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Nutrition support in adults: oral supplements, enteral tube feeding and parenteral nutrition

FOREWORD

Malnutrition is both a cause and a consequence of ill-health. It is surprisingly common in the UK, especially in those who are unwell. Many older people and those with any long-term medical or psycho-social problems are chronically underweight and so are vulnerable to acute illness. Even people who are well-nourished eat and drink less if they are ill or injured and although this may only be short-lived as part of an acute problem, if it persists the person can become undernourished to an extent that may impair recovery or precipitate other medical conditions.

The consequences of malnutrition include vulnerability to infection, delayed wound healing, impaired function of heart and lungs, decreased muscle strength and depression. People with malnutrition consult their general practitioners more frequently, go to hospital more often and for longer, and have higher complication and mortality rates. Surgical patients who have malnutrition for example, have around three times as many post-operative complications and four times greater risk of death than well nourished patients having similar operations. If poor dietary intake or complete inability to eat persists for weeks, the resulting malnutrition can be life-threatening in itself.

The provision of normal food and drink along with physical help to eat if necessary, when unwell will often suffice. However, if this fails, is impractical or is unsafe, measures to provide nutrition support may be indicated. These include, either alone or in combination: extra oral intake such as extra food and special drinks; feeding via a tube into the gastro-intestinal tract (enteral tube feeding - ETF); or giving nutrients intravenously (parenteral nutrition - PN). Choosing the most effective and safest route is essential, yet current knowledge of nutrition support amongst most UK health professionals is poor.

The need for nutrition support is essentially absolute if patients are unable to meet the majority of their nutrient needs for prolonged periods (e.g. in complete dysphagia or intestinal failure). However, when nutritional intakes are closer to meeting needs, or when the likely period of inadequate intake is uncertain, decisions are more complex, especially as providing nutrition support is not without risk. Oral supplementation can cause pneumonia in dysphagic patients, while ETF and PN can cause gastrointestinal problems, infections, metabolic upset and trauma. These risks raise issues of informed consent and difficult clinical and ethical issues are also posed by patients who do not want to 'artificially' prolong their life and, in the case of patients who cannot express a wish, how clinicians should act in that person's best interest.

The objective of these guidelines is to improve the practice of nutrition support by providing evidence and information for all healthcare professionals, patients and their carers so that malnutrition whether in hospital or in the community, is recognized and treated by the best form of nutrition support at the appropriate time. However, although the recommendations have been systematically

Nutrition support in adults: full guideline DRAFT (August 2005) Page 2 of 262

developed and based on trial evidence wherever possible, the Guideline Development Group (GDG) have met with some difficulties: the breadth of our remit was enormous; time and resources were finite; and the evidence base for nutrition support is difficult to interpret. The last of these was most problematic. Most of the evidence consists of many small trials, applying different interventions and outcome measures, to very variable populations. This not only leads to individual trials being statistically underpowered but makes combining them into meta-analyses more difficult. The varied study settings also create difficulties in making firm recommendations for patients in the community when most research was conducted in hospitals. Furthermore, in the case of the more 'invasive' ETF and PN techniques, problems with the evidence are near insurmountable. It is unethical to include patients who are unable to eat at all for significant periods in any randomized trial of ETF or PN (where feeding may be witheld). The scientific trials therefore examine 'elective' supplementary usage of ETF and PN rather than their use in patients with an absolute need for such support and so the results do not necessarily apply to routine clinical practice.

In the light of the problems above, many of the recommendations in this guideline are good practice points, derived from a combination of clinical evidence, clinical experience and expertise. Many are also quite general, applying to all patients with malnutrition whatever their disease or care setting. However, all health care professionals who have contact with patients should find the recommendations relevant for we believe that they contain an obvious, simple message:

'Do not let your patients starve and when you offer them nutrition support, do so by the safest, simplest, effective route.'

This is essential to good patient care,

Mike Stroud

Chair, Guideline Development Group.

G	UIDELI	NE DEVELOPMENT GROUP MEMBERSHIP AND ACKNOWLEDGMENTS	7
S	ГАКЕН	OLDER INVOLVEMENT	11
A	BBREV	IATIONS	13
G	LOSSA	RY OF TERMS	15
1		RODUCTION AND METHODS	
	1.1.	THE NEED FOR GUIDELINES IN NUTRITION SUPPORT	28
	1.2	WHAT IS A GUIDELINE?	
	1.3	REMIT OF THE GUIDELINE.	
	1.4	WHAT THE GUIDELINE COVERS	30
	1.5	WHAT THE GUIDELINE DOES NOT COVER	31
	1.6	WHO THE GUIDELINE IS FOR	
	1.7	WHO DEVELOPED THE GUIDELINE?	
	1.8	METHODOLOGY	
	1.9	HIERARCHY OF CLINICAL EVIDENCE	
	1.10	HEALTH ECONOMICS METHODS	
	1.11	FORMING AND GRADING THE RECOMMENDATIONS	
	1.12	SPECIFIC PROBLEMS WITH EVIDENCE RELATING TO THE DEVELOPMENT OF NUTRITION SUPP INES	
	1.13	PATIENT-CENTRED CARE	
	1.14	SUMMARY OF THE RECOMMENDATIONS	
2	MA	LNUTRITION AND THE PRINCIPLES OF NUTRITION SUPPORT	
-			
	2.1	INTRODUCTION	
	2.2	THE EFFECTS OF MALNUTRITION	
	2.3	THE PREVALENCE OF MALNUTRITION	
	2.5	PRINCIPLES UNDERLYING INTERVENTION	
3		GANISATION OF NUTRITION SUPPORT	
٠			
	3.1	INTRODUCTION	
	3.4	METHODS	
	3.5	CLINICAL EVIDENCE	
	3.6	COST EFFECTIVENESS EVIDENCE	
	3.7	Conclusion	
	3.8	RECOMMENDATIONS	88
	3.7.1.1	ALL HEALTHCARE WORKERS IN HOSPITAL AND THE COMMUNITY WHO ARE DIRECTLY	
	INVOLV	ED IN PATIENT CARE SHOULD RECEIVE TRAINING IN:	88
4	NUI	TRITIONAL ASSESSMENT AND 'SCREENING'	91
	4.7	NUTRITIONAL ASSESSMENT	91
	4.8	WHY AND HOW TO SCREEN	
	4.9	METHODS	
	4.10	CLINICAL EVIDENCE	93
	4.11	COST-EFFECTIVENESS EVIDENCE	94
	4.12	CONSENSUS DEVELOPMENT METHODS	
	4.13	IMPACT OF NUTRITIONAL ASSESSMENT ON THE PATIENT	
	4.14	RECOMMENDATIONS FOR NUTRITION SCREENING	
	4.15	RESEARCH RECOMMENDATIONS	
5	IND	ICATIONS FOR NUTRITION SUPPORT	101

Nutrition support in adults: full guideline DRAFT (August 2005) Page 4 of 262

DRAFT FOR SECOND CONSULTATION

	5.1	INTRODUCTION	. 101
	5.2	METHODOLOGY	. 101
	5.3	APPROPRIATE NUTRITION SUPPORT AND ETHICAL/LEGAL ISSUES	. 102
	5.4	RATIONALE FOR RECOMMENDATIONS	104
	5.5	PATIENT PATHWAY ALGORITHM	
	5.6	ORAL ALGORITHM	. 109
	5.7	ENTERAL AND PARENTERAL ALGORITHM	. 110
6	WH	AT TO GIVE	112
	6.1	BACKGROUND	. 112
	6.3	CALCULATING REQUIREMENTS	. 113
	6.4	CONCERNS WITH PRESCRIBING LEVELS	
	6.5	RECOMMENDATIONS	
	6.6	RE-FEEDING PROBLEMS	. 117
	6.7	RECOMMENDATIONS	
	6.8	RECOMMENDATIONS FOR RESEARCH	. 122
7	MO	NITORING NUTRITIONAL SUPPORT	123
	7.1	INTRODUCTION	
	7.2	METHODS	124
	7.3	RECOMMENDATIONS	. 124
8	ORA	L NUTRITION SUPPORT	134
	8.1	Introduction	. 134
	8.2	$O RAL\ NUTRITIONAL\ INTERVENTIONS\ VERSUS\ STANDARD\ CARE\ IN\ MALNOURISHED\ PATIENTS\ .$	135
	8.3	DIETARY ADVICE VERSUS STANDARD CARE	141
	8.3.5	COST-EFFECTIVENESS EVIDENCE FOR DIETARY ADVICE	
	8.4	ORAL NUTRITIONAL SUPPLEMENTS VERSUS DIETARY ADVICE	143
	8.5	RECOMMENDATIONS	
	8.7	RECOMMENDATIONS	
	8.8	ORAL NUTRITION SUPPORT IN PANCREATITIS PATIENTS	
	8.9	ORAL MULTIVITAMIN AND MINERAL SUPPLEMENTATION IN MALNOURISHED PATIENTS	
	8.11	NUTRITION SUPPORT IN PATIENTS WITH DYSPHAGIA	
	8.12	RECOMMENDATIONS	
	8.13	RESEARCH RECOMMENDATIONS	
9	ENT	ERAL TUBE FEEDING	
	9.1	Introduction	
	9.2	GENERAL INDICATIONS FOR ENTERAL TUBE FEEDING	
	9.4	ENTERAL TUBE FEEDING VERSUS STANDARD CARE	
	9.6	ENTERAL TUBE FEEDING ROUTES OF ACCESS	
	9.11	TYPES OF ENTERAL FEEDS.	
	9.12	MODE OF DELIVERING ENTERAL TUBE FEEDING	
	9.14		
	9.16 9.18	COMPLICATIONS OF ENTERAL TUBE FEEDING	
10			
10		ENTERAL NUTRITION	
	10.1	INTRODUCTION	
	10.2	PN VERSUS NO PN	
	10.3 10.5	PARENTERAL VERSUS ENTERAL TUBE FEEDING	
	10.5	VENOUS ACCESS FOR PN	
	10.17	TAILORED PN PREPARATIONS VERSUS STANDARD PN PREPARATIONS	
	10.24	DELIVERY OF PN CYCLICALLY VERSUS CONTINUOUSLY	
	10.24	COMPLICATIONS FROM PN	211

