

The benefits of supplementary prescribing in CSII: A case study

Gill Morrison, Philip Weston

Article points

1. Many people with diabetes using continuous subcutaneous insulin infusion (CSII) have intricate care needs.
2. Theoretically, supplementary prescribing offers people who use insulin pump therapy, and the professionals providing care for them, a pathway that allows for efficient proactive management of complex care needs.
3. A system where nurses can easily make changes to therapy and immediately instigate treatment themselves has, in the authors' opinion, the potential to improve patient care, encourage holistic management and improve patient satisfaction.

Key words

- Continuous subcutaneous insulin infusion
- Supplementary prescribing
- Patient-centred care

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Evidence has shown that proactive management of glycaemic control and any actual or potential complications of diabetes is associated with a reduction in morbidity and mortality (UK Prospective Diabetes Study Group, 1998). The National Institute for Health and Clinical Excellence (NICE) criteria for guidance on the use of continuous subcutaneous insulin infusion for people with diabetes has encouraged the use of insulin pump therapy in people with complex glycaemic control requirements who may also have marked diabetes-related complications (NICE, 2003). In this article Gill Morrison and Philip Weston look at how the emergence of supplementary prescribing powers for nurses could benefit such people, citing a case study as an exemplar model.

Government policies regarding the modernisation of health care provision, such as the NHS Plan (Department of Health [DoH], 2000), emphasise the need for the organisation and delivery of NHS services to be patient-centred. In addition, the *National Service Framework for Diabetes: Delivery Strategy* (DoH, 2002) focuses on the provision of providing structured care in order to support people with diabetes to manage their condition and its related complications successfully.

Many people with diabetes using continuous subcutaneous insulin infusion (CSII) have intricate care needs; therefore, regular reviews are essential and should be held in a specialist insulin pump clinic by the diabetes specialist nurse (DSN) working in partnership with other members of the multidisciplinary diabetes team. In the authors' opinion, it is essential that any care plan endorses post-diagnosis review and encompasses educational topics relating to pump therapy such as cannula site management,

lifestyle issues and glycaemic control. It should also provide for the review of any complications related to the patient's diabetes and allow for assessment and management of any other health care needs such as pancreatic enzyme replacement. Inevitably such a strategy will lead to a review of medication that may, in turn, include a change in dose or therapy.

Prior to the development of the nurse prescribing initiative, the Medicines Act of 1968 was the primary legislation providing the legal framework for prescribing medication (Humphries and Green, 2002). This Act restricted prescribing to UK-registered doctors and dentists, thus effectively making these practitioners the 'gatekeepers' to pharmacological intervention. In a situation where there is greater flexibility in the workforce, and in who can review medication, repeat prescribe, adjust medication dosage or initiate pharmaceutical treatment, it would be logical to assume that the prompt instigation of therapy due to increased

access will benefit patients (Brooks et al, 2001). Also, as highlighted by both Luker and colleagues (1997) and Brooks and colleagues (2001), an additional positive feature of allowing nurses to prescribe is that it would allow both medical and nursing staff to work more efficiently as a result of the effective use of time.

An overview of prescribing options for nurses

Current prescribing options for nurses include patient group direction (PGD), independent prescribing and supplementary prescribing. When reviewing service provision it is essential to examine all avenues in order to apply the most effective prescribing mechanism for any given clinical situation.

Patient group direction

A PGD, formerly known as a group protocol, is defined as:

'A written instruction for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment. It is not a form of prescribing and there is no specific training that health professionals must undertake before supplying medicines in this way.' (DoH, 2004)

Essentially, this is a delegation of authority under section 58.2(b) of the 1968 Medicines Act by an appropriate practitioner (National Prescribing Centre, 2004). Nurses are one of the groups of healthcare professionals who can supply medicines to a patient on a PGD (NHS Executive, 2000). The PGD was developed in order to provide for emergency care and one-off situations – it was not designed to cope with the continuing care requirements of a chronic condition such as diabetes.

