and activity level, oppositional food behaviour, the increased vulnerability of the developing brain to low blood glucose levels, and the risk of more rapid development of DKA where glycaemic control is poor. All of these issues lead to increased inpatient stays and require intensive use of health resources. An additional challenge in paediatric type 1 diabetes management is the need to provide diabetes education to the many adults who care for children, such as parents, grandparents, childcare staff, and teachers.

These considerations led the Diabetes Expert Advisory Group (EAG) subgroup to recommend that Continuous Subcutaneous Insulin Infusion (pump therapy) should be the primary treatment option in children, especially those aged less than five years, even without a prior trial of multiple daily insulin injections¹.

It is estimated that there are approximately 3,000 children with Type 1 diabetes in Ireland, of whom 180 are aged less than five years of age² with 50 new cases in this age group diagnosed each year³. The prevalence of type 1 diabetes in young children is increasing with worldwide incidence rising by about 3.9% per year⁴.

CSII therapy uses rapid acting insulin only. The pump device releases insulin in two formats: basal and bolus insulin. A continuous supply of background (basal) insulin is delivered using a variable hourly rate across the 24hour period through a subcutaneous cannula. This is supplemented with bolus insulin through the same cannula at mealtimes. This pattern of delivery of insulin more closely mimics the normal physiology of the pancreas and results in more predictable insulin absorption and more stable blood glucose control than conventional injections. With good management and support, this can result in less blood glucose variability, less admissions for high blood glucose (hyperglycaemia) and low blood glucose (hypoglycaemia), a reduction in average blood glucose and

¹ Diabetes EAG Subgroup: Report on Provision of Continuous Subcutaneous Insulin Infusion (CSII) for the Treatment of Type 1 Diabetes Mellitus. Unpublished HSE document.

² Dr Edna Roche, April 2011, cited in DEAG subgroup report.

³ Dr. Edna Roche, November 2011, oral presentation, Paediatric Diabetes Study Day, Crowne Plaza Hotel Dublin.

⁴ Patterson et al Lancet 2009;373:2027-33

HbA1c (with reduced risk of chronic complications), greater flexibility, an improvement in the quality of life⁵ and better parental satisfaction⁶.

The development of chronic complications in diabetes is clearly related to the duration of diabetes and blood glucose control. Children with early onset diabetes are more likely to develop long-term complications. An Irish study of 129 people with onset of type 1 diabetes before the age of 10 years found that, at an average follow up of 28.3 years, 52.7% had established complications with a mean time to the onset of complications of 21.7 years from diagnosis (i.e. at 28 years of age). In addition, the average blood glucose control over months, measured by Glycosylated Haemoglobin or HbA1c, was related to the development of diabetes complications, with the time to onset of first complication being 17 years later in those with a mean HbA1c of less than 8% compared with those whose mean HbA1c was greater than 10%⁷. This emphasises the need to reduce average blood glucose, optimise glycaemic control, in those with early onset (<5years) of diabetes in childhood.

Tight blood glucose control is difficult to achieve in young children using conventional insulin injections without the risk of severe hypoglycaemia. Major concerns exist over the effect of recurrent hypoglycaemia on the developing brain. Research has shown that blood glucose and severe hypoglycaemic episodes can be reduced in this age group with pump therapy⁸. Irish studies in established tertiary pump centres support this finding in older children, e.g. Children's University Hospital⁹ and Our Lady's Hospital for Sick Children¹⁰.

Pump therapy allows the delivery of very much lower quantities of insulin more accurately than injections in keeping with the small body mass and increased insulin sensitivity of young children. In addition CSII therapy is an ideal modality of insulin delivery to cope with the highly variable eating (food refusal) and exercise patterns of young children.

In summary as stated by the DEAG subgroup, there are a number of compelling advantages to the use of insulin pump therapy in young children. These include:

- unpredictable exercise and eating patterns
- inability to recognise, articulate and deal with hypoglycaemia
- the impact of hypoglycaemia on the developing brain
- the necessity to optimise control in view of the likely prolonged disease duration in the very young and the ensuing high risk of complications
- improved quality of life of the children and their families.

As a consequence, the National Paediatric Diabetes Working Group has developed this national model of care for the Provision of CSII for the Treatment of Type 1 Diabetes in the under 5 age group.

⁵ Cummins E, Royle P, Snaith A, et al. (2010). Clinical effectiveness and cost-effectiveness of continuous subcutaneous insulin infusion for diabetes: systematic review and economic evaluation. *Health Technology Assessment*, 14 (11): iii-iv, xi-xvi, 1-181.

⁶ Churchill JN, Ruppe RL, Smaldone A. (2009). Use of continuous insulin infusion pumps in young children with type 1 diabetes: a systematic review. *Journal of Paediatric Health Care*, 23(3): 173-9.

⁷ Gallagher EJ, Kinsley BT, Keenan P, Gayer L, Vizzard N, Forde R, Loughnane T, Connolly C, Firth RG. (2006). Diabetes control and time to onset of complications in subjects with type 1 diabetes diagnosed under the age of 10. Presented at the 66th Scientific Session of the American Diabetes Association, Washington DC, June 2006.

⁸ Weinzimer SA, Ahern JH, Doyle EA, et al. (2004). Persistence of benefits of continuous subcutaneous insulin infusion in very young children with type 1 diabetes: a follow-up report. *Pediatrics*, 114 (6): 1601-5.

⁹ Onwuneme C, Devenney D, Corcoran F, McDonnell C, Murphy N. (2009). Ongoing benefit of CSII in the improvement of HbA1c and BMI in a cohort of children with type 1 diabetes. Presented at the British Society for Paediatric Endocrinology and Diabetes, Reading UK Nov 2009.

¹⁰ Hughes CR, McDowell N, Cody D, Costigan C. (2012). Sustained benefits of continuous subcutaneous insulin infusion. *Archives of Disease in Childhood*, www. Arch Dis Child 2012;97:245-247 doi:10.1136/adc.2010.186080 – Accessed April 10th 2012.

2.3 Multidisciplinary Team Member Involvement

Paediatric diabetes care involves a wide range of professional groups from the primary care GP, public health nurses, ambulance services, accident and emergency staff, paediatric consultants, specialist registrars, psychologists, ward and specialist nurses, dietitians, social workers, hospital catering staff and pharmacists.

In caring for children with diabetes, professionals need to understand the importance of involving the extended family unit in the child's diabetes management. Young children are unable to provide their own diabetes care, therefore, education about how to care for a child with diabetes must be provided to the entire family unit, emphasising age- and developmentally appropriate self-care and integrating this into the child's diabetes management^{11,12,13}. Management is a partnership with the child, extended family, and the multidisciplinary team. It is recognised that structured education in the early period following diagnosis is particularly critical in improving both quality of life and clinical outcomes¹⁴. In addition it is vital to provide ongoing education to the child and family as they advance with their intensive diabetes care towards CSII therapy.

The Paediatric Endocrinologist, Diabetes Nurse and Dietitian deliver most of the diabetes education required, individually and together. Due to inconsistencies in information which can be confusing to a distraught family, education should be provided to all caregivers simultaneously in a clear and structured fashion. National guidelines have recently been developed by the Paediatric Diabetes Working Group to ensure consensus in management of paediatric diabetes at diagnosis nationwide. These guidelines are shortened and more practical versions of the longer ISPAD guidelines; however all are web-linked to the full versions and can therefore be accessed on the HSE and RCPI website. The group has maintained the full version of the BSPED DKA Guideline as this is associated with high morbidity/mortality and therefore any shortening of this guideline may reduce its comprehensive safety features.

