

# Continuous subcutaneous insulin infusion therapy in type 1 diabetes: 2013 clinical guidelines and recommendations from the Association of Clinical Endocrinologists of South Africa (ACE-SA)

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## Introduction

The first external insulin pump device to deliver continuous subcutaneous insulin infusion (CSII or "insulin pump") therapy was used more than 30 years ago. Subsequently, the Diabetes Control and Complications Trial (DCCT) has convincingly demonstrated that stricter glycaemic control, using insulin delivered by multiple-dose injections (MDI) or CSII, prevents and retards the progression of microvascular complications. Technological improvements in pump design and functionality, the wider dissemination of accumulated knowledge and the desire to achieve blood glucose values as close to the normal range as possible, have resulted in a significant increase in insulin pump use throughout the world. An increasing body of evidence supports the ability of insulin pump therapy to improve glycaemic control while reducing hypoglycaemic episodes when used in appropriately selected patients with type 1 diabetes.

The local use of insulin pumps has expanded significantly since its reintroduction into South Africa in 2001, and it can no longer be ignored as a therapeutic option for selected patients with type 1 diabetes in this country. However, if CSII is to be a viable and sustainable therapeutic alternative in appropriate patients, a balance needs to be struck between CSII use and the ability of the healthcare network to support the additional costs. The benefits of CSII should be measurable and demonstrable. Creation of an environment in which these benefits can be realised will ensure the viability and sustainability of this form of therapy in the diabetes care armamentarium.

In order to obtain the maximum and expected benefits from CSII therapy, the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA), Paediatric and Adolescent Endocrinology and Diabetes Society of South Africa (PAEDS-SA) and the

Centre for Diabetes and Endocrinology (CDE) have collaborated, under the banner of the Association of Clinical Endocrinologists of South Africa (ACE-SA), to issue guidelines on CSII in South Africa.

The role of ACE-SA will be to:

- Co-ordinate the training and continuing medical education for new and established CSII facilities.
- Establish and co-ordinate the CSII training for registrars and fellows seeking certification in Endocrinology and Metabolism.
- Establish a voluntary database of CSII users in South Africa, and to review this data to critically analyse the impact of CSII therapy.
- Publish and review CSII guidelines, and make recommendations for the recognition of CSII providers.

## Insulin pump technology

The insulin pump is a small, pager-sized portable device, with a refillable storage reservoir for insulin, connected to the body by means of a thin tube attached to a subcutaneously inserted cannula. The cannula usually needs replacing every 2-3 days. The pump can be programmed to deliver insulin at variable rates throughout the day.

There are two main types of programmable insulin delivery:

- *Basal rate insulin supplied continuously:* A single, basal insulin rate can be planned and pre-programmed for the entire day (24 hours), or the basal rate can be varied for different times of the day, e.g. based on changing requirements during the day and at night.
- *Bolus insulin:* Here, a higher insulin dose is given with the press of a button, either as a single bolus, or infused over a short period at meal times. It can also be used to correct high blood glucose levels.

Insulin pumps can deliver insulin more consistently and precisely than pen devices and syringes. Dose adjustments as small as 0.05 units are possible with some pump models, and this can be particularly useful when dealing with smaller children.

### Advantages of continuous subcutaneous insulin infusion

CSII enables users to lead a flexible and spontaneous lifestyle in terms of meal times and physical exercise. It:

- Enhances the flexibility to adjust the insulin dose according to food intake.
- Uses only short-acting insulin analogues. As a result, it can better mimic physiological insulin secretion and ensure continuous insulin availability throughout the day (24 hours).
- Enables users to programme and vary the basal insulin rate in accordance with varying requirements over 24 hours, thus reducing fluctuating blood glucose levels and hypoglycaemic episodes.
- Enables users to increase the basal rate during the second half of the night, thus overcoming the dawn phenomenon and preventing high blood glucose values in the morning, without having to endure hypoglycaemia during the night.
- Insulin pump therapy can result in improved metabolic control in correctly selected patients, without increased frequency of severe hypoglycaemia that is characteristic of intensive therapy by injection.

### Disadvantages of continuous subcutaneous insulin infusion

Disadvantages of continuous subcutaneous insulin infusion include:

- The fact that direct costs are greater.
- CSII therapy is labour-intensive for both providers and patients, or their caregivers.
- Since only short-acting insulin is used, accidental disconnection or malfunction of the infusion will cause insulin deficiency within minutes, together with the risk of ketoacidosis after several hours if suitable measures are not taken. This risk requires frequent blood glucose tests and attention to elevated test values.
- A risk of infection at the insertion site. However, this can be prevented by following aseptic insertion techniques, varying the insertion site every three days and applying an antibiotic ointment if necessary.
- Users have an external device attached to their body at all times.