Independent prescribing

Independent prescribing is where:

'The prescriber takes responsibility for the clinical assessment of the patient, establishing a diagnosis and the clinical management required, as well as the responsibility for prescribing where necessary and the appropriateness of any prescription' (DoH, 2004)

The Medicines Act of 1968 restricts the prescribing of prescription-only medicines to 'appropriate practitioners' defined by the Act as registered medical, dental and veterinary practitioners. The Medicinal Products Prescriptions Act (as described in Humphries and Green, 2002) paved the way for 'certain' nurses to prescribe a limited range of products from a designated nurse prescriber formulary, providing they had completed a nurse-prescribing course and registered as a nurse prescriber with their professional regulators (NHS Executive, 1998). The nurse was required to be a first level nurse with a district nurse or health visitor qualification and authorised by their employer to prescribe.

A restrictive factor was that prescribing could only take place in a primary care setting with the nurse working in the role of a district nurse, health visitor or practice nurse. From a DSN perspective this method of prescribing is of little benefit, as many nurses would not be eligible to use it, as they do not hold a community nurse qualification and, in addition, practice is not usually confined to a primary care setting. Analysis of the current products listed in the nurse prescriber formulary indicates that it is very limited and it is not comprehensive enough to meet the intricate needs of people with diabetes.

Following a consultation document by the Medicines and Healthcare Products Regulatory Agency in July 2002 (Medicines and Healthcare Products Regulatory Agency, 2002), first level nurses or registered midwives, having followed a specific training programme, are now able to prescribe from the nurse prescribers extended formulary (DoH, 2003). The medicines to be prescribed by extended nurse prescribers include all general sales-list and pharmacy medicines. It also includes a list of prescription-only medicines, which cover areas of minor illness, minor injury, health promotion and palliative care. Unfortunately, the extended formulary does not satisfy the complex requirements of people on insulin pump therapy.

Supplementary prescribing

Following the recommendations of the second Crown Report (DoH, 1999) the Health

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3. Independent prescribing is where 'the prescriber takes responsibility for the clinical assessment of the patient, establishing a diagnosis and the clinical management required, as well as the responsibility for prescribing where necessary and the appropriateness of any prescription.'

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1. Supplementary prescribing may be described as 'a voluntary partnership between an independent prescriber (a doctor or dentist) and a supplementary prescriber to implement an agreed patient-specific clinical management plan with the patient's agreement.'
2. Good record keeping is an integral part of nursing practice and is also a legal requirement.
3. Nursing and Midwifery Council standards for record keeping apply specifically in relation to prescribing records: the date must be highlighted; the nurse prescriber's name included; and information indicating that a supplementary prescriber has generated the prescription documented.

and Social Care Act of 2001 has enabled supplementary prescribing by nurses to develop after they have had appropriate level 3 training and are registered with the Nursing and Midwifery Council (NMC). This option gives nurses the flexibility to treat polypathologically complex chronic conditions, such as diabetes, after initial assessment of the patient by a doctor.

Supplementary prescribing may be described as:

'A voluntary partnership between an independent prescriber (a doctor or dentist) and a supplementary prescriber to implement an agreed patient-specific clinical management plan [CMP] with the patient's agreement' (DoH, 2003)

There are no legal restrictions placed on the clinical condition that can be treated under supplementary prescribing although there is an expectation that supplementary prescribing will be the option of choice for chronic conditions. With the exception of controlled drugs there is no restriction on the range of medicines a supplementary prescriber can prescribe from.

The cornerstone to supplementary prescribing is the ability of the independent and supplementary prescriber to work in partnership in order to develop an appropriate CMP for a given clinical situation (NHS Modernisation Agency, 2005). These plans must be simple, must refer to the appropriate guidelines for the treatment of a condition and must also be flexible. At present it is the independent prescriber who takes responsibility for the diagnosis and setting the boundary of the CMP. Either of the prescribing partners must obtain consent from the patient and then, providing that the independent and supplementary prescriber both agree with the proposed care package, the healthcare professionals must sign the CMP. This management plan must be entered into the record shared with the independent prescriber, preferably within 24 hours.