Type 1 diabetes in the under fives is complex in nature and very different to the management of type 1 diabetes in adults. The Paediatric Diabetes Working Group recommends that the day to day management and sick-day management of these children be under the direction of a Consultant Paediatric Endocrinologist including a multidisciplinary team with paediatric diabetes nurse and specialised dietitian.

¹¹ Psychosocial factors are associated with metabolic control in adolescents: research from the Hvidoere Study Group on Childhood Diabetes. Hilary Hoey *Pediatr Diabetes*. 2009 Dec;10 Suppl 13:9-14.

¹² Good Metabolic Control Is Associated With Better Quality of Life in 2, 101 Adolescents With Type 1 Diabetes. *Diabetes Care* 2001; 24: 1923-1928

Hoey H, Aanstoot HJ, Chiarelli F, Daneman D, Danne T, Dorchy H, Fitzgerald M, Garandeanu P, Greene S, Holl R, Hougaard P, Kaprio E, Kocova M, Lynggaard H, Martul P, Matsuura N, McGee HM, Mortensen HB, Robertson K, Schoenle E, Sovik O, Swift P, Tsou RM, Vanelli M, Aman J, Hvidøre Study Group on Childhood Diabetes.

¹³ Quality of Life in 1043 Young Children with Diabetes: A new Smiley Faces International QOL Assessment Tool. H.Hoey, K.Lange, C de Beaufort et al *Ped Diabetes* 2011, Suppl 15, 88-89

¹⁴ The Best Practice Guidelines for the Management of Type 1 Diabetes in Children and Adolescents. www.health.qld.gov.au/publications Accessed 10th April 2012

3.0 Model of Care

3.1 Key Objectives

This paediatric diabetes MOC for the under fives relies on a partnership approach to deliver a quality diabetes service to all children with diabetes nationwide.

The key objectives are to:

- Provide CSII therapy to under fives where appropriate.
- Ensure that the diabetes services and staffing levels are equitable in the pump centres and nationwide
- Reduce acute and chronic complications of type 1 diabetes
- Improve the quality of life of children and their families living with diabetes

This Model of Care is focused solely on the Provision of CSII for the Treatment of Type 1 Diabetes in **children under five years of age**.

3.2 Diagnosis of Type 1 Diabetes

The diagnosis of Type 1 diabetes in children is clearly defined by the WHO, ADA and ISPAD. The majority of children newly diagnosed with type 1 diabetes present with a several-week history of progressive symptoms (polyuria, polydipsia, polyphagia, weight loss). However, others may present with acute hyperglycaemia and, if ketones are present, the life-threatening condition of diabetic ketoacidosis (DKA), the situation is a medical emergency and requires immediate management¹⁵.

Untreated type 1 diabetes can result in rapid clinical deterioration with increased morbidity (DKA) and mortality. Therefore, unnecessary delays in the diagnosis must be avoided with immediate commencement of insulin therapy. Concomitant education should be initiated immediately to aid family coping and to equip the child and family with the knowledge and skills necessary for self-management after initial treatment. The diagnosis of type 1 diabetes has a profound effect on the entire family unit and referral to appropriate support mechanisms are essential to facilitate adaptive coping.

In Ireland 25% of children with newly diagnosed type 1 diabetes present in moderate/severe DKA and 66% of those under two years presented in moderate/severe DKA¹⁶. When type 1 diabetes patients are admitted acutely ill with DKA, immediate treatment in accordance with DKA guidelines should be commenced (See Appendix 2.0). The incidence of DKA at presentation is higher in the under five age group as the symptoms of diabetes are more subtle and more difficult to detect in small children.

Those presenting with type 1 diabetes who are not acutely ill still require hospitalisation for medical management as the family support and self-management education required is intensive. When diabetes is diagnosed in a child, the parents must cope with the diagnosis of a chronic illness and learn the myriad skills of daily diabetes management – injections, blood testing, balancing food/medication/exercise and recognising when imbalance causes low and high blood glucose levels and their subsequent effects. Younger children do not exhibit the classic signs of low blood glucose and are unable to communicate sensations associated with being unwell; thus, the risk of severe hypoglycemia, with seizures or coma, is higher. Parents often suffer extreme anxiety related to the perceived vulnerability of their child to devastating diabetes-related problems such as seizures,

¹⁶ Roche EF, Menton A, Gill D, Hoey H. (2005) Clinical presentation of type 1 diabetes. Paediatric Diab 2005;6(2):75-8

neurocognitive damage, or death¹⁷. Parents struggle with trying to balance their child's risk of long-term complications versus a significant fear of severe low blood glucose and their immediate consequences¹⁸. Thus, parents of younger children need the support of a diabetes team that understands the difficulties of dealing with diabetes in the young and is able to provide emotional support to manage their concerns.

Once the initial hyperglycaemia is treated, children are started on an individualised insulin regimen, which may be two, three or four injections of insulin daily based on the needs of the child and capabilities of the family.

As type 1 diabetes is a chronic, lifelong illness it is important that children be cared for at specialised paediatric centres led by the Consultant Paediatric Endocrinologist and multidisciplinary team rather than at primary care level. The average GP will have only a handful of children with diabetes in the practice; however as primary physician to the family, the GP will be actively included in the child's care. Normal childhood illnesses will affect the blood glucose control of children with diabetes. Thus primary care physicians must have some knowledge of children's diabetes. However it is crucial to identify that all diabetes-related care for children with type 1 diabetes remains the remit of the paediatric diabetes hospital multi-disciplinary team.

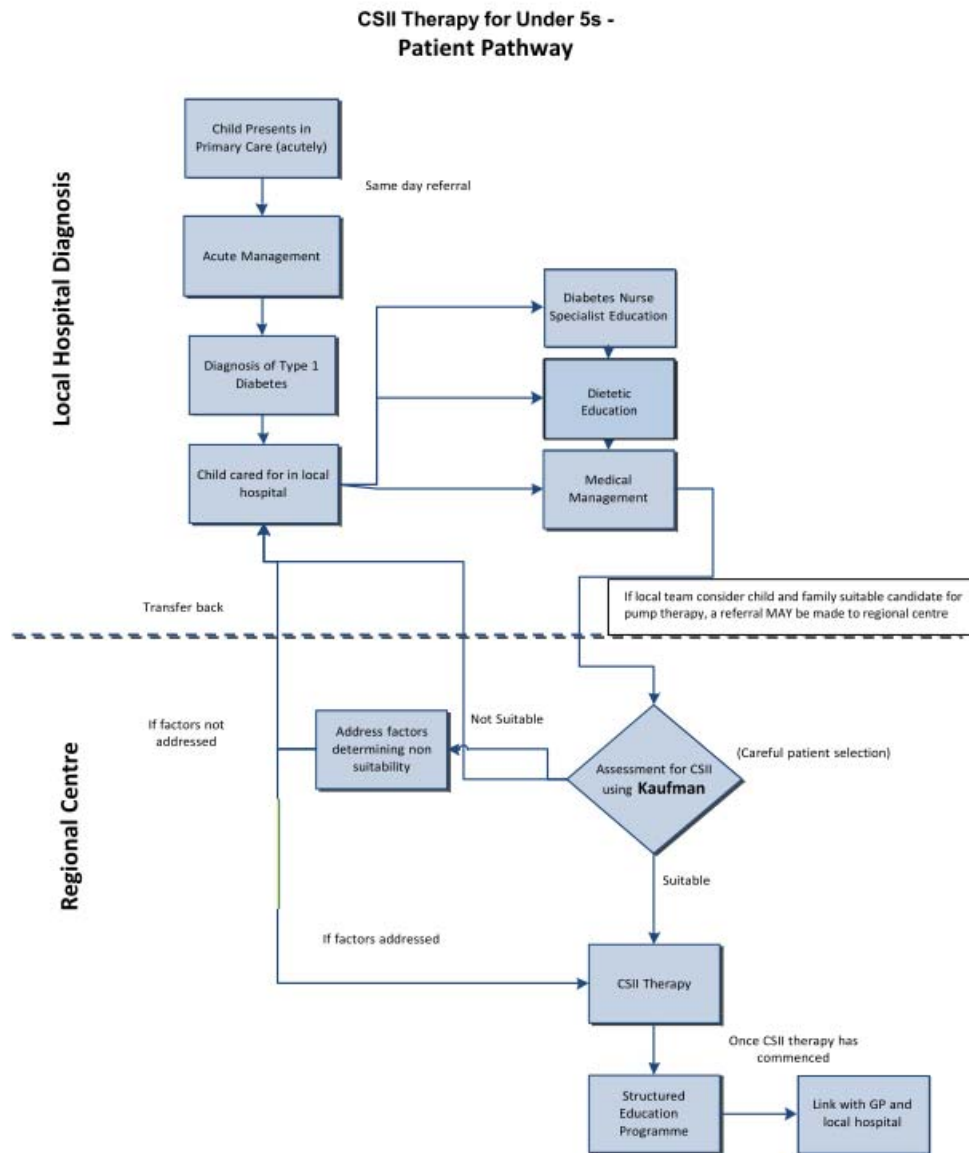
3.3 Care Pathway for Children diagnosed with Type 1 diabetes.