Nutrition support in adults: full guideline DRAFT (August 2005) Page 5 of 262

DRAFT FOR SECOND CONSULTATION

10.28 Research recommendations	212
11 NUTRITION SUPPORT AT HOME	214
11.1 Home enteral tube feeding	214
11.3 HOME PARENTERAL NUTRITION	
11.5 WORKING IN PARTNERSHIP WITH PATIENTS, FAMILIES AND CARERS	
12 AUDIT CRITERIA	
APPENDIX ONE: SCOPE	
GUIDELINE TITLE	229
SHORT TITLE	
BACKGROUND	
CLINICAL NEED FOR THE GUIDELINE	
THE GUIDELINE	231
POPULATION	231
HEALTHCARE SETTING	232
CLINICAL MANAGEMENT	232
AUDIT SUPPORT WITHIN GUIDELINE	
Status	
FURTHER INFORMATION	235
REFERRAL FROM THE DEPARTMENT OF HEALTH AND WELSH ASSEMBLY GOVERNMENT	
APPENDIX TWO: THE CLINICAL QUESTIONS	237
APPENDIX THREE: LITERATURE SEARCH STRATEGIES	239
RESEARCH METHODOLOGICAL SEARCH STRATEGIES	239
SCREENING SEARCH STRATEGIES	
ORAL INTERVENTIONS SEARCH STRATEGIES	
ENTERAL TUBE FEEDING SEARCH STRATEGIES	247
PARENTERAL NUTRITION SEARCH STRATEGIES	
Dysphagia Search Strategies	
NUTRITION SUPPORT TEAMS AND MONITORING SEARCH STRATEGIES	
PATIENT VIEWS SEARCH STRATEGIES	256
APPENDIX FOUR: EVIDENCE TABLES	259
NUTRITIONAL SCREENING	259
ORAL NUTRITION SUPPORT	264
Enteral tube feeding	
PARENTERAL NUTRITION SUPPORT	
NUTRITION SUPPORT TEAMS	577
APPENDIX FIVE: COST-EFFECTIVENESS ANALYSIS OF MALNUTRITION SCREENIN	G 595
3.9 Methods	595
3.10 RESULTS	600
APPENDIX SIX: META-ANALYSES ORAL VERSUS STANDARD CARE	616
APPENDIX SEVEN: META-ANALYSES ORAL VERSUS NIL POST OPERATIVE NUTRIT SUPPORT	-
APPENDIX EIGHT: META-ANALYSES ENTERAL VERSUS NIL POST OPERATIVE NUTRITION SUPPORT	
APPENDIX NINE: PERIPHERAL PN. INTERVENTION DETAILS: CONTINUOUS VS	
CYCLICAL PN	635

Appendices 1–9 are in a separate file

Nutrition support in adults: full guideline DRAFT (August 2005) Page 6 of 262

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Nutrition support in adults: full guideline DRAFT (August 2005) Page 7 of 262

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Conflict of Interests

The Guideline Development Group was asked to declare any possible conflict of interest and none that could interfere with their work on the guideline were declared. All documentation is held by the National Collaborating Centre for Acute Care.

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The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring its quality. The members of the Guideline Review Panel were as follows.

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Nutrition support in adults: full guideline DRAFT (August 2005) Page 9 of 262

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The following stakeholders registered with NICE and were invited to comment on draft versions of these guidelines:

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Patient Involvement Unit for NICE

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Kingston Primary Care Trust

Leeds Teaching Hospitals NHS Trust

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Mid Essex Hospitals NHS Trust Middlesbrough Primary Care Trust

National Nurses Nutrition Group

North Glamorgan NHS Trust - Merthyr

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Royal United Hospital Bath NHS Trust Sheffield Teaching Hospitals NHS Trust

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Age Concern England Alzheimer's Society British Dyslexia Association **British Liver Trust** Children's Liver Disease Foundation Depression Alliance Eating Disorders Association, The Fibroid Network Charity Help the Aged Help the Hospices

Nutrition support in adults: full guideline DRAFT (August 2005) Page 11 of 262

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Nutrition Society

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National Patient Safety Agency National Public Health Service - Wales NHS Information Authority, (PHSMI Programme)

NHS Modernisation Agency, The
NHS Quality Improvement Scotland
Scottish Intercollegiate Guidelines
Network (SIGN)

Welsh Assembly Government (formerly National

Abbreviations

aa Amino acid

ASPEN American Society for Parenteral and Enteral Nutrition

BAPEN British Association for Parenteral and Enteral Nutrition

BDA British Dietetic Association

BMI Body Mass Index

CEA Cost-effectiveness analysis

CI Confidence interval CO₂ Carbon dioxide

COPD Chronic obstructive pulmonary disorder

CVA Cerebrovascular disease
CUA Cost-utility analysis
CVC Central venous catheter

DEALE Declining Exponential Approximation of Life Expectancy

DH Department of Health EN Enteral nutrition

ESPEN European Society of Parenteral and Enteral Nutrition

(European Society for Clinical Nutrition and Metabolism)

ETF Enteral tube feeding

GDG Guideline Development Group

GI Gastrointestinal
GP General Practitioner
GPP Good practice point

GRADE Guidelines Recommendations Assessment Development

Evaluation

GRP Guideline Review Panel (formerly known as the Guidelines

Advisory Committee, from which Designated Committee

Members were selected)

HETF Home enteral tube feeding
HIV Human Immunodeficiency Virus
HPN Home parenteral nutrition
HRQL Health Related Quality of Life
HTA Health technology assessment

HTBS Health Technology Board for Scotland ICER Incremental cost-effectiveness ratio

IP Inpatient
IV Intravenous
LOS Length of Stay
LY Life-year

MAC Mid arm circumference

MAMC Mid arm muscle circumference

MDT Multidisciplinary team
MNA Mini Nutritional Assessment

MNA-SF Mini Nutritional Assessment-Short Form

MND Motor neuron disease

Nutrition support in adults: full guideline DRAFT (August 2005) Page 13 of 262

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MRC Medical Research Council

MS Multiple sclerosis

MUST 'Malnutrition Universal Screening Tool'

NCC National Collaborating Centre

NCC-AC National Collaborating Centre for Acute Care

NCEPOD National Confidential Enquiry into Patient Outcome and

Death

ND Nasoduodenal NG Nasogastric

NHS National Health Service

NI Nutrition intake

NICE National Institute for Health and Clinical Excellence

(formerly National Institute for Health and Clinical

Excellence) Nasojejunal

NNT Number needed to treat

O₂ Oxygen

NJ

ONS Oral Nutritional Supplement

PEG Percutaneous endoscopic gastrostomy
PEJ Percutaneous endoscopic jejunostomy
PICC Peripherally inserted central catheters

PICO Framework incorporating patients, interventions,

comparisons, outcomes

PIU Patient Involvement Unit (formerly known as the National

Guidelines and Audit Patient Involvement Unit)

PN Parenteral nutrition

PPIP Patient and Public Involvement Programme

QALY Quality-adjusted life year
RCT Randomised controlled trial
RDA Recommended Dietary Allowance

RQ Respiratory quotient

SIGN Scottish Intercollegiate Guidelines Network

SR Systematic review **TPN** Total parenteral nutrition

TSF Tricep skinfold

Glossary of Terms

Amended from a glossary produced by the Patient Involvement Unit, NICE.

Absolute risk reduction (Risk difference)

The difference in event rates between two groups (one subtracted from

the other) in a comparative study.

Summary of a study, which may be published alone or as an introduction **Abstract**

to a full scientific paper.

Acute Phase Response (APR) A group of physiologic processes occurring soon after the onset of infection, trauma, inflammatory processes, and some malignant conditions. The most prominent change is a dramatic increase of acute phase proteins, especially C-reactive protein, in the serum. Also seen are fever, increased vascular permeability, and a variety of metabolic and

pathologic changes².

A statistical procedure in which the effects of differences in composition of Adjustment

the populations being compared (or treatment given at the same time)

have been minimised by statistical methods.

Algorithm (in guidelines)

A flow chart of the clinical decision pathway described in the guideline, where decision points are represented with boxes, linked with arrows.

Allocation concealment The process used to prevent advance knowledge of group assignment in a RCT. The allocation process should be impervious to any influence by the individual making the allocation, by being administered by someone

who is not responsible for recruiting participants.

Ancillaries The equipment and consumables required for enteral and parenteral

nutrition.

The degree to which the results of an observation, study or review are **Applicability**

likely to hold true in a particular clinical practice setting.

Appraisal of Guidelines, Research and **Evaluation** (AGREE)

An international collaboration of researchers and policy makers whose aim is to improve the quality and effectiveness of clinical practice guidelines (http://www.agreecollaboration.org). The AGREE instrument, developed by the group, is designed to assess the quality of clinical

quidelines.

Appraisal Committee A standing advisory committee of the Institute. Its members are drawn from the NHS, patient/carer organisations, relevant academic disciplines

and the pharmaceutical and medical devices industries.

Arm (of a clinical study) **Assessment**

Sub-section of individuals within a study who receive one particular intervention, for example placebo arm.

protocol **Assessment** Report

Written instructions for the conduct and analysis of the assessment of a technology.