### Selection of healthcare providers

The concept of specialised and designated facilities for CSII is becoming an international norm and helps to ensure the best possible outcomes for patients and funders. Insulin pump therapy requires an above-average level of diabetes management, more intensive patient education and training, and close follow-up. All of this needs to take place within a care framework that is suitably equipped to take the technological peculiarities of this form of treatment, its associated risks, the entailed change in lifestyle and its cost, into account. The establishment of a diabetes treatment facility conceived specifically to deal with patients who are treated by pumps is an ideal for which to strive.

This requires a full multidisciplinary team, that at the very least, must include:

- A physician with a special interest in type 1 diabetes and insulin pump therapy.
- A diabetes nurse or educator with special training in CSII.
- A dietitian with special expertise in managing type 1 diabetes.

### Team selection

Currently, there is no medical supervision or certifying process to regulate the use of this complex therapy. Any medical practitioner is free to prescribe CSII. The growth in the number of doctors wanting to prescribe CSII has been driven mainly by the manufacturers of CSII devices, and often patient support is provided only by employees of the manufacturer, a practice that should be discouraged. Both funders and patients receive no guidance with regard to provider expertise.

At present, ACE-SA is unable to issue comprehensive guidance on the choice or accreditation of all medical practitioners who wish to provide CSII services. This stems from the fact that any practitioner may claim to have a special interest (without formal training) in type 1 diabetes and CSII, and it is not possible for ACE-SA to verify these individual claims. However, endocrinologists (paediatric and nonpaediatric), by the very nature of their training, are deemed to have the requisite knowledge and experience to manage type 1 diabetes and MDI.

### Therefore, ACE-SA recommends the following:

- All registered endocrinologists who have completed an ACE-SA-approved training course in CSII, should be considered to be preferred providers for the initiation and maintenance of pump therapy.
- Training in the use of CSII should become available to endocrine registrars and fellows, either through access to a local CSII facility, or through the

establishment of CSII facilities and expertise within training hospitals, so that graduating endocrinologists will automatically qualify to initiate pump therapy in the future.

- Practitioners who are considered to be diabetologists by their peers, and who are referred patients by their colleagues for CSII, should also be considered as preferred providers for CSII therapy, provided that they have completed an ACE-SA-approved training course in CSII. For the purposes of this document, a diabetologist is defined as a medical practitioner whose workload involves managing diabetes mellitus > 80% of the time.
- ACE-SA recommends that for non-endocrinologists and non-diabetologists wishing to undertake CSII therapy, the funders of health care (public and private) will need to establish managed-care programmes in conjunction with known experts in this field, in order to facilitate a wider preferred provider network for CSII, if this is deemed necessary.
- *Educator and dietitian selection:* Members of the Diabetes Education Society of South Africa (DESSA) and dietitians wanting to manage insulin pump therapy must first be experienced in managing type 1 diabetes. Then, they will also need to acquire the additional skills necessary for managing CSII patients. It is hoped that DESSA will establish a formal training course for this purpose. Dietitians must also possess additional expertise in educating patients on carbohydrate counting. Educators and dietitians are also required to attend at least one ACE-SA-approved CSII course.
- All members of the specialist team should engage in continuing medical education activity relating to CSII annually.
- The initiation and maintenance of insulin pump therapy by industry representatives is no longer an acceptable practice. However, industry representatives may only participate in device training and troubleshooting prior to, or during, the initiation process. They are not permitted to participate in insulin dose setting or adjusting.

**The responsibilities of the healthcare team will include:**

- The provision of an environment and facility that is fully capable of training and educating the patient (and family) in pump usage.
- The provision of a 24-hour emergency number or "hotline" staffed by someone who understands pump therapy, and who can provide medical and technical counselling 24 hours a day throughout the year.
- Having access to and knowledge of continuous glucose monitoring systems.
- Getting informed consent from patients to enter

their demographic, clinical, laboratory and self-blood glucose monitoring data into a national CSII register.

**Patient selection**

**The following is very important:**

Insulin pump therapy should not be considered as "an easy way out" for patients who are nonadherent to their treatment regimens, who do not wish to perform self-blood glucose monitoring, or who are seeking an "easy" alternative to multiple injections. Rather, CSII should be reserved for those patients who are concerned about their glycaemic control, who are extremely motivated and meticulous with their self-care, and who despite this, fulfil the criteria outlined below. The healthcare provider should not automatically consider or prescribe CSII because a patient or parent requests it, or because glucose control is not optimal. Pump therapy should be primarily reserved for patients with specific problems which may include the wish to achieve the quality-of-life benefits of insulin pump therapy. Patients should be under the management of a specialist care team, as outlined in the previous section.