A CMP must include the following information (DoH, 2006).

- Patient identification details.
- The range of medicines, doses and an indication of the conditions they are to be used

for.

- Criteria for referral back to the independent prescriber for review.
- The dates on which the arrangement will begin and be reviewed (this interval should not exceed one year).
- Any known patient sensitivities or adverse reactions to any medication.
- The plan for the notification of any adverse drug reactions.
- Evidence base behind the CMP.

Supplementary prescribing can be discontinued by the independent prescriber or at the request of the supplementary prescriber or patient. Where an independent prescriber is replaced the CMP must be reviewed by the successor.

Professional communication and documentation

Good record keeping is an integral part of nursing practice and is also a legal requirement (Anderson, 1995). Good communication between healthcare professionals is essential for high-quality healthcare provision (DoH, 1989). In the authors' opinion, effective record keeping in relation to prescribing is an efficient means of disseminating information within the team.

NMC standards for record keeping apply specifically in relation to prescribing records (NMC, 2002): the date must be highlighted; the nurse prescriber's name included; and information indicating that a supplementary prescriber has generated the prescription documented. Details should also include the medication, its dose, frequency and duration of treatment along with the consultation details. Nurses using separate notes have a responsibility to ensure this information is entered into the independent prescriber's medical records as soon as possible.

Practical application: Using supplementary prescribing in CSII

Theoretically, supplementary prescribing offers people who use insulin pump therapy, and the professionals providing care for them, a pathway that allows for efficient proactive management of complex care needs. However, it is only by the application of this method into daily practice

that its true strengths and weaknesses will be identified.

Case Profile

ND is a 28-year-old gentleman who was seen jointly in the insulin pump clinic by the DSN and consultant diabetologist. He has had type 1 diabetes for 20 years and has, over time, developed complications including hypertension, hypercholesterolaemia and microalbuminuria. ND has no other known medical conditions or allergies. His current medication includes lisinopril 5 mg od and simvastatin 20 mg nocte, and his concordance with medication is good. He drinks approximately 10 units of alcohol per week and has never smoked. ND follows a healthy eating plan as assessed by the dietitian. He lives with his partner and works as a self-employed plumber. Apart from normal work and home activities no exercise is taken.

In keeping with NICE (2003) criteria, ND was converted on to CSII using insulin lispro because disabling episodes of hypoglycaemia adversely affected the quality of his life despite a high level of self-care and an optimised insulin regimen. His HbA_{1c} results were also above target, placing him at increased risk of the complications of diabetes (Diabetes Control and Complications Trial Research Group, 1993).

Six months later, on review, his HbA_{1c} was sub-optimal at 7.4%, hypoglycaemic episodes were infrequent, accountable, recognised and appropriately treated. ND monitored his blood glucose levels approximately 4–5 times per day with glycaemic trends ranging from 5.5–11 mmol/l. Daily insulin requirements were:

- 1 unit of lispro per 10 g of carbohydrate
 - correction ratio of 1 unit for a 2.5 mmol/l reduction in blood glucose
 - set basal rate 16.7 units
 - average total daily insulin dose of 46.7 units.
- No episodes of pump failure had occurred.

Physical examination, which included review of infusion sites, retinal screening and peripheral vascular/neurological examination, revealed no abnormalities. No episodes of infected cannula sites were reported. ND's blood pressure was, however, elevated at 144/92 mmHg. His weight remained steady at 78 kg (body mass index:

25 kg/m²). Urine dipstick urinalysis revealed no abnormalities.

Biochemistry values showed ND's cholesterol was elevated at 6.6 mmol/l and the albumin creatine ratio was raised at 7. Urea and electrolytes, liver function and thyroid function tests were normal.