In technology appraisals, a critical review of the clinical and cost effectiveness of a health technology/technologies. It is prepared by the Assessment Group. To prepare the report, the Assessment Group carries out a review of the published literature and the submissions from

manufacturers and sponsors.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 15 of 262

Statistical relationship between two or more events, characteristics or **Association**

other variables. The relationship may or may not be causal.

Audit See 'Clinical audit'.

Records of action to assess practice against standards. Also a record of **Audit trail**

actions, for example changes to a draft guideline so that reasons can be

apparent to a third party.

The initial set of measurements at the beginning of a study (after run-in **Baseline**

period where applicable), with which subsequent results are compared. Influences on a study that can lead to invalid conclusions about a

treatment or intervention. Bias in research can make a treatment look better or worse than it really is. Bias can even make it look as if the treatment works when it actually doesn't. Bias can occur by chance or as a result of systematic errors in the design and execution of a study. Bias can occur at different stages in the research process, e.g. in the

collection, analysis, interpretation, publication or review of research data.

Keeping the study participants, caregivers, researchers and outcome Blinding (masking)

assessors unaware about the interventions to which the participants have

been allocated in a study

A measure of body weight relative to height used to determine whether **Body Mass Index**

people are underweight, at a healthy weight, over weight or obese.

Bolus/intermittent feeding

Bias

The administration of a feed through an enteral tube delivered as a single

portion over a short period of time.

Costs of purchasing major capital assets (usually land, buildings or **Capital costs**

equipment). Capital costs represent investments at one point in time.

This refers to residential and nursing care. **Care homes**

Someone other than a health professional who is involved in caring for a Carer (caregiver)

person with a medical condition.

Comparative observational study in which the investigator selects **Case-control study**

individuals who have experienced an event (for example, developed a disease) and others who have not (controls), and then collects data to

determine previous exposure to a possible cause Detailed report on one patient (or case), usually covering the course of

Case report (or case study)

that person's disease and their response to treatment.

Report of a number of cases of a given disease, usually covering the Case series

course of the disease and the response to treatment. There is no

comparison (control) group of patients.

Classification of recommendations Clinical audit

A code (such as A, B, C, D) given to a guideline recommendation, indicating the strength of the evidence supporting that recommendation.

A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change.

The extent to which an intervention is active when studied under **Clinical efficacy**

controlled research conditions.

Clinical effectiveness Clinical impact The extent to which an intervention produces an overall health benefit in

routine clinical practice.

The effect that a guideline recommendation is likely to have on the treatment or treatment outcomes, of the target population.

In guideline development, this term refers to the guestions about

Clinical question treatment and care that are formulated to guide the development of

evidence-based recommendations.

Clinician A healthcare professional providing direct patient care, for example

doctor, nurse or physiotherapist.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 16 of 262

Cochrane Library

Cluster A closely grouped series of events or cases of a disease or other related

health phenomena with well-defined distribution patterns, in relation to time or place or both. Alternatively, a grouped unit for randomisation. A regularly updated electronic collection of evidence-based medicine

databases, including the Cochrane Database of Systematic Reviews. A systematic review of the evidence from randomised controlled trials **Cochrane Review** relating to a particular health problem or healthcare intervention, produced

by the Cochrane Collaboration. Available electronically as part of the

Cochrane Library.

Cohort study A retrospective or prospective follow-up study. Groups of individuals to be

followed up are defined on the basis of presence or absence of exposure to a suspected risk factor or intervention. A cohort study can be

comparative, in which case two or more groups are selected on the basis

of differences in their exposure to the agent of interest.

Use of different treatments in combination (for example surgery, **Combined modality**

chemotherapy and radiotherapy used together).

Organisations that engage in the appraisal process but that are not asked Commentator

to prepare a submission dossier, and that receive the Final Appraisal Determination (FAD) for information only, without right of appeal. These organisations are manufacturers of comparator technologies, NHS Quality Improvement Scotland; the relevant National Collaborating Centre; other

related research groups and other groups where appropriate.

Table compiled by NICE to show all the comments and responses Comments table

generated as part of the consultation process.

See 'In confidence' Commercial in confidence

This may refer to care homes (including residential care and nursing **Community care** care), domiciliary care (also known as 'home' care) and primary care. Co-existence of more than one disease or an additional disease (other Co-morbidity

than that being studied or treated) in an individual.

Similarity of the groups in characteristics likely to affect the study results Comparability

(such as health status or age).

The extent to which a person adheres to the health advice agreed with Compliance

healthcare professionals. May also be referred to as 'adherence'.

Compilation of papers presented at a conference. Conference

proceedings Confidence interval

(CI)

A range of values for an unknown population parameter with a stated 'confidence' (conventionally 95%) that it contains the true value. The interval is calculated from sample data, and generally straddles the sample estimate. The 'confidence' value means that if the method used to calculate the interval is repeated many times, then that proportion of

intervals will actually contain the true value.

In a study, confounding occurs when the effect of an intervention on an Confounding

outcome is distorted as a result of an association between the population or intervention or outcome and another factor (the 'confounding variable') that can influence the outcome independently of the intervention under

study.

Techniques that aim to reach an agreement on a particular issue. Formal Consensus consensus methods include Delphi and nominal group techniques, and methods

consensus development conferences. In the development of clinical quidelines, consensus methods may be used where there is a lack of strong research evidence on a particular topic. Expert consensus methods will aim to reach agreement between experts in a particular field.

The process that allows stakeholders and individuals to comment on initial Consultation

versions of NICE guidance and other documents so their views can be

taken into account when producing the final version.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 17 of 262

Consultee

Organisations that accept an invitation to participate in the appraisal. Consultees can participate in the consultation on the draft scope, the Assessment Report and the Appraisal Consultation Document; consultee organisations representing patient/carers and professionals can nominate clinical specialists and patient experts to present their personal views to the Appraisal Committee, AND are given the opportunity to appeal against the Final Appraisal Determination (FAD).

CONSORT statement (Consolidated reporting of clinical trials) Control group Recommendations for improving the reporting of randomised controlled trials in journals. A flow diagram and checklist allow readers to understand the conduct of the study and assess the validity of the results.

Controlled clinical trial (CCT)

A group of patients recruited into a study that receives no treatment, a treatment of known effect, or a placebo (dummy treatment) - in order to provide a comparison for a group receiving an experimental treatment, such as a new drug.

A study testing a specific drug or other treatment involving two (or more) groups of patients with the same disease. One (the experimental group) receives the treatment that is being tested, and the other (the comparison or control group) receives an alternative treatment, a placebo (dummy treatment) or no treatment. The two groups are followed up to compare differences in outcomes to see how effective the experimental treatment was. A CCT where patients are randomly allocated to treatment and comparison groups is called a *randomised controlled trial*.

Cost benefit analysis

A type of economic evaluation where both costs and benefits of health care treatment are measured in the same monetary units. If benefits exceed costs, the evaluation would recommend providing the treatment.

Costconsequences analysis (CCA) Cost-effectiveness analysis (CEA) A type of economic evaluation where various health outcomes are reported in addition to cost for each intervention, but there is no overall measure of health gain.

An economic study design in which consequences of different interventions are measured using a single outcome, usually in 'natural' units (for example, life-years gained, deaths avoided, heart attacks avoided, cases detected). Alternative interventions are then compared in terms of cost per unit of effectiveness.

Cost-effectiveness model

An explicit mathematical framework, which is used to represent clinical decision problems and incorporate evidence from a variety of sources in order to estimate the costs and health outcomes.

Cost-utility analysis (CUA) Content expert

A form of cost-effectiveness analysis in which the units of effectiveness are quality-adjusted life-years (QALYs).

Criterion (in audit)

An individual with skills or knowledge relating to the subject being investigated.

An explicit statement that defines the appropriateness of healthcare

which follows a set of people over a period of time).

Cross-sectional study

decisions, services and outcomes, and that can be measured. The observation of a defined set of people at a single point in time or time period – a snapshot. (This type of study contrasts with a *longitudinal study*

Decision analysis

A systematic way of reaching decisions, based on evidence from research. This evidence is translated into probabilities, and then into diagrams or decision trees which direct the clinician through a succession of possible scenarios, actions and outcomes.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 18 of 262

Decision analytic

techniques

A way of reaching decisions, based on evidence from research. This evidence is translated into probabilities, and then into diagrams or decision trees that direct the clinician through a succession of possible

scenarios, actions and outcomes.

Decision problem

A clear specification of the interventions, patient populations and outcome measures and perspective adopted in an evaluation, with an explicit justification, relating these to the decision which the analysis is to inform. The provision of instructions on modifying food intake to improve

nutritional intake.

Discounting

Dietary advice

Costs and perhaps benefits incurred today have a higher value than costs and benefits occurring in the future. Discounting health benefits reflects individual preference for benefits to be experienced in the present rather than the future. Discounting costs reflects individual preference for costs to be experienced in the future rather than the present.

Dosage

The prescribed amount of a drug to be taken, including the size and timing of the doses.

Double blind study

A study in which neither the subject (patient) nor the observer (investigator/clinician) is aware of which treatment or intervention the subject is receiving. The purpose of blinding is to protect against bias.

Drop-out

A participant who withdraws from a clinical trial before the end.

Dysphagia

Any impairment of eating, drinking and swallowing.

Economic evaluation

Efficacy

Comparative analysis of alternative health strategies (interventions or programmes) in terms of both their costs and consequences.

See 'Clinical efficacy'.

Effect (as in effect measure, treatment effect, estimate of effect, effect size) The observed association between interventions and outcomes or a statistic to summarise the strength of the observed association.

