

Diabetes Postgraduate Programmes

Sample Portfolio

CSII Therapy

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Warwick
Medical School

THE UNIVERSITY OF
WARWICK

PORTFOLIO
ALTERNATIVE OPTION

Experience in developing an insulin pump service in the local district hospital.

Introduction

There are patients with diabetes who use intensified insulin regimens with commitment and have good self-management skills but are unable to achieve good glycaemic control and/or suffer recurrent severe hypoglycaemia.

Insulin pump therapy (IPT) offers a more physiological delivery of insulin which can produce decreases in the HbA1C variously reported as much as 0.85% (1) and 0.9% (2) when compared with MDI therapy. The same studies showed a reduction in glycaemic variability and this has been shown to be associated with a reduction in harmful free radicals (3) and reduction in the microvascular complications as seen in the DCCT (4). There is evidence for reduction of frequency and severity of hypoglycaemia (5).

An insulin pump could be an optimal form of insulin delivery for the patients who are unable to achieve good glycaemic control with potential benefits on reduction of diabetic complications and improvements in quality of life (6). The needs of these patients are only starting to be addressed in the UK with an estimated 1% of patients with type 1 diabetes using pump therapy (7).

Current service provision.

Patients selected as suitable candidates for IPT have been referred to the central teaching hospital 20 miles from the local district hospital to date. Funding for treatment and long-term follow-up has been arranged by that hospital.

The local district hospital provides care for 3487 patients with diabetes of whom 22% have type 1 diabetes.

.Patient preference has led to some patients self referring back to the district hospital with their pumps, and new patients have joined the clinic with pumps from elsewhere in the UK, all requiring expert follow-up.

The paediatric department in the hospital have developed an insulin pump service which began in 2003 and there are now a total of eight children using pumps. There has been a significant reduction in the HbA1C of all the patients in keeping with current research (2), however the paediatric consultant has noted a general reduction in HbA1C of most patients since the introduction of intensified insulin regimens in all children with newly diagnosed diabetes, rather than the previous twice daily insulin therapies. Audits are pending of this data, which will be conducted following the recent appointment of the first paediatric diabetes specialist nurse for the children's diabetes service.

Protocols for patient selection for IPT, as well as patient education on pump technology and management of the CSII have been written (appendix 1) and recently disseminated to the adult diabetes service.

To date families have self-selected for consideration of the insulin pump and after due consultation with the diabetes multidisciplinary team, have applied for funding to the board on an individual basis.

As larger patient numbers are anticipated to be involved in the adult pump service a business case for more extended funding as well as protocols for audit to provide evidence for effectiveness and efficiency are currently being planned.

Need for development of a local insulin pump service.

Presently there are patients using pumps who are attending the local hospital diabetic clinic, who need staff with expertise in caring for these patients.

There is the need for patients who meet the criteria for IPT as per the current NICE guidelines (8) to be met.

As a group pf enthusiastic members of the multidisciplinary diabetes team, there is the need for the team to be able to provide a progressive programme of care for the patients sensitive to their

physical and psychosocial needs, with the ultimate aim of improving quality of life and reducing long-term complications of their diabetes.

It is felt by the team that to date this comprehensive service has not been provided by not offering an on-site pump service.

Financial Issues.

The costs of IPT have been estimated to be about three times higher than an intensified insulin regimen, £1731 versus £571 annually (9).

Despite the higher costs of IPT there is evidence for sustained clinical effectiveness (10), indeed many of the older studies were of short duration (1) and possibly underestimated the benefits in improvement in glycaemic control. Indeed a meta-analysis by Weissberg-Benchell on IPT in 2003 (11) identified several medical benefits for the patients but many of the studies included in the meta-analysis used older pumps, did not use the analogue insulins and were of short duration, so possibly underestimating the benefits that could be gained from IPT. The important issue of improvements in quality of life have been difficult to assess but have been calculated as a cost per QALY of £26,648 (9) or £25,648 by Roze et al (12). In Roze's study it was concluded that non-medical costs such a loss of productivity through the ill health of poorly controlled diabetes and its complications were difficult to calculate so a cost-effective analysis of IPT would underestimate its value, both financially and for the patients.

This poses the dilemma of presenting to the Health Board who will be funding the pump service a treatment which appears much more expensive but has potential benefits for a particular group of patients.

A business case has been submitted to the board (appendix 2) to secure appropriate finances in February 2008. An initial response is awaited.

As several patients who joined the clinic had been using the Accu-Chek Spirit pump a decision was made to approach the manufacturers Roche for education and to obtain costings of the pump and disposables. As the patient base for pump therapy expands these products could be purchased in

bulk to obtain discount and they also provide a 24 hour back-up service for the equipment.

However the paediatric service have been using the Paradigm pump by Medtronic. The multi-disciplinary team are therefore debating which pump to gain expertise in.