Following a consultation using the Pendleton model (Pendleton et al, 1984), which allows the practitioner and patient to work in partnership by encouraging discussion of the patient's concerns and expectations in order to find a solution satisfactory to all parties, an initial plan was developed:

- simvastatin was increased to 40 mg nocte for lipid management
- lisinopril increased to 10 mg od for control of hypertension and management of microalbuminuria.

In partnership with the patient, independent and supplementary prescribers, a CMP was devised which would allow for the ongoing management of ND's diabetes, insulin pump therapy and other clinical conditions (*Appendix 1*). Consent from the patient was obtained.

Key components of the proposed CMP included the following.

- Treatment must be evidence-based and not necessarily pharmaceutically driven.
- Consent and agreement of the independent prescriber, supplementary prescriber and patient.
- Type 1 diabetes managed with CSII and currently associated with sub-optimal glycaemic control.
- Hypertension.
- Microalbuminuria.
- Hypercholesterolaemia.

Obviously non-nurse prescribers can care for people with diabetes on insulin pump therapy, but, in order to fulfill legal obligations, any pharmaceutical intervention requires a medical prescription. A system where nurses can easily make changes to therapy and immediately instigate treatment themselves has, in the authors' opinion, the potential to improve patient care, encourage holistic management and improve patient satisfaction.

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1. Obviously non-nurse prescribers can care for people with diabetes on insulin pump therapy, but, in order to fulfill legal obligations, any pharmaceutical intervention requires a medical prescription.
2. A system where nurses can easily make changes to therapy and immediately instigate treatment themselves has, in the author's opinion, the potential to improve patient care, encourage holistic management and improve patient satisfaction.
3. Diabetes specialist nurses working in partnership with people utilising CSII will be familiar with the evidence base regarding both insulin pump therapy and general diabetes management.

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1. As the diabetes specialist nurse will have regular contact with the pump user, the accepted use of supplementary prescribing is one avenue by which diabetes management can be optimised for these patients.
2. Although supplementary prescribing provides an ideal opportunity to enhance the care, it is very much dependent on an effective working relationship between the independent and supplementary prescribers.
3. Providing there is an encouraging environment, and adequate support from medical colleagues, professional bodies and employers, it is the authors' view that supplementary prescribing will serve to benefit patients.

Conclusion

DSNs working in partnership with people utilising CSII will be familiar with the evidence base regarding both insulin pump therapy and general diabetes management. As the DSN will have regular contact with the pump user, the accepted use of supplementary prescribing is one avenue by which diabetes management can be optimised for these patients.

Although supplementary prescribing provides an ideal opportunity to enhance care, it is very much dependent on an effective working relationship between the independent and supplementary prescribers. Extending practice that encompasses elements of prescribing undoubtedly brings greater accountability and responsibility for the nurse, therefore nurses must be prepared to develop professionally and acquire new skills.

In keeping with the code of professional conduct, nurses must ensure they possess the expertise to prescribe and are aware of their limitations. Providing there is an encouraging environment, and adequate support from medical colleagues, professional bodies and employers, it is the authors' view that supplementary prescribing will serve to benefit patients.

The Department of Health recently announced that, from spring 2006, qualified extended formulary nurse prescribers will be able to prescribe any licensed medicine for any medical condition, except controlled drugs (DoH, 2005). However, nurse prescribers will still have to work within their employer's clinical governance frameworks and will be accountable to both their employers and their regulatory bodies for their actions. Although doctor representative organisations have voiced criticism and intend to lobby against changing the necessary legislation, the widening of prescribing should prove even more effective and popular with patients. In the area of diabetes care, where there is overlap of clinical areas due to multiple pathology, the greater flexibility will allow patients to easily access the medicines they need. ■

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Appendix 1. Clinical management plan for a 28-year-old man with type 1 diabetes. Personal details not included.