Effectiveness

See 'Clinical effectiveness'.

Elective

Name for clinical procedures that are regarded as advantageous to the patient but not urgent.

Electrolytes

Anions and cations in the blood, tissue fluids and cells e.g. sodium, potassium and chlorine.

Enteral nutrition

see enteral tube feeding

Enteral tube feeding

Nutrition support directly into the gut via a tube (the term as used in these guidelines does not include oral intake).

Epidemiological study

The study of a disease within a population, defining its incidence and prevalence and examining the roles of external influences (for example,

infection, diet) and interventions

Nutrition support in adults: full guideline DRAFT (August 2005) Page 19 of 262

Evidence Information on which a decision or guidance is based. Evidence is

obtained from a range of sources including randomised controlled trials, observational studies, expert opinion (of clinical professionals and/or

patients).

Evidence table A table summarising the results of a collection of studies which, taken

together, represent the evidence supporting a particular recommendation

or series of recommendations in a guideline.

Exclusion criteria (literature review) Exclusion criteria

Explicit standards used to decide which studies should be excluded from

consideration as potential sources of evidence.

Criteria that define who is not eligible to participate in a clinical study.

(clinical study)
Expert consensus

Extended dominance

If Option A is both more clinically effective than Option B and has a lower cost per unit of effect, when both are comparted with a do-nothing alternative then Option A is said to have extended dominance over Option B. Option A is therefore more efficient and should be preferred, other

things remaining equal.

See 'Consensus methods'.

Extrapolation In data analysis, predicting the value of a parameter outside the range of

observed values.

Facilitator An individual whose function is to promote the effective functioning of the

group.

Focus group A *qualitative research* technique. It is a method of group interview or

discussion of between 6–12 people focused around a particular issue or topic. The method explicitly includes and uses the group interaction to

generate data.

Follow up Observation over a period of time of an individual, group or initially

defined population whose appropriate characteristics have been assessed in order to observe changes in health status or health-related variables. A project planning tool showing the timing of tasks within a project. Dates the from left to right and each task is represented by a herizontal bar, the

run from left to right and each task is represented by a horizontal bar, the left end of which marks the expected beginning of the task and the right

end of which marks the planned completion date.

Gastrojejunostomy

Gantt Chart

tube

Enteral tube inserted through the abdominal wall which passes through

the stomach into the jejunum for the purpose of nutrition support.

Gastrostomy Enteral tube inserted through the abdominal wall into the stomach for the

purpose of nutrition support.

Generalisability The extent to which the results of a study based on measurement in a

particular patient population and/or a specific context hold true for another population and/or in a different context. In this instance, this is the degree to which the guideline recommendation is applicable across both geographical and contextual settings. For instance, guidelines that suggest substituting one form of labour for another should acknowledge

that these costs might vary across the country.

Generic name The general non-proprietary name of a drug or device.

Gold standard A method, procedure or measurement that is widely accepted as being

the best available.

Goodness-of-fit How well a statistical model or distribution compares with the observed

data.

Good Practice

Points

Recommended good practice based on the clinical experience of the

Guideline Development Group.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 20 of 262

Grading evidence

A code given to a study or other evidence, indicating the quality and generalisability of the research. The highest grade evidence will usually

be obtained from randomised controlled trials.

Grey literature

Reports that are unpublished or have limited distribution, and are not

included in the common bibliographic retrieval systems.

Harms

Health economics

The study of the allocation of scarce resources among alternative health care treatments. Health economists are concerned with both increasing

the average level of health in the population and improving the distribution

of health.

Health related quality of life

A combination of an individual's physical, mental and social well-being;

not merely the absence of disease.

Adverse effects of an intervention.

Health technology

Any method used by those working in health services to promote health, prevent and treat disease, and improve rehabilitation and long-term care. Technologies in this context are not confined to new drugs or pieces of

sophisticated equipment.

Heterogeneity

Or lack of *homogeneity*. The term is used in *meta-analyses* and *systematic reviews* when the results or estimates of effects of treatment from separate studies seem to be very different – in terms of the size of treatment effects or even to the extent that some indicate beneficial and others suggest adverse treatment effects. Such results may occur as a result of differences between studies in terms of the patient populations, outcome measures, definition of variables or duration of follow-up.

Home enteral tube feeding

The practice of enteral tube feeding in the community.

Home parenteral Nutrition

The practice of parenteral nutrition in the community.

Homogeneity

This means that the results of studies included in a *systematic review* or *meta analysis* are similar and there is no evidence of *heterogeneity*. Results are usually regarded as homogeneous when differences between studies could reasonably be expected to occur by chance.

Hypothesis Implementation In confidence material A supposition made as a starting point for further investigation. Introducing the use of the guidance recommendations in practice. Information (for example, the findings of a research project) defined as 'confidential' as its public disclosure could have an impact on the commercial interests of a particular company or the academic interests of a research or professional organisation.

Inclusion criteria (literature review) Incremental analysis Incremental cost Explicit criteria used to decide which studies should be considered as potential sources of evidence.

Incremental cost effectiveness ratio (ICER)

The analysis of additional costs and additional clinical outcomes with different interventions.

The difference in the mean costs in the population of interest divided by

the differences in the mean outcomes in the population of interest.

In epidemiology and related sciences, this wo scale, for example, a set of numbers derived to

In epidemiology and related sciences, this word usually means a rating scale, for example, a set of numbers derived from a series of observations of specified variables. Examples include the various health status indices, and scoring systems for severity or stage of cancer.

Indication (specific)

The defined use of a technology as licensed by the Medicines and

Healthcare products Regulatory Agency (MHRA).

Nutrition support in adults: full guideline DRAFT (August 2005) Page 21 of 262

Intention-to-treat analysis (ITT analysis)

An analysis of the results of a clinical study in which the data are analysed for all study participants as if they had remained in the group to which they were randomised, regardless of whether or not they remained in the study until the end, crossed over to another treatment or received an alternative intervention

Intermediate outcomes

Outcomes that are related to the outcome of interest but may be more easily assessed within the context of a clinical study: for example, blood pressure reduction is related to the risk of a stroke.

Internal validity

The degree to which the results of a study are likely to approximate the 'truth' for the participants recruited in a study (that is, are the results free of bias?). It refers to the integrity of the design and is a prerequisite for applicability (external validity) of a study's findings. See 'External validity'. Healthcare action intended to benefit the patient, for example, drug

Intervention

treatment, surgical procedure, psychological therapy.

Jejunostomy

Enteral tube inserted through the abdominal wall directly into the jejunum

for the purpose of nutrition support.

See 'Product licence'.

Length of stay

The total number of days a participant stays in hospital.

Licence Life year

A measure of health outcome which shows the number of years of remaining life expectancy.

Life-years gained Longitudinal study Average years of life gained per person as a result of the intervention. A study of the same group of people at more than one point in time. (This type of study contrasts with a cross sectional study which observes a defined set of people at a single point in time).

Cavity or channel within a tube Lumen

Malnutrition

A state of nutrition in which a deficiency of energy, protein and/or other nutrients causes measurable adverse effects on tissue/body form, composition, function or clinical outcome 91 (in these guidelines we do not use the term to cover excess nutrient provision).

Malnutrition, severe

BMI <18.5 and or recent weight loss >10% within the previous 3-6 months

Malnutrition, moderate

BMI 18.5-20 and >5% weight loss within the previous 3-6 months

Malnutrition, at risk

has eaten very little and or is unlikely to eat more than very little amounts for the next 5 days

Medicines and Healthcare **Products** Regulatory Agency (MHRA)

The Executive Agency of the Department of Health protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely.

Meta-analysis

Results from a collection of independent studies (investigating the same treatment) are pooled, using statistical techniques to synthesise their findings into a single estimate of a treatment effect. Where studies are not compatible e.g. because of differences in the study populations or in the outcomes measured, it may be inappropriate or even misleading to statistically pool results in this way. See also *Systematic review & Heterogeneity*.

Motility agent

A medication used to aid the movement of food from the stomach into the intestine.

Nasoduodenal (tube) feeding

Nutrition support provided via a tube inserted via the nose, oesophagus and stomach into the duodenum.

Nasogastric (tube) feeding

Nutrition support provided through a tube inserted through the nose via the oesophagus into the stomach.

Nasojejunal (tube) feeding

Nutrition support provided through a tube inserted through the nose via the oesophagus, stomach and duodenum into the jejunum.

NICE Technology Appraisals

Recommendations on the use of new and existing medicines and other treatments within the NHS in England and Wales, such as: medicines (for example, drugs), medical devices (for example, hearing aids and inhalers), diagnostic techniques (tests used to identify diseases), surgical procedures (for example, repair of hernias), health promotion activities (for example, patient education models for diabetes).

Non-experimental study

A study based on subjects selected on the basis of their availability, with no attempt having been made to avoid problems of bias.

Number needed to treat (NNT) Nutrition assessment

The number of patients that who on average must be treated to prevent a single occurrence of the outcome of interest.

A more detailed, specific, and in-depth evaluation of a patient's nutritional state, typically by an individual with nutritional expertise (e.g. a dietitian, clinician with an interest in nutrition, or nutrition nurse specialist) or by a nutritional support team⁹¹.

Nutrition screening

A rapid, simple and general procedure used by nursing, medical or other staff, often at first contact with the patient, to detect those who have significant nutritional problems or significant risks of such problems, in order that clear guidelines for action can be implemented, e.g. simple dietary measures or referral for expert help⁹¹.

