BMJ Open Adult parenteral nutrition in the North of England: a region-wide audit

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ABSTRACT

Objectives: Parenteral nutrition (PN) is widely used to provide nutritional support to patients with inaccessible or inadequate length of gut or non-functioning gut. The objective was to compare practice in PN administration to results of the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report, 'A Mixed Bag', and to establish whether good practice was being followed within this part of the UK. **Setting:** Using the Northern Nutrition Network (NNN), we examined the care of adult patients receiving PN in all 10 secondary care hospitals in our region.

Participants: All patients receiving PN were included with no exclusions. Data were collected on 192 patients (51% females, median age 65 years (range 18–96)).

Outcome measures: A data collection tool was designed based on the recommendations of the NCEPOD report.

Results: PN was used for a median of 7 days with a 30-day mortality rate of 8%. Metabolic complications occurred in 34%, of which only 13% were avoidable. The catheter sepsis rate was 1.5 per 1000 PN days. The audit suggests that nutrition team input improves patient assessment prior to starting PN and review once PN is established. Risk of refeeding syndrome was identified in 75%. Areas for improvement are documentation of treatment goal (39%), review of PN constitution (38%), ensuring patients are weighed regularly (56%) and documentation of line-tip position (52%).

Conclusions: This region-wide prospective audit suggests improved practice within the UK compared to the NCEPOD audit with lower mortality and line sepsis rates. However, documentation remains suboptimal. This work strengthens the case for introducing nutrition teams in hospitals without this service. These findings are likely to be reproduced across the UK and in other healthcare settings. We provide a template for similar audits of clinical practice.

BACKGROUND

Parenteral nutrition (PN) is widely used to provide nutritional support to patients with inaccessible, inadequate length of gut or non-functioning gut (intestinal failure). However, PN can have potentially fatal complications and patients require an accurate

Strengths and limitations of this study

- This type of region-wide review of clinical practice is key to improving patient care in complex areas of healthcare delivery such as parenteral nutrition (PN).
- The Northern Nutrition Network includes a range of hospital trusts in terms of size of population served, frequency of use of PN and level of consultant expertise in nutrition.
- Dissemination of the audit results will hopefully help to improve equity of care across the region.
- The advantages of this type of team approach can be to develop robust, evidence-based protocols.
- Data collection was retrospective and completeness of the audit relied on local reviewers identifying all patients who received PN in their hospitals.

assessment of nutritional requirements, dedicated intravenous access and careful monitoring for electrolyte imbalance and changing nutritional requirements. The importance of multidisciplinary nutrition support teams has been described. There are national and international (ESPEN; European Society for Clinical Nutrition and Metabolism) guidelines for nutritional support in adults. The American Society for Parenteral and Enteral Nutrition (ASPEN) has recently highlighted the need for frameworks to guide institutions in developing and maintaining competencies for safe PN due to its complexity and likely increasing use of this feeding route.

In 2010, there was a UK National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report focused on PN, 'A Mixed Bag'. The primary aim of the study was to examine the process of care of patients receiving PN in hospital in order to identify remediable factors in the care received by these patients. There were six main themes in the report: indication for PN, type of PN, PN prescribing, catheter choice, insertion and care, complications and nutrition teams. 'A Mixed Bag' found that only 19% of adult patients who had PN



care considered to represent good practice. The response rate in this national audit was 49% (questionnaires and case notes returned). This report has focused attention on the in-hospital use of PN within all parts of

The Northern Nutrition Network (NNN) was established in 2003 and is a collaboration of North East-based multidisciplinary nutrition teams, including physicians, surgeons, dieticians, nurses, pharmacists and biochemists, consisting of nine acute trusts including North Cumbria. The NNN has previous experience of conducting region-wide audits with high response rates. 10

AIMS AND METHODS

The aim of this study was to compare practice in the administration of PN in hospitals in the North of England to results of the recent NCEPOD study and whether there had been any improvements in care since that audit. The hospitals in our region serve a population of ~2.7 million people. Our findings are likely to be similar to those in different parts of the UK and other healthcare settings and may provide a template for other prospective audits of care.