The integrated model of care pathway for the management of type 1 diabetes starts at the point of diagnosis of diabetes and continues indefinitely. It must be flexible to respond to the needs of the patient as the child develops and ages. The key feature being access to the appropriate healthcare professional at a frequency appropriate to the patients needs. It is hoped that this will make the overall service more patient-focused and efficient. See Figure 1 below.

¹⁷ Eugster E,E. & Francis G, Children With Type 1 Diabetes Position Statement: Continuous Subcutaneous Insulin Infusion in Very Young, *Pediatrics* 2006;118:e1244, <http://pediatrics.aappublications.org/content/118/4/e1244.full.pdf> accessed April 11th 2012

¹⁸ Vandagriff JL, Marrero DG, Ingersoll GM, Fineberg NS. Parents of children with diabetes: what are they worried about? *Diabetes Educ.* 1992;18:299–302, Ref Roche et al, *Paediatr Diab* 2005;6(2):75-8.

Figure 1 Pump Patient Pathway for Children under 5 years of age diagnosed with type 1 diabetes



The Model of Care for the management of type 1 diabetes in the under five age group is adapted from the ISPAD and BSPED guidelines¹⁹. The national model of care is for use by all health care professionals involved in the care of children with type 1 diabetes, primary care physicians, accident and emergency professionals, consultants, registrars, paediatric diabetes nurse specialists, diabetes nurses, general ward nurses and dietitians.

Initial diagnosis of type 1 diabetes may occur in any of the 19 acute hospitals providing diabetes care for children in Ireland²⁰. Children under five years of age at diagnosis may be referred to one of the designated pump centres for assessment of suitability for CSII therapy. In local hospital basic dietary

¹⁹ ISPAD guidelines. <http://www.ispad.org/FileCenter.html?CategoryID=5>

²⁰ Savage T, Clarke A, Costigan C, Loftus G, Cody D. (2008) Services for children with diabetes. Ir Med J. 2008 Jan;101(1):15-7.

education will be commenced; however specialist dietetic support may not be available and therefore carbohydrate counting may have to be initiated in the pump centre. Engagement between the local and specialist centre should be promoted. Once assessed, initiation of CSII therapy can proceed if the child and family are indeed found to be suitable.

It is agreed through this MOC that any child deemed suitable for assessment by the local centre **MAY** be referred to a pump centre, however not every child under 5.99 years needs to be referred for pump therapy and this must be individually determined by the local clinician and diabetes team. If referred to a pump centre, children should be managed in the following way:

- Attend a Paediatric Endocrinologist on a quarterly basis for diabetes control and stabilisation (more frequently if necessary)
- Attend a diabetes centre treating ≥ 150 children with type 1 diabetes
- Attend a centre staffed with a Paediatric Diabetes Nurse Specialist, a Dietitian and psychosocial support as the minimum.
- Undergo assessment for suitability for CSII (Appendix 1.1)
 - If suitable, CSII will be offered.
 - If not, the factors dictating non-suitability will be discussed. Targets and issues will be identified and attempted to be addressed over a 6-12month period. If the child and family do not attain these targets then it is important to clearly address this and determine that CSII may not be suitable for this family.

3.4 Initiation of CSII in young Children

In all children, the management of type 1 diabetes is difficult, in part due to the interplay between growth and nutrition. Type 1 diabetes can be particularly difficult to manage in very young children because of their small physical size, unpredictability of behaviour and immature communication. Specifically, these factors result in increased risk of dangerous low blood glucose levels and high blood glucose levels.

Insulin pump therapy can be initiated at time of diagnosis however most pump centres will start with subcutaneous injections and education so that the family have the skills associated with multiple daily injections to fall back on if the pump dysfunctions.

3.5 Benefits of Insulin Pump Therapy

It is well established that CSII therapy has a number of advantages over MDI in the care of young children with Type 1 diabetes, particularly in children less than 5 years of age. The advantages include:

- CSII therapy is associated with reduced frequency of daytime and nocturnal hypoglycaemia and so will increase the ability of the child and their family to recognise, deal with and treat hypoglycaemia appropriately.
- There is a concern over the impact of hypoglycaemia on the developing brain, on cognitive function and an increased risk of seizures in young children. Reducing the risk of hypoglycaemia by CSII therapy may protect the developing brain from these dangers in young children.
- Improvement in glycated haemoglobin (HbA1c).
- Reduced daily glycaemic excursions.
- Smoother blood glucose profiles at times of unpredictable exercise and eating patterns.
- Ability to deliver insulin through a pump rather than the need for an injection during pre-school or school hours.
- The necessity to optimise glucose control in view of the likely prolonged disease duration in the very young and the ensuing high risk of diabetes related complications.
- The favourable impact on the quality of life of the children and their families.

- Because of these advantages and the flexibility of CSII therapy for both the child and their families the National Institute for Health and Clinical Excellence NICE Guidelines (2008) state that “CSII therapy should be recommended for children younger than 12 years with Type 1 diabetes as a treatment where clinically appropriate”.

Therefore, CSII is the preferred method of insulin administration in this age group, where appropriate.

3.6 Selection Criteria for CSII Therapy

Careful child and family selection is essential for safe and successful CSII therapy. The Kaufman Competency Scale²¹ is an objective tool that is recommended for this purpose.

If the child and family reach a competence level of ≥ 5 out of 8, then they are considered competent to start CSII therapy (Appendix 1.0). The Kaufman Scale is a useful tool to demonstrate to the family their level of readiness for CSII therapy and to provide a targeted approach to work towards their goals.

Any child under five years of age with type 1 diabetes not meeting these criteria should be supported to achieve them. CSII therapy should only be considered when children and families meet these criteria.

Baseline selection criteria for CSII in children should include having motivated parents with good adherence with diabetes care and demonstrated ability to carbohydrate count. In the absence of these, appropriate support should be given to identify issues that need to be addressed prior to referral.

In order to benefit from CSII, patients and families must demonstrate that they are willing to:

- Attend the diabetes clinic on a quarterly basis, and more frequently, if requested by the diabetes multidisciplinary team.
- Demonstrate good diabetes management skills (glucose monitoring, insulin adjustment, problem solving).
- Be prepared to do home blood glucose monitoring 5 to 7 times daily.
- Be willing to attend education sessions on the skills necessary to undertake CSII as a therapy and must be assessed as being competent.
- Be assessed as competent in carbohydrate counting.
- Avail of psychosocial support to explore their expectations of pump therapy and identify issues that may need to be addressed prior to pump initiation.
- Maintain close contact with the diabetes team following initiation of pump therapy, particularly in the early stages and follow up appropriately.