Nutrition support

The provision of nutrients and any necessary adjunctive therapeutic agents to patients orally and/or enterally by administration into the stomach or intestine and/or by intravenous infusion (parenterally) for the purpose of improving or maintaining a patient's nutrition status' (JPEN 2002:19;1)

Nutrition Support Team

A multidisciplinary team with dietetic, nursing, pharmacy and medical expertise to provide safe nutrition support.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 23 of 262

Observational study

Retrospective or prospective study in which the investigator observes the natural course of events with or without control groups; for example,

cohort studies and case-control studies.

Older people

People over the age of 65 years.

Operating costs
Oral Nutritional
Supplement
Oral nutritional
support

Ongoing costs of carrying out an intervention, excluding capital costs. A commercially available product for use in oral nutrition support

The modification of food and fluid by: fortifying food with protein, carbohydrate and/or fat; the provision snacks and sip feeds as extra nutrition to regular meals, changing meal patterns or the provision of dietary advice to patients on how to increase nutrition intake by the above.

Orogastric (tube) feeding

Nutrition support provided by a tube inserted through the mouth via the oesophagus into the stomach

Opportunity cost

The opportunity cost of investing in a healthcare intervention is the other healthcare programmes that are displaced by its introduction. This may be best measured by the health benefits that could have been achieved had the money been spent on the next best alternative healthcare

intervention.

Outcome Measure of the possible results that may stem from exposure to a

preventive or therapeutic intervention. Outcome measures may be intermediate endpoints or they can be final endpoints. See 'Intermediate

outcome'.

P value The probability that an observed difference could have occurred by

chance, assuming that there is in fact no underlying difference between the means of the observations. If the probability is less than 1 in 20, the P value is less than 0.05; a result with a P value of less than 0.05 is

conventionally considered to be 'statistically significant'.

Parenteral nutrition
The provision of nutrition support through intravenous administration of

nutrients such as amino acids, glucose, fat, electrolytes, vitamins and

trace elements.

Perioperative The period from admission through surgery until discharge,

encompassing pre-operative and post-operative periods. Studies included in this guideline for surgical patients sometimes start or end their intervention outside this period. However, they always include nutrition

support during some of the perioperative phase.

Peer review A process where research is scrutinised by experts that have not been

involved in the design or execution of the studies.

Pilot study A small scale 'test' of the research instrument. For example, testing out

(piloting) a new questionnaire with people who are similar to the population of the study, in order to highlight any problems or areas of concern, which can then be addressed before the full scale study begins.

Placebo An inactive and physically identical medication or procedure used as a

comparator in controlled clinical trials.

Placebo effect A beneficial (or adverse) effect produced by a *placebo* and not due to any

property of the placebo itself.

Power See 'Statistical power'.

Primary care Healthcare delivered to patients outside hospitals. Primary care covers a

range of services provided by GPs, nurses and other health care

professionals, dentists, pharmacists and opticians.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 24 of 262

Primary research

Study generating original data rather than analysing data from existing

studies (which is called secondary research).

Product licence Prognosis

An authorisation from the MHRA to market a medicinal product.

A probable course or outcome of a disease. Prognostic factors are patient or disease characteristics that influence the course. Good prognosis is associated with low rate of undesirable outcomes; poor prognosis is

associated with a high rate of undesirable outcomes.

Proprietary name

The brand name given by the manufacturer to a drug or device it

produces.

Prospective study

A study in which people are entered into the research and then followed up over a period of time with future events recorded as they happen. This

contrasts with studies that are retrospective.

Qualitative research

Research concerned with subjective outcomes relating to social, emotional and experiential phenomena in health and social care.

Quality adjusted life years (QALYS) An index of survival that is adjusted to account for the patient's quality of life during this time. QALYs have the advantage of incorporating changes in both quantity (longevity/mortality) and quality (morbidity, psychological, functional, social and other factors) of life. Used to measure benefits in

cost-utility analysis.

Quality of life

See 'Health related quality of life'

Quantitative research

Research that generates numerical data or data that can be converted into numbers, for example clinical trials or the national Census which counts people and households.

Quick Reference Guide (for a guideline or appraisal) **Random allocation** or Randomisation

An abridged version of NICE guidance, which presents the key priorities for implementation and summarises the recommendations for the core clinical audience

Allocation of participants in a research study to two or more alternative groups using a chance procedure, such as computer-generated random numbers. This approach is used in an attempt to ensure there is an even distribution of participants with different characteristics between groups and thus reduce sources of bias.

Randomised controlled trial (RCT)

A comparative study in which participants are randomly allocated to intervention and control groups and followed up to examine differences in outcomes between the groups.

Rapid update

Review of existing guidance carried out sooner than originally planned because new data have become available.

Reference standard (or gold An agreed standard, for example for a test or treatment, against which

other interventions can be compared.

standard) Relative risk (RR)

The number of times more likely or less likely an event is to happen in one group compared with another (calculated as the risk of the event in group

A/the risk of the event in group B).

Reliability/repeatab ility

The degree of agreement exhibited when a measurement is repeated under identical conditions. Reliability refers to the degree to which the results obtained by a measurement procedure can be replicated.

Remit

The brief given by the Department of Health and Welsh Assembly Government at the beginning of the guideline development process. This

defines core areas of care that the guideline needs to address. An independent committee that scrutinises proposals for research to

ensure they are ethically acceptable.

Research Ethics Committee

Nutrition support in adults: full guideline DRAFT (August 2005) Page 25 of 262

Resource implication Retrospective study

The likely impact in terms of finance, workforce or other NHS resources.

Davious of the

A retrospective study deals with the present/ past and does not involve studying future events. This contrasts with studies that are *prospective*.

Review of the literature

An article that summarises the evidence contained in a number of different individual studies and draws conclusions about their findings. It may or may not be systematically researched and developed.

Secondary benefits

Benefits resulting from a treatment in addition to the primary, intended

outcome.

Secondary care

Care provided in hospitals.

Selection bias (also allocation bias)

A systematic bias in selecting participants for study groups, so that the groups have differences in prognosis and/or therapeutic sensitivities at baseline. Randomisation (with concealed allocation) of patients protects against this bias.

Selection criteria

Explicit standards used by guideline development groups to decide which studies should be included and excluded from consideration as potential

sources of evidence.

Sensitivity analysis

A means of representing uncertainty in the results of economic evaluations. Uncertainty may arise from missing data, imprecise estimates or methodological controversy. Sensitivity analysis also allows for exploring the generalisability of results to other settings. The analysis is repeated using different assumptions to examine the effect on the results. One-way simple sensitivity analysis (univariate analysis): each parameter is varied individually in order to isolate the consequences of each parameter on the results of the study. Multi-way simple sensitivity analysis (scenario analysis): two or more parameters are varied at the same time and the overall effect on the results is evaluated. Threshold sensitivity analysis: the critical value of parameters above or below which the conclusions of the study will change are identified. Probabilistic sensitivity analysis: probability distributions are assigned to the uncertain parameters and are incorporated into evaluation models based on decision analytical techniques (for example, Monte Carlo simulation). Recommendations on service delivery primarily aimed at health service commissioners. Service delivery guidance focuses on the broad configuration and provision of clinical services and addresses only those interventions that are likely to have implications for the configuration of

Service delivery guidance

Sip feed

services.

A commercially produced liquid product containing a balanced formulation

Specialised nutrition support

Specificity (of a test)
Standard care

The proportion of individuals classified as *negative* by the gold (or reference) standard, who are correctly identified by the study test.

of protein, fat and carbohydrate, vitamins and minerals.

The situation in which a patient is given no supplementary nutrition support but still eats meals and snacks as appropriate for their clinical status and usual practice.

Standardised Parenteral Nutrition

Admixtures containing fixed formulations of nutrients, such as amino acids, glucose, fat emulsion and electrolytes in a single sterile container system. Additions of other nutrients such as vitamins and trace elements and occasionally supplemental electrolytes are required to ensure complete admixtures are administered.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 26 of 262

Stakeholder

Synthesis of

evidence

guideline under development. Stakeholders include manufacturers, sponsors, healthcare professionals, and patient and carer groups.

sponsors, healthcare professionals, and patient and carer groups. The ability to demonstrate an association when one exists. Power is related to sample size; the larger the sample size, the greater the power

related to sample size; the larger the sample size, the greater the power and the lower the risk that a possible association could be missed.

A generic term to describe methods used for summarising (comparing

Those with an interest in the use of a technology under appraisal or a

and contrasting) evidence into a clinically meaningful conclusion in order to answer a defined clinical question. This can include systematic review (with or without meta-analysis), qualitative and narrative summaries.

Research that summarises the evidence on a clearly formulated question according to a pre-defined protocol using systematic and explicit methods to identify, select and appraise relevant studies, and to extract, collate and

report their findings. It may or may not use statistical metaanalysis. A systemic inflammatory response to at least two criteria leukocytosis,

fever, tachycardia, and tachypnea.

Systematic review

Statistical power

Systemic Inflammatory Response Syndrome (SIRS)

Technical Lead

Appraisals team member who has responsibility for the technical aspects of the appraisal including liaising with the Assessment Group, scoping the appraisal, preparing drafts of consultation documents and advising the Appraisal Committee on technical aspects of the appraisal. There may be more than one Technical Lead for an appraisal.

Technology assessment

The process of evaluating the clinical, economic and other evidence relating to use of a technology in order to formulate guidance on its most efficient use.

Test-and-treat strategy
Time horizon

Testing all individuals presenting with suspected of having a condition, and treating only those with a particular test result.

The time span used in the NICE appraisal which reflects the period over which the main differences between interventions in health effects and use of healthcare resources are expected to be experienced, and taking into account the limitations of supportive evidence.

Treatment allocation Treatment options Utility

The choices of intervention available.

Assigning a participant to a particular arm of the trial.