Using the NNN, we examined the assessment, administration, delivery and monitoring of adult patients receiving PN in our region. PN was defined as intravenous fluids for nutritional support beyond standard intravenous crystalloid fluids. All hospitals in Northern England were invited to participate. A data collection tool was designed by the NNN based on the recommendations from the recent NCEPOD report (see online supplementary data) collecting information on five aspects of PN care: patient and admission details, indication for PN, patient assessment, venous access/line care and metabolic complications.

Our tool was slightly simplified from that used in the NCEPOD report in order to maximise participation in the audit with less focus on the location of the patient. Data were collected by a member of the clinical care team (doctor, dietician or nutrition specialist nurse) at each participating hospital on all adult patients receiving PN in participating centres over a 3-month period from June to August 2013. All members of the data collection team were given training in the use of the data collection tool via the NNN. Local reviewers (different to the independent reviewers of NCEPOD) were asked to judge whether metabolic complications were avoidable. The data collection for NCEPOD occurred in 2008; so, there was no overlap with this audit. The aim of this audit was to assess whether hospitals in the NNN are providing PN in line with the standards outlined in the NCEPOD report, 'A Mixed Bag'. No patient identifiable information was collected, there was no change to direct patient care as a result of the data collected and individual patient consent was not required. As this work is audit, rather than research, a favourable ethical opinion from an NHS Research Ethics Committee (REC) was not

required, in line with guidance from the NHS Health Research Authority. Statistical analysis was performed using two-tailed Fisher's exact test, SPSS, V.21 with a significance level for statistical comparison of p<0.05.

The NCEPOD report asked Advisors to make an assessment of the quality of care delivered to adult patients receiving PN and grade it as: good, room for improvement (clinical, organisational, clinical and organisational) or less than satisfactory. It is difficult to repeat these assessments in a different cohort given the subjective nature of these measurements and the fact that local reviewers were collecting data and submitting the information to the authors. Therefore, we decided not to make a global assessment but to assess specific aspects of PN care.

RESULTS

There were 10 participating centres and 192 proformas were returned (94 males, 98 females). The median age of patients was 65 years (range 18-96). The total number of PN days included in the audit was 2007 with the median duration of PN being 7 days (range 1-66). Using the ESPEN functional classification of intestinal failure, 11 there were 168 (91%) patients with type I intestinal failure (acute, short-term and usually self-limiting condition requiring PN for <28 days) and 16 (9%) patients with type II intestinal failure (prolonged acute condition, often in metabolically unstable patients, requiring complex multidisciplinary care and intravenous supplementation for ≥28 days). This information was unavailable for eight patients. Weight on admission was documented in 95%: median 69 kg (range 29–156). Height was documented in 84%: median 1.67 m (range 1.5–1.9). It was possible to calculate the body mass index in 83%: median 24.9 kg/m^2 (range 10.3-48.8).

The types of admission were emergency admission 76.0%, planned/elective 19.3%, inter-hospital transfer 2.6% and unknown in 2.1%. An initial trial of enteral nutrition (EN) was not possible in 58%, was unsuccessful in 26%, dual therapy was given in 6% and there was no documentation about EN in 10%. The clinical indications for PN are shown in table 1.

Patient assessment

The decision to start PN was made by a doctor or doctor and dietician in 91% of cases (table 1). Only 28% of the clinicians making the decision to start PN were a member of a multidisciplinary nutrition team. The indication for PN was documented in the clinical notes in a 80%. A nutrition team was involved in the decision to start PN in 38% of cases. However, only 5 (50%) of the participating hospitals in Northern England have a nutrition team in place. Of patients who received PN in a hospital where a nutrition team exists, 65% of cases had involvement of the nutrition team. The treatment goal was documented only in 39%. In hospitals with a nutrition team, 60 of 93 (65%) of patients with type I and 9 of 11 (82%) patients with type II intestinal failure had nutrition team involvement.

