

DIETETIC OUTCOMES IN HOME PARENTERAL NUTRITION



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In April 2011 the BDA published a Model for Dietetic Outcomes (1) to encourage exploration of how outcome measures could be developed within the profession. A health outcome is defined in the government white paper 'Equity and Excellence: Liberating the NHS 2010' (2) as 'Change in the health of an individual, group of people or a population which is attributable to an intervention, or series of interventions'. Health outcome measures need to be valid and reliable as potentially the process can become complex, which I discovered whilst developing a protocol for a study performed as part of my PhD focusing on patients with intestinal failure (IF), including those receiving home parenteral nutrition (HPN) (3).

Despite being a life saving therapy for patients, HPN can be associated with life threatening complications including infection and thrombosis. One way of minimising the frequency of complications is to reduce dependency by encouraging adherence to medical and dietetic regimens (known as the IF regimen). Achieving independence from HPN correlates positively with survival ($p < 0.05$) (4) and is an important treatment goal. Factors influencing the likelihood of weaning include length and quality of remaining small bowel, the presence of colon and the ability to consume a suitable hyperphagic diet (5) to compensate for malabsorption to help prevent malnutrition and dehydration. The importance of education in IF has been reviewed and is considered the optimum strategy for delivering a good understanding of the rationale underpinning dietary treatments (6). The authors recommended the provision of written information in combination with educational consultations by an experienced multidisciplinary team. Successful weaning from HPN requires a highly motivated patient, willing and able to comply with the burden of dietary modifications and fluid restrictions.

Measuring outcome is the final stage within the BDA Nutrition and Dietetic Care Model (7) and reference is made to the patient understanding their diet, being empowered to change and following the prescribed diet, but how can this be measured in a valid and reliable way? In a qualitative study involving six adults on HPN, a lack of education and knowledge regarding dietary advice was apparent, which was associated with poor compliance. Difficulty obtaining information was due to the lack of a dietitian as part of the care team (8) and therefore this seemed an excellent opportunity to prove how valuable dietetic intervention can be. These qualitative studies are helpful to explore patient focused measures so that we are working together with patients to achieve

mutually agreed nutrition goals.

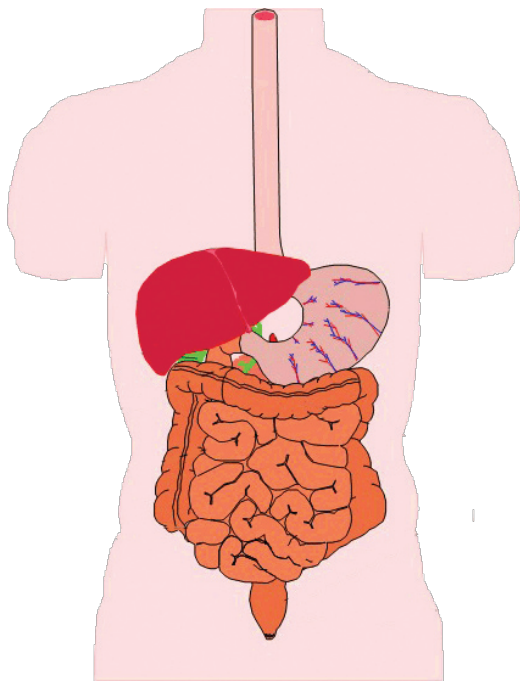
The aim of the study was to evaluate an intervention based on the communication of personalised dietary and therapeutic information using an information booklet for patients with IF. A series of baseline assessments were undertaken which reflected several of the domains within the BDA Model for Dietetic Outcomes (1):

- A questionnaire evaluating knowledge of the IF regimen (patient focused)
- A three-day food, fluid and gastrointestinal output diary (behaviour change)
- Anthropometric measurements (physical)
- The SF-36 and ED-5Q (EuroQoL) quality of life questionnaires (psychological and patient focused measures)

At their appointment, patients were given the information booklet with a verbal explanation by the dietitian, tailored to their individual requirements. Patients were reassessed at their next outpatient appointment using the same tools. Any changes in HPN over the study period were recorded.

When developing the protocol I was unable to identify a validated questionnaire investigating knowledge of the IF regimen. Therefore, I had to devise a questionnaire based on what I considered to be the most important aspects of the IF regimen. The reliability of the questionnaire was assessed using the Bland-Altman limits of agreement method (9) which found that there was little difference indicating good reliability. Thankfully, patients' knowledge significantly improved after the intervention ($p < 0.001$) which, whilst a relief, as I felt it tested my dietetic skills, can I really be sure that the questionnaire was valid? Did the patients really have a better understanding or could the results have occurred without dietetic intervention? As stated in the Model for Dietetic Outcomes, I do not work in isolation and separating my contribution from that of the gastroen-

St Mark's is a national centre for the treatment of patients with complex intestinal failure. Dr Alison Culkin has worked there as a member of the nutrition team since 1998.



terologist is difficult. To confuse the matter further, the exact role played by improved knowledge relating directly to regimen adherence was not thoroughly investigated. Instead surrogate markers were used including food, fluid and gastrointestinal output diaries.