A measure of the strength of an individual's preference for a specific health state in relation to alternative health states. The utility scale assigns numerical values on a scale from 0 (death) to 1 (optimal or 'perfect' health). Health states can be considered worse than death and thus have a negative value.

Introduction and methods

1.1. The need for guidelines in nutrition support

Malnutrition is a state in which a deficiency of energy, protein and/or other nutrients causes measurable adverse effects on tissue/body form, composition, function or clinical outcome ⁹¹ (in these guidelines we do not use the term to cover excess nutrient provision). It is both a cause and a consequence of ill-health and is common in the UK. Since malnutrition increases a patient's vulnerability to ill-health, providing adequate nutrition support to patients with malnutrition should improve outcomes but decisions on the most effective and safe means to do so are complex. Currently, knowledge of the causes, effects and treatment of malnutrition amongst UK health professionals is poor. Guidelines are therefore needed to emphasise the following:

- 1. Malnutrition is common Many people who are unwell at home, in hospital or in the community, are likely to eat and drink less than they need. This impairment of food and fluid intake may be short-lived as part of an acute illness, or prolonged if there are chronic medical or social problems. If impaired food intake persists for even a few days, a patient can become malnourished to a degree that may impair recovery or precipitate other medical problems. This is especially true if the patient was malnourished before they became unwell due to other longstanding medical or psycho-social problems, or a generally poor diet. To compound any disease related reduction in food intake, many patients also have no help with obtaining or preparing meals when they are ill at home, while those in hospital may have further problems relating to poor standards of catering, inappropriate or interrupted meal times, incorrect food consistencies, and inappropriate eating aids and/or staff to help them eat and drink for themselves. The 'Better Hospital Food'257 and the 'Protected Mealtimes' plans are welcome government initiatives which try to improve the provision of hospital meals and snacks.
- 2. Malnutrition increases vulnerability to ill-health The consequences of malnutrition include vulnerability to infections, delayed wound healing, impaired function of heart and lungs, muscle weakness and depression⁹². As a consequence people who are malnourished consult their general practitioners (GPs) more frequently, go to hospital more often for longer periods, and have higher complication and mortality rates for similar conditions. If poor dietary intake persists for weeks, the resulting malnutrition may be life-threatening in itself.
- 3. Decisions on providing nutrition support are complex Although it is clear that clinical outcomes in malnourished groups are poor compared to the better nourished (e.g. malnourished surgical patients have complication rates 2 -3 times higher than their better nourished counterparts), the indications for active nutrition support using dietary supplementation, enteral tube feeding or parenteral nutrition are debatable. When individuals are unable or unlikely to meet the majority of their nutrient

Nutrition support in adults: full guideline DRAFT (August 2005) Page 28 of 262

needs for prolonged periods (e.g. patients with dysphagia or intestinal failure) the need for appropriate support is absolute unless artificially prolonging the patient's life is inappropriate. However, if nutritional intake is closer to meeting a patient's needs or the likely period of impaired intake is uncertain, decisions on providing nutrition support and the best means to do so are more difficult with multiple criteria for choosing oral, enteral or parenteral modalities which vary with both individual patient needs and the clinical expertise available to ensure that any intervention can be undertaken safely.

4. Understanding of malnutrition and nutritional support amongst many health care professionals is poor – The many difficulties relating to the need and best mode of nutrition support are compounded by a lack of knowledge about malnutrition and its treatment amongst many health-care professionals. There has been little emphasis on nutrition education in either undergraduate medical or nursing courses. This has led to poor recognition of both nutritional risks and the dangers of poorly managed nutrition support. Along with the lack of agreed national guidelines, this has also led to wide variation in nutritional care standards. Heyland et al 156 highlighted the difference between evidence in nutritional healthcare and practice when stating that:

'Approximately 30-40% of patients do not receive care according to present scientific evidence and about 20-25% of care is not needed or is potentially harmful'.

The objective of these guidelines is therefore to improve the practice of nutrition support by providing guidance to assist all health care professionals to correctly identify patients in hospital or the community who require nutritional intervention, and to help them choose and deliver the most appropriate form of nutrition support at the appropriate time. As such, they are in keeping with other recent publications highlighting the importance of good nutritional care e.g. the Department of Health's Essence of Care document⁸², the Welsh Assembly Government's Fundamentals of Care³⁷⁷ and the Royal College of Physicians' report 'Nutrition and patients: a doctor's responsibility'³⁰⁵. They are also about improving people's quality of life by making them feel better through adequate nutrition, and they have been developed with a significant contribution from patient representatives.

1.2 What is a guideline?

Guidelines are recommendations for the care of individuals in specific clinical conditions or circumstances – from prevention and self-care though primary and secondary care to more specialised services. Clinical guidelines are based on the best available evidence, and are produced to assist health care professionals and patients make informed choices about appropriate health care. While guidelines assist the practice of healthcare professionals, they do not replace their knowledge and skills.

Clinical guidelines for the NHS in England and Wales are produced as a response to a request from the Department of Health and the Welsh Assembly Government. They select topics for guideline development and before deciding whether to refer a particular topic to the National Institute for Health and Clinical Excellence (NICE) they consult with the relevant patient bodies, professional organisations and companies. Once a topic is referred, NICE then commissions one of seven National Collaborating Centres to produce a guideline. The Collaborating Centres are independent of government and comprise partnerships between a variety of academic institutions, health profession bodies and patient groups.

1.3 Remit of the guideline

The following remit was received from the Department of Health and National Assembly for Wales in as part of NICE's 7th wave programme of work:

"To prepare a guideline on appropriate methods of feeding people who

are still capable of deriving at least some of their nutritional requirements by conventional feeding and/or

have difficulty in swallowing

including the use of nutritional supplements and enteral and parenteral nutrition methods."

1.4 What the guideline covers

These guidelines cover most aspects of nutrition support in adult patients (>18 years) who are either malnourished or are at 'risk' of malnutrition. In some cases specific guidance related to patients in specific care settings or with specific diseases has been provided but in general the guidance is applicable to patients whatever their setting (hospital and community) or disease. The guideline therefore includes:

- information on the prevalence of malnutrition and the benefits of good nutrition
- guidance on the appropriate forums for the organization of nutrition support in all settings
- guidance on who should be screened for malnutrition and when, along with the criteria for consideration when assessing patients' nutritional status.
- The general indications for nutrition support together with ethical and legal considerations that may arise.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 30 of 262

- guidance on the process and special considerations required to prescribe nutrition support and details information on the important parameters to monitor for patients receiving nutrition support.
- Detailed guidance on the administration of oral, enteral and parenteral nutrition including; the appropriate types of access for enteral and parenteral nutrition and the optimum mode of delivering these.
- Specific guidance on the management of providing nutrition support to patients with dysphagia
- issues to consider for patients receiving enteral and parenteral nutrition support at home
- Issues arising for patients and their carers .

For more detailed information please see the full scope of this guideline Appendix One: scope.

1.5 What the guideline does not cover

The guideline does not provide guidance on:

- the provision of normal food and drinks
- Patients requiring specific specialist therapeutic or maintenance nutrition regimens in the context of diseases such as inborn errors of metabolism, diabetes and chronic renal or liver failure.
- Pregnant women, since the nutritional demands on the mother and baby require specialist considerations
- Patients with eating disorders, because the aims of intervention differ significantly from those with malnutrition related to disease.
- Primary prevention of malnutrition in healthy individuals in the general population.
- Children and adolescents under the age of 18 years.

The guideline also provides no recommendations on:

- The suitability of individually named oral supplements or enteral and parenteral nutrition solutions.
- The use of novel substrates such as glutamine or arginine (we are aware that there is some evidence suggesting potential benefit from the use of these substrates and believe that this should be addressed by NICE in the format of a health technology assessment).

- Types of tubing and receptacles used for enteral and parenteral nutrition support.
- The management of infections and infection control related to enteral and parenteral nutrition support although reference is made to the existing NICE guidance on Infection Control where appropriate.

1.6 Who the guideline is for

This guideline does not include recommendations covering every detail of nutrition support. Instead they seek to ensure that all health care professionals consider every patient's nutritional status and the length of time the patient has or will have an inadequate food intake, whatever the disease state or care setting. They are therefore relevant to all health care professionals who come into contact with patients, as well as to the patients themselves and their carers. It is also expected that the guideline will be of value to those involved in clinical governance in both primary and secondary care to help ensure that arrangements are in place to identify, treat and audit malnutrition and the use of nutrition support within their organisations.

1.7 Who developed the guideline?

A multidisciplinary Guideline Development Group (GDG) comprising professional group members and consumer representatives of the main stakeholders developed this guideline (see Guideline Development Group Membership and acknowledgements).

The National Institute for Health and Clinical Excellence funds the National Collaborating Centre for Acute Care and thus supported the development of this guideline. The GDG was convened by the National Collaborating Centre for Acute Care (NCC-AC) and chaired by Dr Mike Stroud in accordance with guidance from the National Institute for Health and Clinical Excellence (NICE).

The Group met every 6-8 weeks during the development of the guideline. At the start of the guideline development process all GDG members' interests were recorded on a standard declaration form that covered consultancies, fee-paid work, share-holdings, fellowships and support from the healthcare industry. At all subsequent GDG meetings, members declared arising conflicts of interest which were recorded.

Staff from the NCC-AC provided methodological support and guidance for the development process. They undertook systematic searches, retrieval and appraisal of the evidence and drafted the guideline. The Glossary to the guideline contains definitions of terms used by staff and the GDG.

1.8 Methodology

1.8.1 Outline of methods used

The guideline was commissioned by NICE. The guideline development process involved several steps and was developed in accordance with the guideline development process outlined in *Guideline development methods:* information for National Collaborating Centres and guideline developers²⁵⁴.