²¹ Kaufman F, (2001) Insulin therapy in young children. Diabetes Spectrum Volume 14, Number 2, 2001, 84-89.

3.7 How CSII will be delivered

The provision of CSII therapy should be in accordance with the ISPAD and BSPED guidelines. The patient care should be from a multidisciplinary team, led by a Consultant Paediatric Endocrinologist in a pump centre.

These steps may include:

- Patient is discussed at MDT
- Once suitability is determined, families are required to demonstrate that they are competent and adherent in their diabetes care (Kaufman Scale and NICE guidelines) over 4 to 6 months
- If competent, patient and family attend a structured pump education programme, i.e. Pump School (see section 4)
- On completion of the pump education programme, parents are asked to sign a 'competency training checklist' to confirm that they have been trained and are happy with the instruction received.
- Patient has a pump trial
- At this time pump should be ordered
- Pump school (PS) with MDT approach
- Suggest contact with Diabetes MDT and intensive supervision as follows:
 - BG 2-4 hourly for the first 48 hours
 - Daily phone contact by the MDT over the first week and weekend (local arrangements, if possible)
 - Pump clinic (or as per local arrangements) appointment within 1-2 week from pump school
 - Pump clinic (or as per local arrangements) appointment within 6 weeks from pump school
 - Routine follow up 3 months in dedicated pump clinic (or as per local arrangements) (See Figure 2. Pump School)
- This is an intensive process and stresses the additional workload this generates for the Diabetes MDT but specifically for the Paediatric DNS.
- Rarely pump failure occurs and pump withdrawal may be necessary. If this is the case, patients return to MDI and routine follow up in the diabetes clinic and the CSII pump will be made available for another child in that region.

3.8 Specific requirements for the under fives

Category 1. Routine Care (70% of under 5s)

The majority of children (70%) under 5years can be commenced on a CSII with a low basal rate 0.025iu/hr and without sensor capability i.e. Continuous Glucose Monitoring (CGM).

Some features specific to CSII therapy in the under 5 age group are listed below:

Programmable features:

- Multiple basal programmes:
 - Starting basal rate of 0.025iu/hour
 - Adjustable in 0.025 increments
- The Pump must have temporary basal option.
- Extended bolus options
- Insulin bolus calculator including adjustable:
 - Carbohydrate Ratios
 - Insulin Sensitivity Factor (ISF)
 - Active insulin time
- Carbohydrate ratios changing in 0.1iu increments from 0-10iu
- The pump must have programmable features, e.g. alerts and reminders

Safety features including:

- Child block or lock key pad
- Internal safety check system
- A fail/safe function
- Maximum basal and bolus feature
- A lock out function to prevent overdosing
- A feature to measure or detect leaks of insulin
- Remote control option

Needle size and infusion set length:

- The under 5s require the smallest infusion set with 27/28 gauge needle inserted at 45 to 90 degree angle. A Teflon catheter with depths of 6 and 8mm and the infusion pump tubing should be short and range between 45 and 60 cm in length.

Category 2. High Risk Care (30% of under 5s)

In exceptional cases (those at high risk*), children in this age group may require a Sensor Augmented Pump (SAP) with CGM facility and this will be done on a case by case basis. This will be at the discretion of The Paediatric Endocrinologist in each Pump Centre. The criteria where a SAP will be considered include the following clinical scenarios:

- Hypoglycaemic unawareness*
- Hypoglycaemic seizures*
- Multiple DKA* and/or hypoglycaemic admissions compromising diabetes care in the home, crèche and nursery environment.

4.0 Patient / Family Education

When a patient is referred to a centre for CSII therapy, the centre will assess the suitability of the patient / family and undertake the necessary education, described below.

4.1 Diabetes Education

Self-management of diabetes is the ultimate goal for all patients with diabetes. In order to do this, the carers of a young child need to be able to balance insulin replacement with dietary intake and exercise levels in order to maintain blood glucose control and prevent/recognise the occurrence of complications. The success of self-management is measured by blood glucose testing and the incidence of acute and chronic complications.

Education is essential at diagnosis. Each centre providing CSII therapy must establish a structured education programme. The family must be given basic survival education, including;

- What is diabetes?
- The role of insulin and delivery methods, administration and storage/disposal.
- Diabetes and food – relation of food to blood glucose levels
- Diabetes and exercise
- Blood glucose monitoring – targets, technique and actions based on results
 - Low blood glucose management
 - High blood glucose management
- Who and how to access help

- Support and Entitlements for daily living with diabetes

Once basic skills are mastered, a more intensive educational programme can be initiated based on the families stage of engagement, including;

- Causes, symptoms, treatment, prevention of hypoglycaemia, glucagon/glucogel administration
- Causes, symptoms, treatment, prevention of hyperglycaemia- DKA and sick day management
- HbA1c – what it is, relationship to Home blood glucose monitoring (HBGM) and benefits of attaining target levels
- Exercise – how to manage/insulin adjustment/practical tips and importance of regular activity
- How to manage diabetes in crèche/school/holidays
- Long term complications – what they are and how to avoid their development
- Injection sites
- The diabetes team roles
- Regular review – importance and necessity of attending
- Recognising patterns through review of food intake, blood glucose levels, insulin dosage and activity
- Adjusting insulin dosage to meet targets

4.2 Nutrition Education

Dietetic education can help people to balance and adjust their food choices according to their activity and insulin levels, avoid and treat high blood glucoses and low blood glucoses and adjust meal patterns when feeling unwell.

Initially the education (local hospital) given should focus on recognising food types and how they influence blood glucose levels. Topics should include;

- Healthy eating and food groups
- Effects of different food groups on blood glucose levels
- Carbohydrate sources and tools to calculate carbohydrate content per serving
- Options for meals, snacks and drinks.

Once basic skills are mastered, a more intensive educational programme (pump centre) should be initiated based on the families stage of engagement including;

- Reading food labels and quantifying carbohydrates accurately
- Measuring accurately carbohydrates in food portion sizes by using weighing scales
- Carbohydrate adjustment when exercising or eating out
- Fats and their effect on absorption
- Estimating carbohydrates in recipes and complex meals
- Insulin /Carbohydrate ratio and correction doses.

Competence in carbohydrate counting needs to be assessed (Kaufman) before progressing to a structured education programme for starting CSII.

Below is a sample structured education programme (Pump School):