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Indication	No. of patients	Per cent	Per cent in NCEPOD
Postsurgical complications/ileus	66	34.3	27
Obstruction	29	15.1	10
Perforated/leaking gut	26	13.5	8
Non-functioning gut	15	7.8	9
No access for enteral nutrition or failed EN	29	15.1	13
Malabsorption	7	3.7	2
Crohn's disease	6	3.1	1
Short bowel	3	1.6	2
Cancer	2	1.0	3
Other	9	4.8	25
Assessment prior to starting PN	Number of patients who had this form of assessment	Per cent	
Nutritional assessment	166	87	
Clinical assessment	166	87	
Standard electrolytes*	154	80	
Anthropometry†	68	35	
Nutritional requirements	149	78	
MUST‡	98	51	
Oral intake	90	47	
Other	31	16	
Risk of refeeding§	144	75	50
Decision to start PN		Per cent	Per cent in NCEPOD
Doctor		54	49
Doctor and dietician		37	22
Dietician		3	4
Doctor, dietician and other		1	15
Unknown		5	3

EN, enteral nutrition; NCEPOD, National Confidential Enquiry into Patient Outcome and Death; PN, parenteral nutrition.

Other

Once the decision to start PN had been made, 84% of patients received PN within 24 hours. By far the commonest reason for the delay was difficulties with obtaining intravenous access (83%). It was not possible to establish the time of day when PN was started in 42%. However, for patients where this was clearly documented, 82% were started during daytime working hours (0800–2000 hours). The majority (88.5%) were started on PN during the working week (Monday to Friday). Only 9.9% of PN was started at a weekend or on a bank holiday. This information was unavailable for 1.6%.

Table 1 shows the forms of assessment that were documented in patient notes prior to starting PN. There were no electrolyte abnormalities prior to starting PN in 14% of patients and this information was unavailable for 12%. Of the 74% who had documented electrolyte abnormalities, they were appropriately corrected (to within standard normal ranges) in 55% prior to starting PN.

Type of PN

The type of PN first given was documented in 98% and all but 1 patient were given 'off-the-shelf' multichamber bags

with (49%) or without (49%) additives. The PN prescription was documented in the notes in 81% and documentation was assessed as adequate in 78%. This was defined as stipulating a specific 'off-the-shelf' bag or a locally manufactured 'bespoke' bag with defined constituents.

Vascular access and complications

The type of intravenous access used for PN was documented in the notes in 87% of patients. The type of access used was central line 53%, midline 22%, standard dedicated peripheral cannula 21%, PICC line 2% and unknown in 2%. Insertion of the feeding line was documented in the notes in 75%. The use of aseptic technique was recorded in 67%. Radiographic confirmation of position of the line tip was documented in the patient notes in only 52% of centrally placed catheters. The grade and job description of person inserting the line were documented in 55%.

Line complications occurred in 29 patients (15%). We used a definition of line infection adapted from the ESPEN guidelines¹² and National Healthcare Safety Network (NHSN) surveillance definitions.¹³ Three patients suffered a systemic line infection giving a line

^{*}Standard electrolytes=Sodium, potassium, magnesium, phosphate.

[†]Anthropometry=grip strength and triceps skinfold thickness.

[‡]Malnutrition Universal Screening Tool. 16

[§]Based on NICE guidance.²

sepsis rate of 1.5 per 1000 PN days. Administration of PN was interrupted due to line complications in 8% of patients. Table 2 shows the types of line complications encountered by patients.

Monitoring after initiation of feeding

Following the initiation of PN, 88% of patients were reviewed by a doctor and at least 1 other member of a multidisciplinary team (dietician, nutrition nurse or pharmacist). Only a doctor reviewed 8% of patients and only a dietician reviewed 2% of patients. This information was not available for 2%. Nearly a third (32%) of patients were reviewed daily (7 days a week), 35% were reviewed daily (Monday to Friday) and 28% were seen 3-4 days/week. The remaining 6% of patients were seen <1-2 times/week regarding their PN.

Metabolic complications

Metabolic complications were encountered in 43% of patients; 13% of these were felt to have been avoidable. Local reviewers judged that 94% of metabolic complications were managed appropriately. Table 2 shows the metabolic complications that patients experienced. We included abnormal liver function tests (LFTs) as a metabolic complication. However, if this is excluded (as in the NCEPOD audit), then the complication rate was 34%.