1.8.2 Development of clinical questions

The Guideline Development Group proposed a list of clinical questions (Appendix Two) related to the initiation and administration of oral, enteral and parenteral nutrition support. With the exception of the nutrition screening, monitoring and refeeding syndrome questions, the remaining questions were developed to investigate the benefit of one type or mode of intervention with another.

1.8.3 Types of study interventions

The Guideline Development Group agreed on the definition of terms and the inclusion and exclusion criteria for oral, enteral and parenteral interventions. These were included in the search strategies and considered throughout the process of systematic reviewing.

1.8.4 Types of study population

The search strategies were not restricted to specific patient/population groups since the GDG wished to determine the likely benefit or risks of nutrition support to all patient groups. Papers on children, pregnant mothers and people with eating disorders were excluded since they were out of the scope of this guideline.)

1.8.5 Types of outcomes

The Guideline Development Group requested that all outcomes should be recorded, with the exception of biochemical outcomes which were not clearly associated with clinical benefit (e.g. changes in nitrogen balance or plasma protein concentrations).

1.8.6 Types of studies

Study design was restricted to systematic reviews, meta-analyses of randomised controlled trials and randomised controlled trials. No other study designs were considered because of the potential bias associated with observational study designs. Also, the wide inclusion criteria agreed for

Nutrition support in adults: full guideline DRAFT (August 2005) Page 33 of 262

populations, interventions and outcomes would have made the task of including observational studies in the systematic reviews too great for the resources available.

1.8.7 Literature search

A literature review was conducted to identify and synthesise relevant evidence from the published literature. Three main search strategies were developed for oral, enteral and parenteral nutrition interventions. Four other search strategies were developed for nutritional screening, monitoring, dysphagia and patient issues.

Search filters to identify systematic reviews (SRs) and randomised controlled trials (RCTs) were applied to the search strategies. No language restrictions were applied to the search; however, foreign language papers were not requested or reviewed.

The following databases were included in the literature search:

- The Cochrane Library up to 2005 (Issue 1)
- Medline (Dialog Datastar) 1966-2005 (week)
- Embase (Dialog Datastar) 1980-2005 (week)
- Cinahl (Dialog Datastar) 1982-2005
- Allied & Complementary Medicine (Dialog Datastar) 1985-2005
- British Nursing Index (Dialog Datastar) 1994-2005

Although literature searching was started in 2003 update searches were run for each search to ensure all reviews included literature up to the same cutoff date. Therefore, each database was searched from its start date up to 3rd March 2005. Papers identified after this date were not considered, with the exception of the draft BAPEN report on 'The cost of malnutrition in the UK and the economic case for the use of oral supplements (ONS) in adults'93, which the GDG had been anticipating but which was received shortly after the cut-off date. Search strategies can be found in Appendix Three.

There was no systematic attempt to search for all the 'grey literature' (conferences, abstracts, theses and unpublished literature). We searched for guidelines and reports from relevant websites, including the following listed below. Bibliographies of identified reports and guidelines were also checked to identify relevant literature.

- National Institute for Health and Clinical Excellence (NICE) (www.nice.org.uk)
- National electronic Library for Health (NeLH) (http://www.nelh.nhs.uk/)
- National Institutes of Health Consensus Development Program (consensus.nih.gov)
- New Zealand Guidelines Development Group (NZGG) (http://www.nzgg.org.nz/)
- Scottish Intercollegiate Guideline Network (SIGN) (www.sign.ac.uk)
- US National Guideline Clearing House (www.guidelines.gov)

Nutrition support in adults: full guideline DRAFT (August 2005) Page 34 of 262

- Web sites of relevant members of the Guidelines International Network (http://www.g-i-n.net/)
- Google (www.google.com)

1.8.8 Study selection

One reviewer independently scanned the titles and abstracts of the literature searches. Full publications were obtained for any studies considered relevant or where there was insufficient information from the title and abstract to make a decision.

1.8.9 Data extraction and quality assessment

A team of reviewers individually applied the inclusion/exclusion criteria to determine all potentially relevant studies. The reviewers also assessed the quality of eligible studies by referring to the SIGN quality checklists for systematic reviews/meta-analyses and randomised control trials. Of all the relevant studies data on the type of population, intervention, comparator and outcomes was summarised onto evidence tables (Appendix Four). In the instances where there was missing data we did not attempt to contact the authors because of limited resources.

1.8.10 Meta-analysis

For some of our results we were able to produce a meta-analysis using Review Manager version 4.2, the software used by the Cochrane Collaboration. For some studies we approximated the mean length of stay using the median and estimated the standard deviation as a weighted mean of the standard deviations of the other studies.

1.8.11 Absence of literature

The recommendations in this guideline have been systematically developed with as much scientific rigour as possible when accounting for the absence of RCT evidence on a number of our clinical questions. In cases which either did not lend themselves to controlled trials and systematic reviewing, or for which there were too few trials identified to make substantive recommendations quasi randomised or observational studies were considered. Invariably, however, we also needed to use additional approaches such as surveys or formal consensus development to assist with some areas of the guidance.

Nutritional screening: because of weaknesses in the methodologies and designs of the studies identified, no firm conclusions could be made. A modified Delphi approach for consensus development was used, consisting of two rounds of Delphi questionnaire surveys and then a nominal group

Nutrition support in adults: full guideline DRAFT (August 2005) Page 35 of 262

technique meeting. See Screening Chapter 4.12 Consensus development methods.

Indications for oral, enteral and parenteral interventions: the guidance could not be derived from controlled trials thus the recommendations were drafted by the technical team at the NCC-AC and modified and agreed by informal consensus with the GDG.

Ethical and Legal issues: The brief important comments on the ethical and legal issues of nutrition support contained within these Guidelines were derived from GDG expertise and previous expert treatises on these topics

Dysphagia: No RCT's were found to provide guidance on options of nutrition support for patients with Dysphagia. A specialist sub group of speech therapists with a special interest in dysphagia was convened to develop and propose suitable recommendations. These were agreed by informal consensus with the GDG.

Prescription of nutrients: recommendations were proposed by GDG members with relevant expertise and agreed by informal consensus among all GDG members.

Refeeding syndrome: recommendations were formulated by members of the group based on previous published reviews and their own expertise, and agreed by informal consensus among all GDG members.

Monitoring: The GDG were sent questionnaires electronically asking them to determine how often certain nutritional and biochemical parameters are and should be measured. Two GDG members with expertise in this area considered the outcomes of the survey and proposed the guidance/recommendations which the GDG agreed by informal consensus.

Nutritional assessment: two GDG members with expertise in this area proposed the guidance/recommendations to the whole GDG who agreed on these by informal consensus.

Nutrition support teams: both randomised and non-randomised trials were considered for this section as some observational study designs were also appropriate for this question.

Patients' and carers' views: We sent letters requesting evidence on patients' and carers' views of nutrition support to twenty stakeholders. A literature search was conducted to identify relevant evidence for any study design. The following databases were included:

- Medline (1951-2005)
- Embase (1980-2005)

• Cinahl (1982-2005)

Three sub-group meetings with patient representatives on the GDG were held. Patient representatives were involved in the sifting of the abstracts retrieved from the literature search. A systematic reviewer summarised the evidence from the studies. The text was included in discussion with patient representatives at sub-group meetings and in consultation with GDG members at GDG meetings.

1.9Hierarchy of clinical evidence

There are many different methods of ranking the evidence and there has been considerable debate about what system is best. A number of initiatives are currently under way to find an international consensus on the subject, but until a decision is reached on the most appropriate system for the NICE guidelines, the Institute advises the National Collaborating Centres to use the system for evidence shown in Table 1.

Table 1: Levels of evidence for intervention studies (reproduced with permission of the Scottish Intercollegiate Guidelines Network)

Level of evidence	Type of evidence	
1++	High-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias	
1+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias	
1-	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias	
2++	High-quality systematic reviews of case-control or cohort studies High-quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal	
2+	Well-conducted case-control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal	
2-	Case-control or cohort studies with a high risk of confounding bias, or chance and a significant risk that the relationship is not causal	
3	Non-analytic studies (for example, case reports, case series)	
4	Expert opinion	

Nutrition support in adults: full guideline DRAFT (August 2005) Page 37 of 262

The ranking system described above covers studies of treatment effectiveness and is less appropriate for studies reporting diagnostic tests of accuracy.

1.10 Health economics methods

It is important to investigate whether health services are both clinically effective and cost-effective (that is, value for money). If a particular diagnostic or treatment strategy was found to yield little health gain relative to the resources used, then it could be advantageous to re-deploy resources to other activities that yield greater health gain.

To assess the cost-effectiveness of each recommendation, a comprehensive systematic review of the economic literature was conducted. In addition an original cost-effectiveness analysis was performed for malnutrition screening.

The primary criteria applied for an intervention to be considered costeffective were either:

- a) the intervention dominated other relevant strategies (that is, it is both less costly in terms of resource use and more clinically effective compared with the other relevant alternative strategies); or
- b) the intervention cost less than £20,000 per quality-adjusted life-year (QALY) gained compared with the next best strategy (and compared with best supportive care). Between £20,000 and £30,000 per QALY, judgments about the acceptability of the intervention as an effective use of NHS resources have to make more explicit reference to such factors as the degree of uncertainty surrounding the calculation of cost-effectiveness, the innovative nature of the intervention and the particular features of the condition and the population receiving it.