Patients kept a three-day diary recording food and fluid intake which I reviewed and then the description of food quantity was converted to weight using a photographic atlas of food portion sizes (10). CompEat calculated the energy, protein, fat, carbo-

hydrate and fibre intake and mean daily intake determined from the three-day data. It is well established that obese patients often under-report their nutritional intake (11), but there is no published data verifying the use of food and fluid diaries in patients with IF. Did this method give a reliable reflection of what the patients actually consumed? It may be that these patients overestimated their intake as they wanted to

please the researcher. Despite these reservations, there was an increase in energy ($p=0.04$) and fat ($p=0.003$) intake which may suggest an improvement in absorption as previously demonstrated (12), but which cannot be proved from this study as balance studies were not performed.

Several factors are known to affect tools used to test knowledge and measure oral dietary intake. A review in 2002 identified 36 studies assessing knowledge using questionnaires and 69 assessing changes in behaviour and dietary intake including the use of 24-hour recall, three- and seven-day food diaries or food frequency questionnaires (13). The authors stated that because there are a wide variety of tools used to measure knowledge and dietary intake in order to assess the efficacy of nutritional interventions, judgments regarding the validity, appropriateness and reliability of the instruments chosen need to be made. They recommended extensive cognitive testing to ensure questionnaires are appropriate for the intended participants in terms of literacy and that researchers spend time and effort developing robust research tools which are valid and reliable in order to ensure that they are able to detect changes regarding the effectiveness of interventions. Data was collected over three days because research has indicated that this will provide adequate information to assess macronutrient intake and this method has been shown to correlate well with energy intake as determined using bomb calorimetry in this patient population (5).

Motivate your Patients: Monitor Body Composition

Model to illustrate Shifts in Body Composition & Body Cell Mass

Body Cell Mass	Metabolic Tissue 10.4kg	Metabolic Tissue 8.9kg	Metabolic Tissue 10.4kg
	Intracellular Water (ICW) 30.4kg	Intracellular Water (ICW) 30.4kg	Intracellular Water (ICW) 20.1kg
Total Weight 80kgs.	Extracellular Water (ECW) 18.4kg	Extracellular Water (ECW) 18.4kg	Extracellular Water (ECW) 28.7kg
	Fat 8.8kg	Fat 10.8kg	Fat 8.8kg
	Bone Tissue 12kg	Bone Tissue 12kg	Bone Tissue 12kg

A patient understanding what their body composition consists of, is key to improving, motivating and maintaining good health. As the Illustration shows, weight can be the same but inner body composition can be very different.

The concept of body composition is well established. First introduced in a 1921 project which produced a model to estimate total body muscle mass. By the 1930's full investigation of body composition had begun with underwater weighing developed in the 1940's, 1970's DEXA technology and finally, Bioelectrical Impedance Analysis



in the 1980's.

Limitations of the traditionally used Body Mass Index are globally accepted. The need for more in-depth information on body make-up is essential for modern medicine and correct diagnosis for patients. Guidelines by various professional bodies have recognised the need for accurate body composition measurements—Do you? Bioelectrical Impedance Analysis is an ideal motivator and diagnostic test:

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No validated tool was available to assess the gastrointestinal output of patients with IF and, therefore, two existing tools were used. For patients without a stoma, output was assessed using the King's Stool Chart (14) originally devised to assess the faecal output of patients receiving enteral tube feeding. For patients with a stoma, intestinal output was assessed using a specially devised procedure incorporating the Bristol stool form scale originally devised to assess intestinal transit time in patients with irritable bowel syndrome (15). Neither has been validated for use in IF and, therefore, adapting these tools to evaluate the volume and consistency of gastrointestinal output in patients with IF may have diminished their sensitivity and specificity.