Intravenous vitamins and fluids

Additional intravenous vitamins were given in 51% of patients. Intravenous fluids were given in addition to

Table 2 Types of line and metabolic complication	otione	

Table 2 Types of life and	Table 2 Types of life and metabolic complications						
	No. of patients	Per cent	Per cent in NCEPOD				
Type of line complication							
Line misplacement/	9	5	3				
accidental removal							
Line occlusion	4	2	2				
Local line site infection/	4	2	10				
phlebitis							
TPN extravasation	4	2	1				
Other	3	2	1				
Systemic line infection	3	2	5				
Not documented	2	1	16				
Type of metabolic complication							
Abnormal LFTs	35	18	Not				
			documented				
Hypomagnesaemia	23	12	10				
Hypophosphataemia	18	9	18				
Hypokalaemia	16	8	11				
Hyponatraemia	14	7	6				
Hyperphosphataemia	9	5	4				
Hyperkalaemia	8	9	4				
Hypermagnesaemia	3	2	3				
Hypernatraemia	3	2	3				
- Hyperglycaemia	1	1	8				
LET liver function test: NCEP	OD National	Confide	ential Enquiry				

LFT, liver function test; NCEPOD, National Confidential Enquiry into Patient Outcome and Death; TPN, total parenteral nutrition. PN in 70% of patients. Fluids were given to correct deficit in 36% and as routine maintenance fluid provision in 24%. No indication was documented in 39%. The commonest fluids used were normal saline and compound sodium lactate (Hartmann's solution). The audit did not include an overall assessment of volume of PN administered, fluid losses and the volume of intravenous therapy (IVT) given. However, 28% of patients were given more than 2 L of IVT every 24 hours while also receiving PN.

PATIENT OUTCOMES

In our audit, at 30 days, 83% of patients had returned to oral or EN, 4% had been discharged on home PN and 2% continued on inpatient PN. There was an overall 30-day mortality rate of 8%. Cause of death was unavailable in 56%, but 13% died in a hospice setting after PN had been withdrawn and 31% died of sepsis with multiorgan failure.

Role of nutrition teams

We examined some parameters indicating good care of the cohort in terms of whether a member of a nutrition team was involved in the care of the patient (table 3). There was a clear difference in the assessment of patients starting PN and documentation of nutritional goals. The total number of line complications was 13 per 1000 catheter days in the group where nutrition teams were involved compared to 20 per 1000 catheter days in patients without nutrition team involvement.

DISCUSSION

In our region, we established the NNN in 2003 with the aim of improving outcomes for patients in need of nutritional support. Part of the role of the NNN is to conduct region-wide audits and this review of the use of PN in our region is one example of the NNN in action. All centres that are part of the NNN (n=10) participated in the audit.

We have considered the individual recommendations made by the NCEPOD report 'A Mixed Bag' and reviewed our findings in the context of these:

1. PN should only be given when EN has been considered, and excluded, as either inappropriate and/or impracticable.

In the national report, inadequate consideration was given to EN in a third of patients. This is compared to 10% of patients in this audit where consideration of EN was not documented. We found that an unsuccessful trial of EN was used in 26% which is much less than the 52% seen nationally.

2. Where the possibility exists that a patient may require PN, this should be recognised early. Subsequently, should PN become a clinical necessity, this should be rapidly actioned and PN started at the earliest opportunity. However, there is rarely, if ever, an indication to start adult PN out of normal working hours.

PN, parenteral nutrition.

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In our audit, 88.5% were started on PN during the working week (Monday to Friday) which is comparable to the 84% seen in the national report. The time of day when PN was started was not recorded in 42% but when it was, PN was started between 0800 and 2000 hours in 82%. This is again similar to the 79% in the national study. There was an unreasonable delay in starting PN once the need was recognised in 9% in the NCEPOD report. In our region, 84% of patients received PN within 24 hours of the decision being made to start the treatment and 98% within 48 hours.

3. Patient assessment should be robust to ensure that PN is the appropriate nutritional intervention and that adequate PN is administered. The clinical purpose and goal of the PN should be documented.

The indication for PN was documented in the clinical notes in 80% but the treatment goal was documented only in 39% (as compared to 53% nationally). The median duration of PN was 7.5 (range 1-62) days if a nutrition team was involved and 6 (1-66) days if no nutrition team involvement. This compares with a median of 12.2 days nationally. In our cohort, 20% of patients received PN for 3 days or less, which raises the question about whether PN was necessary. Alternatively, the clinical condition of patients may have changed more rapidly than anticipated.

4. Regular documented clinical monitoring, of the patient and PN prescription, should be mandatory. Monitoring should include daily weights (where possible) and documentation of the success of the PN within the overall clinical picture.