Suggested CSII Therapy Structured Education Programme

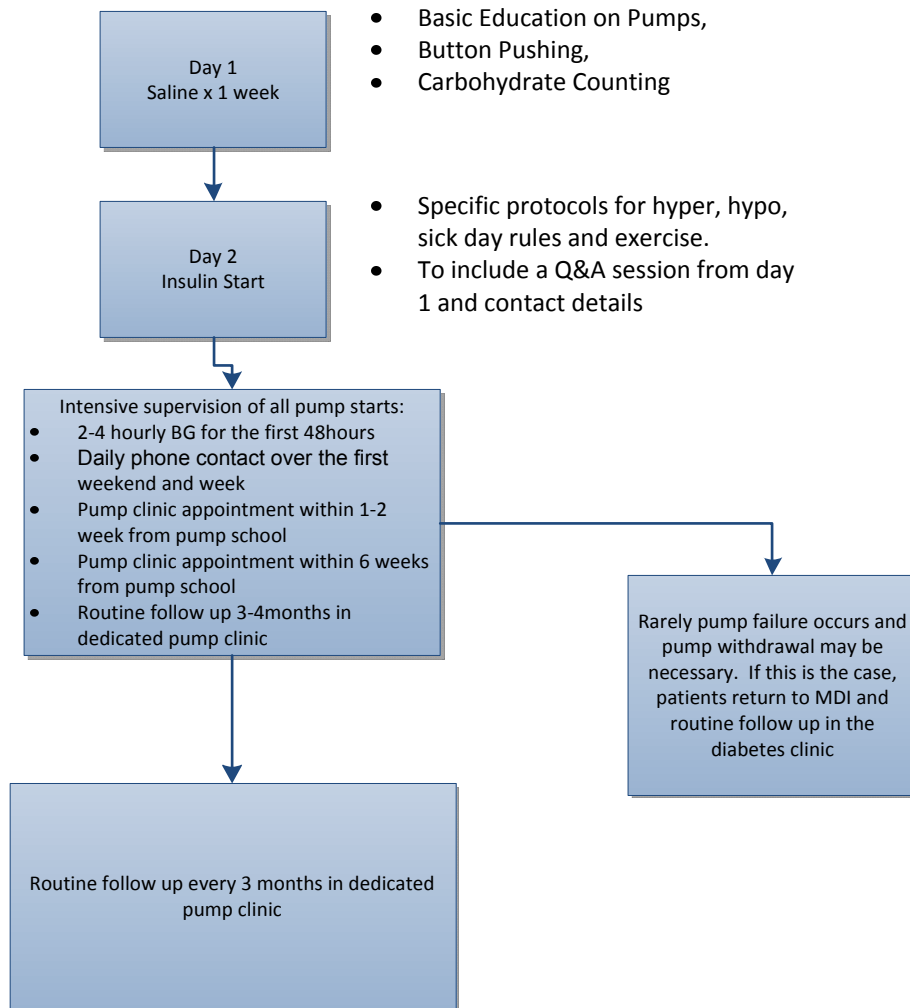


Figure 2. A Structured Education Programme i.e. an example of ‘Pump School’

Each pump centre will deliver a structured educational programme in line with local arrangements and staffing capabilities. In this age group, a pump trial with or without saline is recommended to ensure that the child is happy to be attached to the pump continuously.

Play specialist, elder siblings and extended relatives may be invited to this structured educational programme to engage the under fives and keep them occupied during the educational sessions.

4.3 GP / Community Education

It is the responsibility of each pump centre to provide GP, community and parent support group education days and update sessions on insulin pump therapy during the year. This will be scheduled as per local arrangements based on staff and time available. However these educational sessions are important and we recommend they should be run twice yearly as a minimum. These sessions should also be used as an opportunity to seek feedback from the community, GPs and parents.

5.0 The Team Providing CSII Therapy

The paediatric diabetes team providing CSII therapy consists of:

- A Paediatric Endocrinologist, trained in diabetes
- Paediatric diabetes nurse specialists
- Dietitian
- Psychosocial support (if available)

Diabetes Nurse Specialist:

The Paediatric Diabetes Nurse is the core of the pump service. The DNS role includes identification, selection and initiation of pump therapy through the structured pathway above. The DNS learns and delivers a structured education programme for the under fives and includes work on quality of life assessment. The DNS enhances education and a child friendly approach through play in this young age group.

Dietitian:

The Dietitian is pivotal to the service provided and the pump and insulin regimen are only as good as the carbohydrate counting and the educator who delivers the same. The Dietitian is essential for the success of the structured education.

Consultant Paediatric Endocrinologist:

The Consultant Paediatric Endocrinologist leads the team in careful patient and family selection using the Kaufman scale. He / she participates in education and the delivery of 'Pump School' following centre specifics. The consultant follows up and reviews all children and their families in a dedicated pump clinic with the MDT (according to local arrangements). He / she coordinates data collection and database entry at regular intervals. This valuable information can be used, shared and entered into the National Paediatric Diabetes Register for ongoing development of services and analysis.

6.0 Locations for CSII Treatment – Pump Centres

A paediatric diabetes centre is considered a pump centre to provide insulin pump therapy to children under five if the following are in place:

- A Paediatric Endocrinologist, trained in diabetes
- A minimum of 150 children with type 1 diabetes attend that centre
- Staffed by appropriate support services, paediatric diabetes nurse specialists, clinical nutritionist / dietitian and psychosocial support

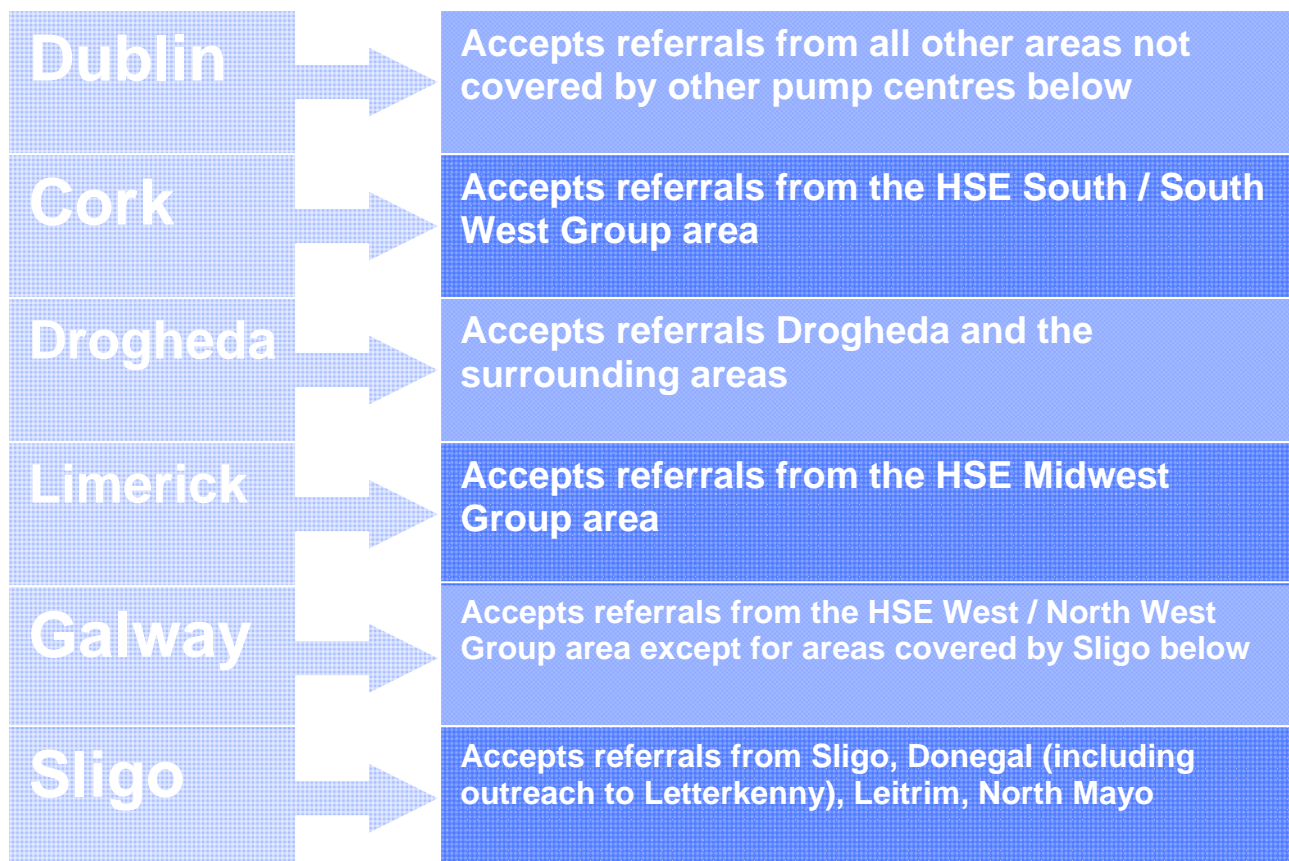
The model of care is provided in the following centres;

- Adelaide & Meath Hospitals, incorporating the National Children's Hospital (AMNCH), (Dublin)
- Children's University Hospital, Temple Street, (Dublin)
- Cork University Hospital, (Cork)
- Limerick Regional Hospital
- Our Lady of Lourdes Hospital, Drogheda
- Our Lady's Hospital for Sick Children, Crumlin, (Dublin)
- Sligo Regional Hospital
- University Hospital Galway,

6.1 Referral Pathways

Prior to 2011, all referrals were made to the three Dublin children’s hospitals. In 2011, Cork University Hospital commenced accepting referrals from the HSE South area, and in 2012 Limerick/Galway was established as a fifth regional centre. Limerick / Galway was initially established as a joint pump centre however as of March 2015, the units are now operating independently. More recently, Sligo and Drogheda have started to accept referrals for CSII.