The reliability of this methodology was explored using patients with IF who were asked to estimate when their stoma bag was $\frac{1}{4}$, $\frac{1}{3}$, $\frac{1}{2}$, $\frac{2}{3}$, and $\frac{3}{4}$ full and then to empty the contents into a measuring jug and record the volume. An overall score was then calculated by multiplying the numerical score for consistency according to the Bristol stool form scale with the fractional amount estimated by the patient (i.e. consistency score 3 and bag $\frac{1}{2}$ full = 1.5 score). A reduction in score between the two time points thus indicated an improvement in consistency and/or a decrease in volume. The reliability of this method was examined by calculating the standard deviation (SD) of the volume of output and the coefficient of variation (CV). The repeatability of the measurements was assessed by calculating the intra-class correlation (ICC). This value is based on the variability that is attributable to both between and within subjects and is calculated as the proportion of variability that is between subjects. Therefore, a high value (near to one) would imply that only a small amount of variability is within subjects, and hence that measurements from the same subjects have good agreement. ICC values are typically interpreted as follows (16): 0.00 to 0.10 – Virtually none, 0.11 to 0.40 – Slight, 0.41 to 0.60 – Fair, 0.61 to 0.80 – Moderate and 0.81 to 1.0 – Substantial. The results of the output quantification showed a substantial amount of variation between subjects. The intra-class correlation for volumes tested indicated substantial agreement between the volumes within individual patients. Therefore as each patient was acting as their own control it was hoped that this method would prove to be reliable.

A concern when advising patients with IF to increase their oral nutrient intake is that this will be accompanied by an undesirable increase in gastrointestinal output, but there was no significant increase in output using all methods. The assessment of bowel output in an outpatient setting is difficult and thus has inherent inconsistency. The practicality of weighing gastrointestinal output was considered during the study design, but the patients, who were free-living were not asked to do so as this was considered socially unacceptable, time consuming and too burdensome. Interestingly, five patients actually recorded the volume in millilitres and, in retrospect, I may have underestimated the dedication of some patients who are keen to be involved in research and are willing to undertake

these measurements. Future studies might incorporate actual faecal measurements which would lead to more robust data and the development of suitable validated tools to assess gastrointestinal output.

During attempts at weaning it is important that nutritional status is not compromised. I feel I can say with some confidence that the anthropometric measurements were reliable, as I evaluated my technique using the coefficient of variation (CV) method. In an ideal situation, there would be very little within subject variability (i.e. little difference between repeat measurements of the same subject). The within subject CVs were relatively low, being less than 3.0% suggesting that the repeatability for both mid arm circumference (MAC) and tricep skinfold thickness (TST) was reasonably good. An increase in BMI ($p=0.02$) and a trend towards an increase in weight ($p=0.06$) were observed with TST and MAMC maintained throughout the study. This may suggest an improvement in absorption, but as previously stated, cannot be proved from this study as balance studies were not performed. Reductions in the requirement for parenteral energy ($p=0.02$), nitrogen ($p=0.003$), lipid ($p=0.08$), volume ($p=0.02$) and frequency of infusions ($p=0.003$) were observed after the intervention which supports, but does not prove, this suggestion.

HPN has been shown to negatively influence quality of life. Tools which have been used in this population include the SF-36 (17) and the ED-5Q/EuroQoL (18). However, it was only after the present study was completed that a validated questionnaire specifically devised for patients on HPN was developed (19). Assessing quality of life is problematic as it is hard to differentiate between issues caused by the underlying disease and HPN. A systematic review in 2007 found quality of life was comparable with or lower than, patients with end-stage renal failure on dialysis (20). Fatigue was common (42 to 58 percent) which was linked with poor sleep quality due to the overnight infusion inducing nocturia (21-23). Patients have reported a desire for fewer infusions in order to reduce sleep disturbance (24) and it has been demonstrated that quality of life reduces with increased frequency of infusions (25). It was tempting to speculate that reducing the frequency of infusions may lead to improvements in quality and quantity of sleep, resulting in reduced fatigue and improved daytime energy levels. Patients who reduced the frequency of infusions showed an improvement in EQ-5D index ($p=0.006$) and the physical functioning aspect of the SF-36 ($p=0.03$) compared to those who maintained the frequency of infusions.

In conclusion, the provision of an information booklet significantly improved patient knowledge of the IF regimen and was associated with a significant reduction in HPN dependence. The amount of preparation during the protocol development was significant due to the lack of validated tools within this speciality. Whilst some dietetic outcome measures are well established such as those in the physical domain, there is still a lot of work to be completed to ensure that a variety of validated tools exist which can be utilised by those wanting to prove their effectiveness in clinical practice.

For article references
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Questions relating to: *Dietetic outcomes in home parenteral nutrition.*

Type your answers below and then **print for your records**. Alternatively print and complete answers by hand.

Q.1	Define a health outcome.
A	
Q.2	Describe one way of minimising the complications of HPN.
A	
Q.3	What are the factors that influence the weaning and achievement of independence from HPN for patients with intestinal failure?
A	
Q.4	What were the four main assessment tools used in Dr Culkin's study?
A	
Q.5	Describe the two methods used in the study to assess gastrointestinal output of patients with IF.
A	
Q.6	How many days are recommended to keep a food record? What is the rationale for this?
A	
Q.7	What did the results of the output qualification show?
Q.8	What reductions were observed to support a suggestion of improved absorption after the intervention?
Q.9	What improvements were made in patients who reduced the frequency of infusions?

Please type extra notes here . . .