The constitution of PN was not reviewed in 38% of patients in our audit. The majority of patients underwent daily review of their clinical status (88%) and ongoing need for PN (86%). In our region, daily

weights are not carried out as routine practice; 56% of patients were weighed once a week or more frequently. This is in line with NICE guidelines from 2006² that advise that patients should be weighed daily if there are concerns regarding fluid balance, but otherwise this can be reduced to weekly for clinical monitoring in patients requiring nutritional support. It was not possible to weigh patients in level 3 care (those receiving advanced respiratory support alone or receiving a minimum of two organ support). 14 In the NCEPOD report, there were deficiencies in the assessment and monitoring of clinical and biochemical status in 56.7% of patients.

5. Regular documented biochemical monitoring should be mandatory to ensure avoidable metabolic complications never occur.

Routine biochemistry was checked daily in 90% of our patients. In the NCEPOD report, metabolic complications occurred in 40% of patients and were judged to be avoidable in 49%. A very similar incidence of metabolic complications was seen in our cohort (43%), but only 13% were felt to have been avoidable. The primary aim of this aspect of the audit was to describe complications of PN. We asked, as in NCEPOD, whether these were avoidable. However, this is a subjective judgement by a member of the team involved and so may be an underestimate. Risk of refeeding syndrome was documented in 75% of patients in our cohort (cf. 50% nationally). However, in the national audit, abnormal LFTs were not included as a 'metabolic complication'. If we exclude abnormal LFTs, then 34% experienced metabolic complications in our cohort, which compares favourably with the national audit.

6. Additional intravenous fluids should only be prescribed where there has been an active assessment of the volume of PN already being administered and

In the NCEPOD report, additional intravenous fluids were given to 75% of patients compared to 70% in our local audit. We found that 28% of patients may have received excess additional fluids which is the same as seen nationally. Documentation of the reasons for additional fluid administration was poor, and this makes it difficult to comment on whether the administration of additional fluids was appropriate. This aspect requires further evaluation as total fluid losses and fluid balance were not recorded.

7. CVC insertion should be clearly documented in the case notes, including the type of line and confirmation of position of the catheter tip.

Attempts to reduce line sepsis over recent years have emphasised the importance of careful aseptic technique which is properly documented. 15 In our audit, the type of intravenous access used for PN was documented in the notes in 87% and insertion of the feeding line was documented in the notes in 75% (compared to 67% nationally). Thrombosis complicating longer term central lines is higher when the line tip is in the proximal superior vena cava and so documentation of line tip is strongly recommended. Position of the line tip was documented in 52% locally and 45% nationally. Overall line complications occurred in 29 patients (15%) which is significantly lower than 26% in the NCEPOD report.

The benefits of nutrition teams have been widely discussed. The NCEPOD report found that, when the overall PN-related care was correlated with whether nutrition teams were involved in the initial decision to give PN, there was a difference seen in the good practice (27.4% vs 15.2%) and less than satisfactory (7.0% vs 11.5%) categories but very little difference in the middle ground represented by the other categories. They could not identify a clear benefit of nutrition teams in terms of good overall care, but this was attributed to grading being based on a large number of parameters and NCEPOD still support a multidisciplinary team approach to PN. It is difficult to assess the direct impact of nutrition teams as patient care is multifactorial. Table 3 shows parameters indicating good care for the cohort in terms of whether a member of a nutrition team was involved in the care of the patient. Assessment prior to starting PN, daily PN and vascular access review, treatment goal documentation and reporting of metabolic complications were greater with nutrition team involvement than without. Interestingly, the reported metabolic complications were significantly higher in the group under review by a nutrition team. This may be due to nutrition teams being involved in the care of higher risk, more complex patients. In our audit we also included abnormal LFTs as a metabolic complication unlike in the national audit. Nationally, 40% of hospitals that administer PN to adult patients do not have a nutrition team and this is slightly higher in Northern England (50%). In our region, even in hospitals with a nutrition team, 35% of patients did

not have multidisciplinary nutrition management. This is clearly an area to focus on. In our audit, 91% of patients had type I and 9% had type II intestinal failure. Nutrition teams appear to be more involved with the complex type II patients, with 82% having nutrition team involvement, as compared to 65% of type 1 patients.

