The start of insulin pump therapy in UK clinical practice: A tribute to Sandra Dudley

This article is a legacy to one Diabetes Specialist Nurse (DSN) who "went the extra mile" and, quite simply, changed the lives of so many people with diabetes. The work of Sandra Dudley, DSN at Harrogate District Hospital, was the catalyst for the rapid expansion of continuous subcutaneous insulin infusion (CSII), or insulin pump therapy, in the UK from 2000 until the present day. In this commentary, we tell the story of how this happened and what needs to be remembered about her actions.

The beginning

In April 2000, an American gentleman attending the Diabetes UK (then the British Diabetic Association) conference in Harrogate walked into the diabetes office at Harrogate District Hospital. He asked if he could talk to someone about insulin pumps. He had type 1 diabetes and was using

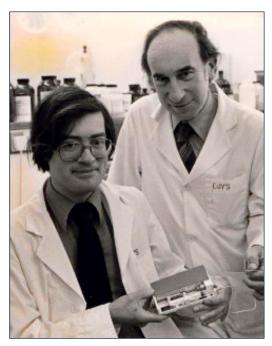


Figure 1. Professor John Pickup (left) and Professor Harry Keen in the 1970s holding an insulin pump in research.

a Disetronic insulin pump, and had come from the US to attend the conference to try and stimulate interest in the product. Unfortunately, he found it very difficult to find diabetes consultants who were receptive to pump therapy.

Previous attempts at using CSII had seen many problems, with poor outcomes and even loss of life for some patients (Centers for Disease Control, 1982). CSII was not commercially available and, since its invention, had only been used in research trials by the fathers of pump therapy, John Pickup and Harry Keen (*Figure 1*).

However, Sandra Dudley, DSN at Harrogate District Hospital (*Figure 2*), was intrigued and listened to what her visitor had to say. After hearing about his personal experiences, she was very excited and introduced him to Dr Peter Hammond, Diabetes Consultant at Harrogate, who is now well known across the world for his knowledge and expertise in CSII. Both Sandra and Peter could envisage the benefits of this new generation of insulin pumps. Technology had dramatically improved the safety, ease of use and size of the device.

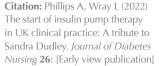


Figure 2. Sandra Dudley, DSN Insulin Pump Therapy Specialist, Harrogate Diabetes Centre.

Anne Phillips

Associate Professor in Diabetes Care, Birmingham City School of Nursing and Midwifery

Lorraine Wray Diabetes Specialist Nurse (retired), Harrogate Diabetes Centre



"Sandra Dudley took on the role of DSN with a special interest in CSII – the first role of this type in the UK – and she was the DSN who recruited and reviewed every participant in the Five Nations trial in Harrogate."

The start of CSII

From this meeting began the process of overcoming obstacles, finding like-minded medical professionals and also persuading an insulin producer to agree to its insulin being used with a pump. It was also imperative to conduct a trial to prove the that the pump was a viable and safe option. Sandra, with the support of Dr Hammond, put together a plan to take it forward. Initially, the insulin producer Eli Lilly & Co. was approached and agreed that its insulin could be used in the trial, and John Hughes, General Manager of Disetronic (now Advanced Therapeutics UK Ltd), became involved.

Dr David Kerr, Consultant Diabetologist, and Joan Everett, DSN, at Bournemouth Diabetes Centre agreed to take part, and the two diabetes centres formed a partnership to undertake the trial in the UK. This began the UK's involvement in the Five Nations trial, an open-label, randomised controlled crossover study conducted in eleven European centres (Hoogma et al, 2006a). The Five Nations trial used the H-TRONplus insulin pump and Humalog insulin.

To learn how to use CSII safely in order to teach participants in the trial, Peter, Sandra and Joan went to the Disetronic plant in the US to see the pump research, review the H-TRONplus (*Figure 3*), and also to see and hear how patients coped using this device.

The Five Nations trial began in 2000, enrolling selected volunteers who were having problems with their type 1 diabetes control. At that time, there was no shortage of participants willing to be involved.