Updated referral pathways are currently as follows:



Through this strengthened association, the main centres will support and assist the development of professional expertise to ensure equity of diabetes care regardless of primary site of delivery.

6.2 Phased Return of Current Patients

There are a number of patients under five years of age currently participating in the provision of CSII therapy who are under the care of the Dublin hospitals who will now be able to receive their care from a pump centre closer to home. It is acknowledged that some patients and their families may wish to remain under the care of the centre where CSII was commenced; however transfer back to the local hospital, if possible, is preferred. The cohort of established CSII patients that are to be transferred should be done so on a phased basis (6-12months) so that the receiving centre can deal with the increase in workload. Close liaison between the two centres must take place. For example, a patient currently cared for by a Dublin hospital would be transferred to Cork as it is now a pump centre.

6.3 Phased return of new CSII patients from pump centres to local hospital

Patients undergoing CSII therapy will remain under the care of the pump centre while the therapy is being established. This period of time will be assessed on a case by case basis; however 6 to 12 months is suggested to consolidate the education and CSII initiation prior to transfer back to a local hospital. In some cases patients may remain under the care of the pump centre or shared care between the local hospital and pump centre may be considered.

7. CSII Therapy - Team Education

Each pump centre must establish and set up certified pump training (CPT) for all staff including link Staff Nurses on the ward to optimise the new pump knowledge for all children with type 1 diabetes.

8. IT Requirements

Each pump centre must record data on patients in a secure database. These data should be age banded according to different age groups for National Diabetes Register and to include the under five years age group. Ideally a specific database system such as 'Twinkle' or 'Diamond' should be used.

9.0 Resources Required to Deliver Model of Care

The Diabetes Expert Advisory Group (DEAG) was commissioned by the HSE to review diabetes care in Ireland, make evidence-based and expert consensus-based recommendations and be involved with the HSE in implementation of these recommendations. The DEAG first report was published in April 2008 and, for paediatric diabetes care, recommended the following staffing levels:

- Paediatric Endocrinologist 1 per 150 children/adolescents with diabetes
- Paediatric DNS 1 per 100 children/adolescents with diabetes
- Paediatric diabetes dietitian 1 per 150 children/adolescents with diabetes
- Paediatric psychologist 1 per 300 children/adolescents with diabetes
- Medical social worker 1 per 300 children/adolescents with diabetes

The DEAG further recommended that the above paediatric diabetes team should be led by a Paediatric Endocrinologist with a specific training in diabetes and that he/she must have a significant commitment to paediatric diabetes.

The National Paediatric Diabetes Working Group, between 2011 and 2015, achieved 11 additional posts for the provision of paediatric diabetes insulin pump therapy nationally. The posts were allocated as follows:

Location	Post	In place?
Cork	Dietitian (0.5)	No
Cork	Diabetes Nurse Specialist (1.0)	Yes, 2014
Crumlin	Dietitian (0.5)	No
Crumlin	Diabetes Nurse Specialist (1.0)	Yes, 2015
Galway	Consultant (0.5) + 0.5 from local funding = 1.0 wte	No
Limerick	Consultant (0.5) + 0.5 from local funding = 1.0 wte	No
Limerick	Diabetes Nurse Specialist (1.5)	Yes, 2014
Limerick	Dietitian (0.75)	Yes, 2014
Sligo	Diabetes Nurse Specialist (1.0)	No

Tallaght	Dietitian (0.5)	Yes, 2014
Tallaght	Diabetes Nurse Specialist (1.0)	No
Temple St	Diabetes Nurse Specialist (0.5)	Yes, 2014
Temple St	Dietitian (0.5)	Yes, 2014

10.0 Corporate and Clinical Governance

10.1 General Principles

Clinical Governance means corporate accountability for clinical performance, built on the model of the CEO/general manager or equivalent working in partnership with the Clinical Director, Director of Nursing/Midwifery and service/professional leads. Clinical governance is about people receiving the right care, at the right time, from the right person in a safe, honest, open and caring environment.

Effective governance arrangements recognise the inter-dependencies between corporate, financial and clinical governance across the service and integrates them to deliver high quality, safe and reliable healthcare. Effective governance and accountability can be achieved by embedding leadership and operational management at a corporate and clinical level. This is underpinned by six key steps:

1. Agree the measurable safety, quality, access and cost objectives you want to achieve which are in line with HSE national priorities.
2. Ensure there is a documented standardised pathway in place, which is supported by standard clinical decision-making and regulatory requirements.
3. Ensure that all parties involved in the pathway have total clarity of their accountability roles, responsibilities and governance arrangements.
4. Ensure there is a balanced set of metrics in place to track the performance of the pathway.
5. Ensure there is an effective meeting held regularly, where those who are managing the pathway identify variance in its operational performance and log actions to be taken to improve the outcome for the patient.
6. Where the reason for the variance is unclear or the action to address variance is significant then ideally there should be some skilled local project and process improvement resource available to guide the clinicians through the change process.

Healthcare organisations are responsible and accountable for delivering safe, high quality, cost-effective care that achieves the best possible health outcomes for people in Ireland. Emphasis is placed on quality and patient safety and the development of an infrastructure for integrated quality, safety and risk management with the aim of achieving excellence in clinical governance. Formalised governance arrangements ensure that everyone working in the health and personal social services are aware of their responsibilities, authority and accountability and work towards achieving improved patient outcomes.

Clear accountability arrangements are a fundamental building block of good clinical governance, bringing clarity to the authorities and responsibilities of individuals, teams and committees (or groups). One of the key principles of good governance is that there are clear lines of authority and accountability at individual, team and whole system levels with a clear hierarchy of single point accountability within a managerial accountability hierarchy. In this model of care each individual child's care feeds into a clinical governance structure.