The costs of the pumps appear to be slightly different, the Accu-Check Spirit costed at £2,375 versus the Paradigm at £2,750 (9) and although these costs may increase with inflation there is also the consideration that with ongoing development in technology pumps may be manufactured more cheaply.

The number of patients on insulin pump therapy would be anticipated to increase with time and therefore this needs to be factored into a five year business plan.

Training of staff.

IPT requires staff specifically trained in IPT who will gain sufficient experience to deliver a high quality service. The multi-disciplinary team have been chosen consisting of a newly-appointed consultant physician, diabetes specialist nurse, dietitian as per NICE guidance (3) and a hospital practitioner. Experience from other well-established services in Cardiff and Bournemouth (13 and 14) have encouraged the local team to aim for a dedicated once monthly pump clinic, rather than being integrated to the current busy adult diabetes clinics, as is the current situation.

Three of the team have now attended a training day run by Roche (appendix 3) and this is planned to be revisited annually.

There is the issue of disseminating some aspects of IPT to other members of the multi-disciplinary diabetes team so consideration is being given to all these professionals attending pump training days.

In addition protocols of care need to be developed for all medical and non-medical professionals who come into contact with an 'insulin-pumper' to manage problems encountered with the patients, especially for casualty and ambulance staff.

There is also the possibility of establishing better links with the regional teaching hospital who currently provide the service for initiation of IPT, to gain from their expertise and experience, and possible sharing of their patient management pathways and other protocols.

Quality Assurance.

The service needs regularly reviewed to improve delivery of care, identify problems and to show that IPT does make a difference. This will be done through ongoing audit. To facilitate this initial medical parameters for each patient will be recorded, including initial HbA1C, weight, total daily dose of insulin, frequency and severity of hypoglycaemia, complications of diabetes and treatment satisfaction questionnaire – possibly the PAID (Problem Area In Diabetes Scale) questionnaire and then reassessed on an annual basis. The information will be used both as a reflective process for the pump service and to provide evidence to the financing Health Board of the clinical and cost-effectiveness of the service. The data obtained could be compared with the outcomes from other hospitals to achieve a uniform high standard of care and possibly to enable a sufficiently powered study for further evidence of efficacy of this relatively new treatment for diabetes.

For IPT to be an effective treatment not only has the provision of the service to be robust but there needs to be full patient participation as well. Careful patient selection is central to the success of pump intervention and the criteria need to be well defined. As in the Bournemouth experience (14) the selection criteria include patients who are well motivated and have realistic expectations as well as monitoring blood sugars regularly (at least four times per day) and demonstrate good self management skills. Clear patient exclusion criteria are needed and would include patients unwilling or unable to engage with the diabetes team, who did not attend clinic appointments, who had significant psychological problems or had drug or alcohol problems.

A low pump discontinuation rate of less than 5% (14) is suggestive of successful treatment selection. This could be a level to aspire to in the local service.

The barriers to an insulin pump service.

In the local diabetes service there has been a shortage of diabetes specialist nursing staff, which has only recently been addressed as well as chronic shortages in the dietetic service. This led to the 'BERTIE' structured education course for patients with type 1 diabetes being suspended.

The first step in managing problems in glycaemic control was to review the knowledge and skills of the patient and part of this process entailed attending the BERTIE course which was run over three days and had a capacity of eight patients per course.

It is anticipated that only patients who have undergone this course and still do not make progress with adequate glycaemic control or have problems with recurrent and severe hypoglycaemia would then be selected for a trial of IPT, in keeping with current NICE guidance (8).

A prerequisite for a local pump service will be the re-establishment of the BERTIE course using the recently enhanced DSN service and redeploying dietetic staff.

Other physicians in the trust who are unfamiliar with IPT have natural concerns over dealing with medical problems that patients with insulin pumps might present. It is anticipated that patients being admitted with insulin pumps would be admitted to the wards covered by the pump team and that written protocols of care will be published on the hospital intranet along with contact numbers for the pump team and the pump manufacturers.

There is evidence that the incidence of infection at the infusion site is low (2,11), the incidence and severity of hypoglycaemia is reduced (1,2,11) and the incidence of DKA is not increased (11), all of which were considered to be problems specifically associated with IPT. With careful patient selection and ongoing support for patients and professionals the problems specific to pump therapy can be minimized.

The Health Board face major restriction of funding in many areas and the application for funding pumps may be met with some concern. The emphasis in the application is on supplying the evidence for cost-effectiveness and that the pump team will apply good judgement and clinical discretion in their patient selection and so demonstrate careful use of limited resources.

The current NICE guidance is quite restrictive and excludes patients who may benefit from IPT, patients with type 2 diabetes or patients with special challenges in their lives, for example athletes and shift workers, who may benefit from the flexibility offered by IPT.

More research to produce evidence for the effectiveness of IPT in a variety of clinical settings is needed, and hopefully as pump technology develops the prices of pumps and consumables will decrease making it more acceptable to patients and the NHS fundholders.

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