Preparation for the trial and introducing CSII

It was agreed that an in-depth education programme would commence, involving all of the diabetes team – especially dietitians – to teach carbohydrate counting and the effects of illness, exercise and alcohol intake on blood glucose control, as the only insulin being used in the CSII was short-acting. Nowadays, healthcare professionals are used to this but, as this was the beginning, some education was required to ensure confidence and knowledge within each team at Harrogate and Bournemouth. Sandra took on the role of DSN with a special interest in CSII – the first role of this type in the UK – and she was the



Figure 3. The H-TRONplus insulin pump used in the Five Nations trial.

DSN who recruited and reviewed every participant in the trial in Harrogate. This required a lot of input initially, and Sandra gave every participant her mobile number and was on call 24 hours a day, 7 days a week.

There were some problems initially; however, the participants grew more confident in using the pump and adjusting insulin doses, and the trial was a resounding success. Participants were randomly allocated to either CSII or multiple daily injections for 8 months, and then switched to the other therapy for a further 8 months. At the end of the 16 months, every participant gave positive feedback and all opted to keep using CSII. This was a real step forward in bringing CSII to the UK.

Accounts from participants included one man who said the therapy had given him his wife back: she had lost her hypoglycaemia awareness and became very aggressive when hypoglycaemic. One day he had been caught in a lift with her when she became hypoglycaemic and she continually rammed their child's pushchair into his legs, causing a lot of trauma. Since switching to CSII she had been able to recognise her hypos, and her husband said the pump had probably saved their marriage. One participant reported having a much better pregnancy experience with her third child, while a teacher recounted that she no longer had to walk out of her class because she knew she was going hypoglycaemic. Other participants were able to take up sport again; the list of benefits was endless.

These initial reports on the effects of CSII on hypoglycaemia awareness, quality of life, and people feeling generally safer and well again were profound and had not previously been reported (Hoogma et al, 2006b).

Post-trial and roll-out for adoption across the UK

The year after the Five Nations trial was completed, the inaugural National Pump Meeting of medical professionals was held in Harrogate, hosted by Sandra, Peter, Joan and David (*Figure 4*). A lot of interest was sparked by this day, so afterwards Sandra started providing training days for healthcare professionals (HCPs) about CSII. Consultants and their teams attended these three-day courses from all over the UK. This was the very first education on CSII available to HCPs, and even the most sceptical, who had witnessed the previous failings of CSII, became some of the greatest converts to the therapy following this education. Sandra was such a motivator, and her knowledge and enthusiasm infected everyone around her.

At this time, a national need was identified for like-minded colleagues who were developing an interest in CSII to support other HCPs in specialist diabetes teams to consider introducing the technology and adopting it in their own centres. The Insulin Pump Therapy Forum was thus conceived and subsequently held study days and workshops across the UK to support others to consider CSII. The events supported HCPs to learn about how to commission, establish, structure, conduct and offer their CSII service thereafter.

As with most change, at the time, early innovators were keen to get started while other diabetes services could only see pitfalls and increased workload, and so were less keen. However, key names became involved in the forum, like Professors Rudy and Mary Bilous and Dr Fiona Campbell. This was the trigger to stimulate the momentum to spread CSII across UK diabetes services.

In 2008, the first NICE Technology Appraisal regarding CSII use was published, and this gave diabetes services the evidence to support CSII use and guided the national roll-out across all diabetes centres (NICE, 2008). Sandra was the DSN representative in the creation of this guidance. Thereafter, new pumps from different manufacturers began to appear in the marketplace.



Figure 4. The first National Pump Meeting in Harrogate. L–R: Dr David Kerr, Sandra Dudley, Joan Everett, Dr Peter Hammond.

Epitaph

What a legacy to leave. Nowadays, others can also claim to be centres of excellence, offering multiple choices of pumps and glucose monitoring technology, but we are very proud to have been colleagues of this amazing lady. Sandra had the guts to try anything to improve her patients' lives, never seeking praise or recognition but just getting on and doing a damned good job.

Sandra was respected by colleagues and patients alike, and we are fortunate to have been part of the introduction of CSII across the UK. From this very solid beginning, the rest is history.



Sandra Dudley Born 14th April 1948, died 28th May 2022

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