Ten principles have been defined for clinical governance:

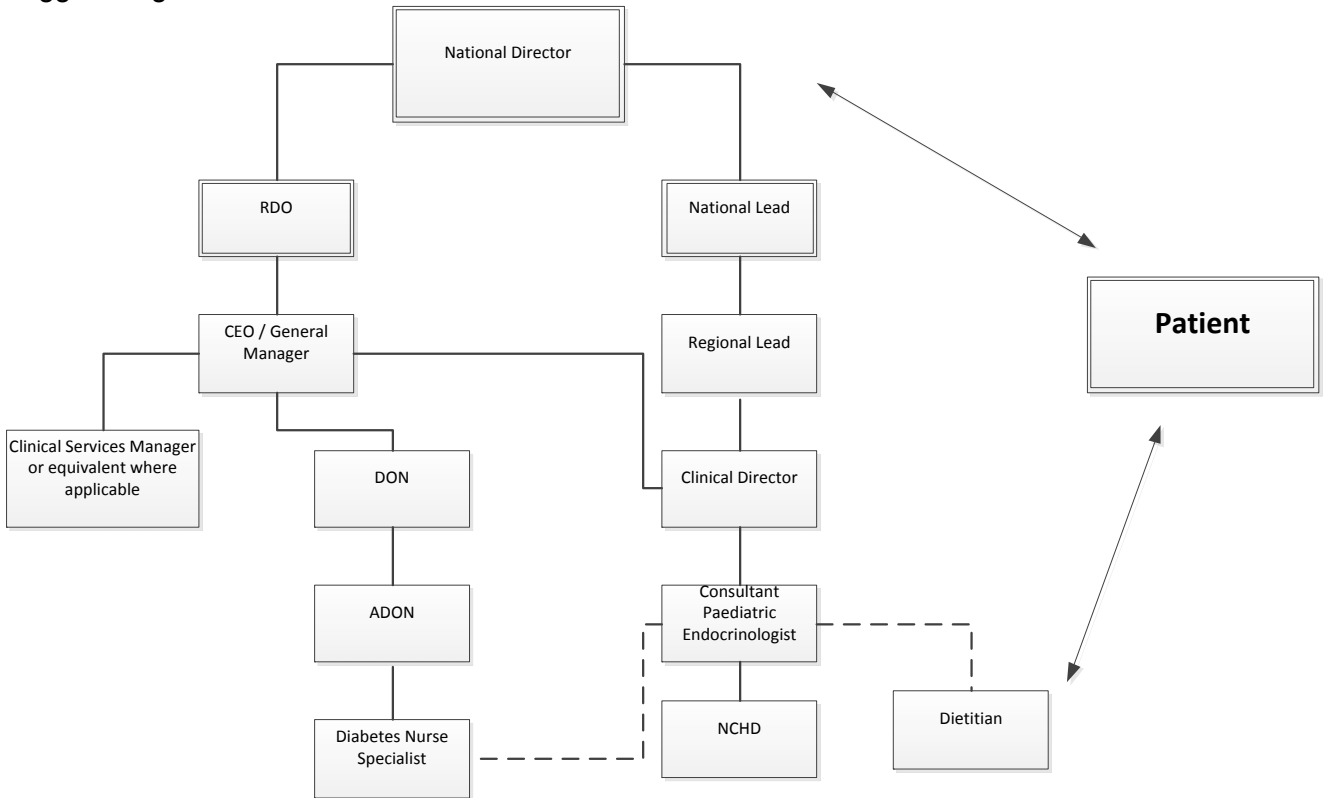


Principle	Descriptor	How principle relates to the MOC
Patient First	Based on a partnership of care between patients, families, carers and healthcare providers in achieving safe, easily accessible, timely and high quality service across the continuum of care.	The whole ethos of this model of care is putting the patient first. The use of insulin pump therapy for children provides better clinical outcomes and an improved quality of life for patients and their carers.
Safety	Identification and control of risks to achieve effective efficient and positive outcomes for patients and staff.	All patients are assessed for suitability for use of pumps prior to commencing. An agreed assessment tool is used. Patients and carers are provided with intensive education and support.
Personal responsibility	Where individuals as members of healthcare teams, patients and members of the population take personal responsibility for their own and others health needs. Where each employee has a current job-description setting out the purpose, responsibilities, accountabilities and standards required in their role.	Each employee has an agreed job description in relation to the provision of insulin pump therapy and are required to have an appropriate level of training.
Defined authority	The scope given to staff at each level of the organisation to carry out their responsibilities. The individual's authority to act, the resources available and the boundaries of the role are confirmed by their direct line manger.	Roles are clearly defined.
Clear accountability	A system whereby individuals, functions or committees agree accountability to a single individual.	Consultant paediatric endocrinologist leads the team.
Leadership	Motivating people towards a common goal and driving sustainable change to ensure safe high quality delivery of clinical and social care.	Clinical leadership is demonstrated in the development of this model of care. In addition, each unit has a lead clinician responsible for leading the team.

Inter-disciplinary working	Work processes that respect and support the unique contribution of each individual member of a team in the provision of clinical and social care. Inter-disciplinary working focuses on the interdependence between individuals and groups in delivering services. This requires proactive collaboration between all members.	The provision of insulin pump therapy requires multidisciplinary team involvement. The model of care clearly defines that each team must have, at a minimum, a consultant paediatrician, diabetes nurse specialist and a dietician. The care could not be given without the input of all team members.
Supporting performance	Managing performance in a supportive way, in a continuous process, taking account of clinical professionalism and autonomy in the organisational setting. Supporting a director/manager in managing the service and employees thereby contributing to the capability and the capacity of the individual and organisation. Measurement of the patients experience being central in performance measurement (as set out in the National Charter, 2010).	KPIs have been agreed. Clinical audit is to be carried out by the team. Clinical effectiveness is built in the model of care.
Open culture	A culture of trust, openness, respect and caring where achievements are recognised. Open discussion of adverse events are embedded in everyday practice and communicated openly to patients. Staff willingly report adverse events and errors, so there can be a focus on learning, research and improvement, and appropriate action taken where there have been failings in the delivery of care.	Progress is transparently monitored at multidisciplinary meetings.
Continuous quality improvement	A learning environment and system that seeks to improve the provision of services with an emphasis on maintaining quality in the future not just controlling processes. Once specific expectations and the means to measure them have been established, implementation aims at preventing future failures and involves the setting of goals, education, and the measurement of results so that the improvement is ongoing.	All staff are educated. Patients and carers are educated. Patients' progress is monitored at MDT meetings. Reviews are built in to the process.

The Paediatric Diabetes Working Group has embedded these principles by adopting a leadership and accountability framework that envisages every clinician and administrator working in the programme having clear roles and responsibilities. The structure of the programme is summarised below where the patient is pivotal to clinical and corporate governance strategy development. It embraces clinical effectiveness, clinical audit, research and development, clinical indicators, integrated pathways, risk management, and organisational development. This governance structures should apply to both local hospitals and pump centres.

Suggested governance:



10.2 Governance Structures

This model of care has been drafted by the Paediatric Diabetes Working Group. The group has been set up under the auspices of the National Paediatric Clinical Programme and the National Diabetes Clinical Programme.

The document must go through an approval process through the following groups:

- Paediatric Clinical Advisory Group and Working Group
- Diabetes Clinical Advisory Group and Working Group
- Directors of Nursing and Midwifery Reference Group
- Therapy Reference Group

10.3 Risk Management and Patient Safety

The Paediatric and Diabetes clinical programmes are committed to risk management and patient safety. The paediatric diabetes teams providing insulin pump therapy will adhere to the HSE Risk Management Handbook and the processes contained within.

In addition, patients are carefully monitored whilst receiving insulin pump therapy; initially to ensure that patients / carers are appropriately educated in order to effectively manage the therapy and then monitored through regular review. Patients that are not deemed suitable for pump therapy are not permitted to use it until they reach the required standard.

11. Key Performance Indicators

- New pump starts in the under 5 age group
- HbA1c
- Health Related Quality of Life (HRQOL) - See appendix 3

11.1 The number of patients under 5 years of age assessed / started for CSII

Exact figures for CSII therapy will be collated as follows:

- CSII assessment
- CSII starts
- Successfully maintained on CSII at 6 months or more.

The relevant information for this will be entered on the National Paediatric Diabetes Register from this year forwards.

11.2 Metabolic Metrics in the under 5 years age group

HbA1c in the under 5s	<69 mmol/mol (8.5%)
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Less than 69mmol/mol (8.5%) is the target.²²

Children under 5 years are a complex and challenging age group. The less than 69mmol/mol target is higher than the rest of the paediatric population for this reason. A lower target of 64mmol/mol (8.0%) is reasonable if it can be achieved without excessive hypoglycaemia

An evaluation of current status of HbA1c in the under fives before this programme begins would be a useful metric. This target will remain at ≤ 69 mmol/mol for the foreseeable future, as there is no other evidence for the contrary in this age group.