**Patients who may be considered for insulin infusion pump therapy**

Before patients can be considered for CSII therapy, they must:

- Have demonstrated knowledge of and adherence to MDIs with appropriate dose adjustments.
- Have demonstrated the willingness to perform home blood glucose monitoring at least four times daily, and preferably six times a day.
- Have shown, to the satisfaction of the healthcare team, that they do not regularly miss injections or abuse their meal plan, and are willing to work with the multidisciplinary team.
- Have been instructed on carbohydrate counting by a qualified dietitian.
- Be motivated to succeed and have realistic expectations.
- Ideally, patients should be required to enter into a contract with the pump centre for pre-pump appraisal, education and ongoing management. Explicit in this contract will be indications for insulin pump therapy, pre-determined follow-up with the insulin pump team, and a definition of treatment targets to be maintained.
- Have none of the contraindications outlined below.

Patients and/or family members must:

- Understand the factors influencing blood glucose levels and have the ability to vary and plan bolus doses based on tested blood glucose levels, planned carbohydrate consumption during the next meal, and planned physical exercise.
- Feel comfortable with the pump and have the ability to operate it.
- Preferably, have a family support system, as well as the support of a healthcare team who is knowledgeable in pump use and who is available 24 hours a day.
- Have experience in intensive therapy with multiple injections.
- Be willing to sign a contract agreeing on patient-specific outcome goals and minimum required annual follow-up visits.
- Undergo an appropriate training and education programme in pump use.

Children must have access to an adult during school hours in case of pump problems, and the ability to programme the bolus dose at school.

### Indications for initiating treatment with continuous subcutaneous insulin infusion

#### Metabolic

The “difficult to stabilise” patient with diabetes is the favoured indication for pump therapy.

Pump therapy should be considered for these patients, particularly in the following circumstances:

- Frequent severe hypoglycaemic episodes, despite a careful management review by an expert team.
- Hypoglycaemia unawareness, or recurrent severe hypoglycaemic episodes, which persist after a trial of therapy with a long-acting insulin analogue (Lantus® or Levemir®).
- Case-by-case consideration given to patients with extremely poor control and recurrent hospital admissions.
- Infants, toddlers and children with diabetes, in whom metabolic control is difficult to achieve using MDIs because of enhanced insulin sensitivity, erratic dietary patterns and logistical issues that relate to insulin delivery.
- Selected patients with anorexia nervosa and bulimia nervosa.
- Patients who are on MDIs, following a prescribed meal plan, testing blood glucose levels four or more times per day, and who are still not achieving their target haemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>).
- Poor control, resulting from severe needle phobia.

#### Lifestyle

Pump therapy is suitable for patients with diabetes who have irregular eating, working and resting times, e.g. those who work shifts, travel frequently or engage in physically demanding sporting activities. Pump treatment enables these patients to achieve satisfactory blood glucose targets, which is difficult to achieve with conventional MDI regimens. It allows for fewer constraints on timetabling and making up meals.

This includes patients with type 1 diabetes who are well controlled using MDIs, but who seek the improved quality of life that is on offer through CSII use.

#### Pregnancy

Insulin pump therapy may be proposed to achieve excellent control of diabetes before conception and during pregnancy. It may also be started early in pregnancy for the rapid improvement of glycaemic control.

Prospective patients who meet the selection criteria and indications for CSII should be referred to a local expert pump team for evaluation, initiation and ongoing management of insulin pump therapy, should it be deemed appropriate by the full multidisciplinary team who is trained in pump therapy.

### Contraindications for initiation or ongoing treatment with continuous subcutaneous insulin infusion

Treatment by pump can be dangerous because of the risk of rapid development of ketoacidosis if the infusion is stopped. Therefore, it is contraindicated in patients who do not monitor themselves with regular home blood glucose monitoring, or who are not capable of troubleshooting insulin pump problems.

The following are absolute contraindications to pump therapy:

- Patients who are poorly committed to pump therapy.
- Patients with a pattern of nonadherence to the recommendations of the managing centre.
- Patients on CSII, who over a period of six months to a year, fail to achieve or maintain improved blood sugar control (improved HbA<sub>1c</sub> and/or a reduction in hypoglycaemia) when this was the primary indication for initiation of CSII therapy.
- At present, there is insufficient evidence to recommend CSII for patients with type 2 diabetes.

### Choice of insulin and pump device

The recommended insulin for pump use is a rapid-acting insulin analogue, e.g. Humalog®, NovoRapid® or Apidra®.

The choice of insulin pump should be at the discretion of the doctor and the patient. Device-specific factors to consider include, inter alia:

- Device size.
- Reservoir size.
- Screen size.
- Ease of programmability.
- Computer software and download and upload capabilities.
- Minimum-dose adjustment increment for basal and bolus rates.
- Water-tightness.
- Compatibility with glucose monitoring devices.
- Cost of device and consumables.
- Device support from the manufacturer.

The recommendations presented herein are not meant to replace the judgement and discretion of physicians who treat individual patients, but rather to formulate guidelines to facilitate their work. This guideline will be reviewed every two years, or sooner, if necessary.

## Acknowledgements

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