Condition(s) to be treated <ul style="list-style-type: none"> ● Diabetes requiring CSII or S/C insulin injections ● Hypertension ● Microalbuminuria ● Hypercholesterolaemia ● Infected cannula site 		Aim of treatment <ul style="list-style-type: none"> ● Target HbA_{1c} ≤7% without causing episodes of hypoglycaemia ● Pre-meal blood glucose values 4–7 mmol/l ● Post-meal blood glucose values up to 9 mmol/l ● Target blood pressure 120/70 mmHg ● Cholesterol ≤4 mmol/l ● Reduce the risk and impact of diabetes related complications ● Resolution of any site infection 	
Treatment plan <ul style="list-style-type: none"> ● Lifestyle modification – encourage regular exercise and healthy eating plan ● Education regarding insulin pump management and diabetes ● Target complication risk factors ● Improve glycaemic control by modification of the current insulin regimen ● In the event of insulin pump failure manage glycaemic control ● Titration of antihypertensive medication and add in other agents as necessary in order to achieve blood pressure targets ● Achieve cholesterol targets in combination with a healthy eating plan titration of lipid lowering therapy and switch medication as required ● Monitor for untoward side effects of therapeutic intervention or any drug interactions ● Review compliance and concordance with therapy 			
Indication	Preparation	Dose schedule	Referral back to IP
Diabetes requiring insulin	Insulin ± oral hypoglycaemic agents (OHAs) OHAs per the BNF	Increase or decrease insulin doses to achieve glycaemic targets	Adverse reaction Failure to optimise glycaemic
Infected cannula site	Antibiotics	As per the BNF	Adverse reaction Infection deteriorates or fails to resolve
Hypertension	ACE inhibitors Thiazide diuretics Beta blockers Angiotensin II receptor antagonists Calcium-channel blockers	As per the BNF Royal Liverpool University Hospital guidelines for the management of hypertension and hypercholesterolaemia in patients utilising CSII	Deterioration in renal function Blood pressure not in target range using 3 agents
Hypercholesterolaemia	Statins	As per the BNF Royal Liverpool University Hospital guidelines for the management of hypertension and hypercholesterolaemia in patients utilising CSII	Adverse reaction Cholesterol targets not achieved
Review and monitoring Supplementary prescriber <ul style="list-style-type: none"> ● Phone review as indicated ● Follow up at nurse led clinic 3-monthly or as indicated ● Six- to 12-week assessment of blood pressure until target, there after 3-monthly ● Review cholesterol levels 1- to 3-monthly until target achieved, thereafter bi- annually 		Supplementary and independent prescriber <ul style="list-style-type: none"> ● Annually or as indicated 	
Process for reporting ADRs <ul style="list-style-type: none"> ● Record in the patients records ● Discuss with independent prescriber ● Report to pharmacy ● Yellow card system 			
Documentation and record keeping <ul style="list-style-type: none"> ● Copy of clinical management plan to be kept in the patient's case notes and CSII record ● Changes in medication to be documented in CSII patient record, case notes and GP to be informed by letter ● Consultations and phone contact to be recorded in the CSII patient record ● Three-monthly DSN review summary and any independent prescriber review in the case notes and GP informed by letter 			
Guidelines supporting SP treatment plan <ul style="list-style-type: none"> ● DCCT (1993) ● NICE Guidelines (2003) <i>Type 1 diabetes: diagnosis and management of Type 1 diabetes in primary and secondary care</i> ● NICE Guidelines (2003) <i>Guidance on the use of continuous subcutaneous insulin infusion for diabetes</i> ● British Hypertension Society guidelines 2004 ● Royal Liverpool University Hospital guidelines for the management of diabetes ● Royal Liverpool University Hospital guidelines for the management of CSII ● Royal Liverpool University Hospital guidelines for the management of hypertension and hypercholesterolaemia in patients utilising CSII ● Royal Liverpool University Hospital drugs formulary ● British National Formulary 			