11.3 Health related quality of life (HRQOL)

Improving HRQOL is one of the primary aims of this programme. This measure will be useful to assess an individual child's and their family's HRQOL at diagnosis, pre- and post- pump start.

²² ADA Clinical Practice Recommendations, Diabetes Care; vol 35, supplement 1, F39 - January 2012

Appendices

Appendix 1 Kaufman Competency Level Scale

Appendix 2 Referral to Pump Centre for CSII Service

Appendix 3 Hvidoere Questionnaire for Parents of Children and Adolescents with Diabetes

Appendix 4 Abbreviations / Definitions

Appendix 1 Kaufman Competency Level Scale

Kaufman Competency Level Scale

Competency	Description of competency level	Level
Safety	Initial Information, injections, blood testing, treatment of hypoglycaemia	1
Basics	Blood glucose targets, actions for levels out of target, Glucagon, action of different types of insulin, diet and carbohydrate	2
Carbohydrate Management	Determine quantity of carbohydrates in food, use of plan for carbohydrate intake	3
Correction	How to correct blood glucose out of target	4
Daily changes	Decision making about changes in daily routine adjusting insulin and carbohydrate intake	5*
Basal dose adjustment	Making basal dose adjustments, review blood glucose values to observe overall effects of treatments	6
Advanced Management	Understand hormone pathways and food absorption; know about strategies to reduce complications	7
Maximised control	Independence in MDI/CSII to maximise control, flexibility and freedom	8

Child and family with diabetes must be Kaufman competent equal to 5 out of 8 to be considered for an CSII*

Reference: Francine Kaufman, Diabetes Spectrum Volume 14, Number 2, 2001

Appendix 2 Referral to Pump Centre for CSII Service in the Under 5 Age Group

Patient Name: Patient Address: DOB:	Primary Carer Name: Secondary Carer Name Phone No: Mobile number of primary carer
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Type 1 Diabetes	Presenting Symptoms	Current Management
Date of diagnoses	DKA <input type="checkbox"/>	Insulin regimen:
Kaufman Score	Ketosis <input type="checkbox"/>	Morning
Latest HbA1c: IFCC.....mmol/l	Symptoms <input type="checkbox"/>	Lunch
Date.....	Hypos <input type="checkbox"/>	Evening
		Bed time
		Total Daily Dose.....

Carbohydrate Counting:

Carb Ratio: 1.0 IU: ___ G BREAKFAST _____ LUNCH _____ DINNER _____

Insulin sensitivity ratio (ISF):

Comments:

Pre-Referral Work-up

Investigation	Results Enclosed	Investigation	Results Enclosed
Full Blood Count		Fasting Cholesterol & Triglycerides	
Urea & Electrolytes		Alb: Creatinine ratio	
HbA1c/IFCC		TFTs & Coeliac results	

Signature _____ Date: ___/___/___

Printed Name _____

Referral Centre _____

Appendix 3 Hvidoere Questionnaire for Parents of Children and Adolescents with Diabetes

Caring for a child or adolescent with diabetes can be difficult in different ways for parents. This form asks about the difficulties or burden experienced by you in managing diabetes. Please tick the box which best indicates the level of burden you experience in each of the areas below.

Section 1

	Major Burden (Difficulty)	Large Burden (Difficulty)	Moderate Burden (Difficulty)	Small Burden (Difficulty)	No Burden (Difficulty)
How much burden (difficulty) is there because of					
a) Medical treatment/nursing tasks that you need to perform?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Disruption in family routines because of caring for the child?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Physical or psychological problems in the child requiring extra parental care?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) General restriction of your child's social and school activities because of diabetes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Concerns about your child's long-term health?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section 2. Has your child's performance at school changed since the onset of diabetes?

It has:

Improved Remained the same Not applicable
 Slightly deteriorated Greatly deteriorated

Section 3. Do you feel that your child's general health at present is?

Very Good Good Fair Poor Very Poor

Section 4. Do you feel that your child's quality of life is?

Very Good Good Fair Poor Very Poor

Section 5. a) Are there two parents living at home? Yes No
 b) Is the father employed? Yes No
 c) Is the mother employed? Yes No

Thank you for your help!

Questionnaire for Paediatrician / Nurse Educator concerning Children or Adolescents with Diabetes

Section 1

	Major Burden (Difficulty)	Large Burden (Difficulty)	Moderate Burden (Difficulty)	Small Burden (Difficulty)	No Burden (Difficulty)
1. Family Burden (Difficulty) Scale)					
How much burden (difficulty) do you estimate there is as a result of:					
f) Medical treatment/nursing tasks the family needs to perform?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Disruption in family routines because of caring for the child?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Physical or psychological problems in the child requiring extra parental care?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) General restriction of the child's social and school activities because of diabetes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Concerns about the child's long-term health?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section 2. Has this patient or its family required other forms of professional psychological help?
(For example: Psychiatrist, Psychologist, Counsellor, Social Worker?)

If so, which of the above? _____

Was this for (please tick relevant box):

Routine Assessment OR Treatment of a specific psychological problem

Section 3. Give your overall evaluation of this patient in the following area:

	Very Good	Good	Fair	Poor	Very Poor
Adherence to treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patient ability to cope	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Family coping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patient's quality of life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Thank you for your help!

Copies of questionnaires are available in the following languages Danish, Dutch, English (Irish, North American and UK), Finish, French, German, Italian, Japanese, Macedonian, Norwegian, Portuguese, Spanish, and Swedish on request from The Hvidøre Study Group at Novo Nordisk, Hummeltoftevej 49, DK-2830, Denmark.

Hoey H, McGee HM, Fitzgerald M, Mortensen H, Hougaard P, Lynggaard H, Skovlund SE, Aanstoot H_J, Chiarelli F, Daneman D, Danne T, Dorchy H, Garandeanu P, Greene S, Holl R, Kaprio E, Kocova M, Martul P, Matsuura N, Robertson K, Schoenle E, Sovik O, Swift P, Tsou R, Vanelli M, Åman J for the Hvidøre Study Group on Childhood Diabetes. Parent and health professional perspectives in the management of adolescents with diabetes: Development of assessment instruments for international studies. *Quality of Life Research*. 2006; 15: 1003- 1042.

Appendix 4 Abbreviations / Definitions

ADA	American Diabetes Association
ADON	Assistant Director of Nursing
AMNCH	Adelaide and Meath Hospitals, incorporating the National Children’s Hospital
BG	Blood Glucose
BMI	Body Mass Index
BSPED	British Society for Paediatric Endocrinology and Diabetes
CEO	Chief Executive Officer
CGM	Continuous Glucose Monitoring
CSII	Continuous Subcutaneous Insulin Infusion
DKA	Diabetic ketoacidosis
DM	Diabetes Mellitus
DNS	Diabetes Nurse Specialist
DON	Director of Nursing
EAG	Expert Advisory Group
GP	General Practitioner
HbA1c	Glycated hemoglobin
HRQOL	Health-related Quality of Life
HSE	Health Service Executive
ISF	Insulin Sensitivity Factor
ISPAD	International Society for Pediatric and Adolescent Diabetes
MOC	Model of Care
MDI	Multiple Daily Injections
MDT	Multidisciplinary Team
NICE	National Institute for Health and Clinical Excellence
PS	Pump School
RCPI	Royal College of Physicians of Ireland
RDO	Regional Director of Operations
SAP	Sensor Augmented Pump
WHO	World Health Organisation
“Diabetes”	In this document, refers to Type 1 Diabetes only
“Under 5”	Refers to children aged <5.99 years old
“Under 18”	Refers to children and young people <17.99 years old