It was reassuring to see that the majority of patients started PN during the working week and during 'normal' hours. This demonstrates a good understanding within the clinical teams that PN is not an emergency intervention and suggests that nutritional assessments are being carried out in a time-appropriate manner. The NICE guidance states that all 'off-the-shelf' multichamber bags of PN should have vitamins added prior to administration.² This was only the case in approximately half of cases in our audit and highlights another area for improvement.

Other strengths within our region demonstrated by the audit are the identification of risk and prevention of refeeding syndrome and a favourable catheter sepsis rate in comparison to national figures.

Areas which we should look to improve regionally are:

- Documentation of treatment goal
- Review of the constitution of PN once started
- Ensuring patients are weighed regularly where this is possible
- Better education of clinicians about fluid balance and need for additional intravenous fluids in the context of concurrent PN
- Documentation of position of line tip
- Improvement in the quality and consistency of documentation related to PN.

This work can be compared to a previous audit published by the NNN in 2007 examining the use of PN in hospitals in the North of England. 10 The study group were very similar with 193 PN episodes being included and a median patient age of 67 years. There has been a dramatic improvement in the rate of line infections from 12% to 4% (including local line site infection/ phlebitis and systemic line infection). This represents a decrease from 21 to 3.5 per 1000 catheter days. There has also been a decrease in overall mortality rates from 20% at 28 days to 8% at 30 days. The NCEPOD reported an overall mortality in adults of 26% with little difference as to whether patients had received PN for more or <14 days. In 1997, 33% of hospitals in Northern England had a nutrition team and this has increased to **Q** 50% in 2015.

There are limitations with this study. Patients were identified prospectively, but data collection were retrospective which led to some difficulties in obtaining information due to poorly filed notes and practical problems locating the information required, for example, intensive care charts. The accuracy of the data collection depends on the individual completing the proforma. Some respondents did not complete all the fields on the proforma. The completeness of the audit relied on local

reviewers identifying all patients who received PN in their hospitals during the study period. It is likely that some patients were not identified. However, most centres felt that all patients had been identified and others felt that only a very small number of patients receiving PN were not identified. We believe that the completion rate has been considerably >90% for all patients receiving inpatient PN in the region in the 3-month period. Some of the data fields relied on local reviewers making an assessment of 'avoidable' or 'appropriateness', which opens the audit to individual variation in clinical opinion. However, all members of the data collection team and reviewers were given training in the use of the data collection tool via the NNN and were experienced members of multidisciplinary nutrition teams and involved in managing patients receiving PN.

This type of region-wide review of clinical practice is key to improving patient care in complex areas of healthcare delivery such as PN. The NNN includes a range of hospital trusts in terms of size of population served, frequency of the use of PN and the level of consultant expertise in nutrition. The sharing of knowledge and expertise is one of the strengths of the NNN and results of this audit will hopefully lead to improvements in patient care across the network to help deliver equity of care across the region. The results of this audit reveal areas where we need to improve the care of adult patients receiving PN. Individual centre results have been fed back to the clinical teams to highlight particular strengths and weaknesses. The advantages of this type of team approach can be to develop robust, evidence-based protocols. The results of this audit have been presented to the NNN and a repeat audit cycle will be completed after the implementation of targeted education and revised local protocols. It is also hoped that the results of this work will help strengthen the case for introducing nutrition teams in the 50% of our hospitals which do not currently have this service. The results of this audit may relate to the North of England; however, the lessons to be learnt are likely to be generalisable to other areas of the UK and other healthcare systems.

CONCLUSIONS

A 3-month region-wide prospective audit was performed with all centres contributing and with a high completion rate. The outcomes suggest improved PN care with fewer line complications, reduced metabolic complications and lower 30-day mortality compared to a previous regional audit and a large national audit. However, documentation of some aspects of care and the use of added vitamins to standard PN bags remain suboptimal. There is evidence that multidisciplinary team involvement contributes to better documentation of care in PN delivery. The complexities of PN and potential risks to patients receiving PN are the same in healthcare settings across the UK and elsewhere in the world, and this study provides a template for other local or regional

prospective audits to continue the cycle of care improvement for patients.

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Collaborators On behalf of the Northern Nutrition Network.

Contributors JKD helped with study design and was the lead author in data analysis and writing the manuscript. NT helped with study design, data analysis and writing the manuscript. All authors approved the final version of the manuscript.

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