1.10.1 Literature review for health economics

We obtained published economic evidence from a systematic search of the following databases:

- Medline (Dialog Datastar) (1966-2005)
- Embase (Dialog Datastar) (1980-2005)
- Health Economic Evaluations Database (HEED)
- NHS Economic Evaluations Database (NHS EED)

For those clinical areas we reviewed, the information scientists used a similar search strategy as used for the review of clinical evidence. However, an economics filter was used in the place of a systematic review or

Nutrition support in adults: full guideline DRAFT (August 2005) Page 38 of 262

randomised controlled trial filter. Although literature searching was started in 2003 update searches were run for each search to ensure all reviews included literature up to the same cut-off date. Therefore, each database was searched from its start date up to 3rd March 2005. Papers identified after this date were not considered. Search strategies can be found in Appendix Three.

Each search strategy was designed to find any applied study estimating the cost or cost-effectiveness of some aspect of nutrition support. A health economist reviewed abstracts. Relevant references in the bibliographies of reviewed papers were also identified and reviewed.

Given the diversity of economic studies, it was not possible to determine a general exclusion criterion based on study quality. Hence, all studies were included in the evidence tables and study quality and applicability are discussed in the review. Papers were only excluded from the evidence tables and review if:

- The study did not contain any original data on cost or costeffectiveness (i.e. it was a review or a clinical paper).
- The analysis was not incremental and was not described adequately
 to allow incremental analysis (so studies reporting only average costeffectiveness ratios [the cost for one treatment divided by the health
 outcome] were excluded unless they provided data to allow the
 calculation of incremental cost-effectiveness ratios [the change in cost
 divided by the change in health outcome]). Only incremental costeffectiveness ratios can inform us about value for money.
- Cost analyses were excluded if the results were not presented in a
 way that would allow the incremental cost per patient to be extracted
 or derived. The total hospital cost is difficult to interpret unless we
 know how many patients are being treated.

For one topic – nutrition support teams – it was decided to exclude studies which had only a single cohort and used conjecture to assess the incremental cost. These studies were excluded since there was other evidence that was deemed to be more rigorous – the included studies all compared two cohorts, and one of them was a randomised controlled trial.

Included papers were reviewed by a health economist. In the text, costs have been converted to £ sterling using the relevant purchasing power parity for the study year. In the evidence tables costs are reported as given in the paper. However, where costs were in a currency other than pounds sterling, US dollars or euros, the results were converted to pounds sterling.

Each study was categorised as one of the following: cost analysis, cost-effectiveness analysis, cost-utility analysis or cost consequences analysis (see glossary). Many of the studies in this review were labelled 'cost consequences analyses' because they present many different health outcomes (in addition to cost) without a single overall measure health gain.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 39 of 262

Often these studies report complications. Where complications averted appears to be the main clinical outcome we have estimated cost-effectiveness by calculating the incremental cost per complication averted. We did not find any 'cost benefit analyses' (studies that put a monetary value on health gain).

1.10.2 Cost-effectiveness modelling

Screening was selected for original economic analysis because it was likely that the recommendations under consideration would substantially change clinical practice in the NHS and have important consequences for resource use

The details of the model are reported in chapter 4 and Appendix Five: Cost-Effectiveness Analysis of Malnutrition Screening. The following general principles were adhered to:

- The GDG was consulted during the construction and interpretation of the model.
- The model was based on the best evidence from the systematic review.
- Model assumptions were reported fully and transparently.
- The results were subject to thorough sensitivity analysis and limitations discussed.
- Costs were calculated from a health services perspective.

1.11 Forming and grading the recommendations

NICE guideline recommendations are graded according to the strength of the supporting evidence, which is assessed from the design of each study (see Table 1). The grading system currently used is presented in Table 2.

The Guideline Development Group was presented with summaries (text and evidence tables) of the best available research evidence to answer the clinical questions. Recommendations were based on, and explicitly linked to, the evidence that supported them. With the exception of the nutrition screening recommendations the Group worked on an informal consensus basis to formulate and grade recommendations according to the level of evidence upon which they were based.

Table 2: Grading of recommendations

Grade	Evidence
А	At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population, or
	A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
	Evidence drawn from a NICE technology appraisal
В	• A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results, or
	Extrapolated evidence from studies rated as 1++ or 1+
С	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results, or
	Extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4, or
	Extrapolated evidence from studies rated as 2+, or
	Formal consensus
D (GPP)	A good practice point (GPP) is a recommendation for best practice based on the experience of the Guideline Development Group

The usefulness of a classification system based solely on the level of evidence has been questioned because it does not take into consideration the importance of the recommendation in changing practice and improving patient care. It is worth noting that NICE is currently assessing the best way of presenting recommendations for future guidelines.

1.12 Specific problems with evidence relating to the development of nutrition support guidelines

Literature searching, appraising the evidence and developing recommendations for this guideline proved to be particularly challenging. In part, this was due to a shortage of randomised controlled trials relating to some of the clinical questions, but the GDG also observed problems with the types of patients entered into many of the selected controlled trials. Providing nutrition is usually seen as a part of basic care, and this creates obstacles to good quality research in nutrition support. For example, although it is obvious that inadequate provision of nutrition for prolonged

Nutrition support in adults: full guideline DRAFT (August 2005) Page 41 of 262

periods eventually leads to death, no randomised trials support this statement.

Other fundamental problems with available evidence include:

- a. In trials of nutritional intervention it is often neither feasible nor ethical to have 'no nutrition' as the control.
- b. Patients who are malnourished and therefore eligible to be recruited for trials of nutrition support have very variable diagnoses and come from a wide variety of settings. Trial populations are therefore very heterogeneous with wide potential variation in outcomes of interest. Large scale studies are therefore needed to demonstrate any potential benefits on outcome but most nutritional trials have been small.
- c. When performing trials on invasive means of nutrition support such as enteral and parenteral nutrition, it is usually considered unethical to randomise patients who have an 'undoubted' need for such support. Trials therefore recruit patients who are at lower nutritional risk than those conventionally fed by these methods and so their results may be inapplicable to normal clinical practice.
- d. Developments in the formulations and delivery of enteral and parenteral nutrition support and consequent reductions in risk have made many older studies less relevant. For instance, in recent years it has been recognised that too much additional nutrient provision can sometimes be more harmful than no nutrition support, yet much of the literature pre-dates this change in thinking.

The GDG also encountered methodological problems with the available nutritional research, including:

- a. Significant heterogeneity in the outcomes reported e.g. for one type of intervention, 5 separate studies may use 5 different indicators to report change in nutritional status.
- b. Lack of information on the period prior to starting nutrition support despite the fact that the duration and intensity of starvation before intervention is clearly pertinent to any outcome.
- c. Study periods which were often too short to determine the true effect of any intervention (e.g. reporting change in body weight two weeks after prescribing a sip feed may not be long enough to establish whether the patient benefits in the long term).
- d. Weak characterisation of patient populations in terms of underlying diagnosis, illness severity or degree of malnutrition.
- e. Lack of information on the amount of feed actually received by patients and/ or the wide variation in the amount received (a particular weakness of older enteral feeding studies).

Nutrition support in adults: full guideline DRAFT (August 2005) Page 42 of 262

- f. The presence of many potentially confounding issues when reporting outcomes attributed by authors to nutritional intervention in small trials (e.g. infection rates and mortality).
- g. The predominance of evidence from limited acute or chronic care settings with complete absence of evidence from other settings makes generalisation of conclusions difficult.

In view of the above, many questions related to nutritional support may be better addressed by study designs other than RCTs but the broad scope of these Guidelines and the difficulties with handling the biases associated with observational studies prevented the GDG from formally searching for sources of non-RCT evidence. In the absence of evidence from RCT's many of the clinical questions have therefore been addressed using expert opinion and consensus techniques.

1.13 Patient-centred care

This guideline offers best practice advice on the care of adults who are malnourished or at risk of malnutrition.

Treatment and care should take into account patients' individual needs and preferences. People who are malnourished or at risk of malnutrition should be involved with making informed decisions about their care and treatment. Where patients do not have the capacity to make decisions, healthcare professionals should follow the Department of Health guidelines – *Reference guide to consent for examination or treatment* (2001) (available from www.dh.gov.uk).

Good communication between healthcare professionals and patients is essential. It should be supported by the provision of evidence-based information offered in a form that is tailored to the needs of the individual patient. The treatment, care and information provided should be culturally appropriate and in a form that is accessible to people who have additional needs, such as people with physical, cognitive or sensory disabilities, and people who do not speak or read English.

Unless specifically excluded by the patient, carers and/or relatives should be consulted regarding care and treatment and their views taken into account in the decision making process.

Carers and relatives should also be provided with the information and support they need.

1.14 Summary of the recommendations

1.14.1 Key recommendations for implementation

The following recommendations have been selected from the full list (section 1.14.2) as priorities for implementation.

Organisation of nutrition support

All healthcare workers in hospital and the community who are directly involved in patient care should receive training in:

- - the importance of nutrition (for patients)
- the indications for nutrition support and its delivery (routes, mode of access, prescription)
- when and where to seek expert advice on nutrition support [D(GPP)]

Screening

All hospital inpatients on admission and all outpatients at their first clinic appointment should be screened for the presence or risk of malnutrition. Screening should be repeated weekly for inpatients and as indicated clinically for outpatients. Departments who identify groups of patients with low risk of malnutrition may opt-out of screening for those groups although opt-out decisions should follow an explicit process via the local clinical governance structure involving experts in nutrition support. [D(GPP)]

All residents or patients in care homes should be screened for the presence or risk of malnutrition on admission and whenever there is clinical concern (for example patients with fragile skin, poor wound healing, apathy, wasted muscles, poor appetite, altered taste sensation, impaired swallowing, altered bowel habit, loose fitting clothes, or prolonged intercurrent illness). [D(GPP)]

Oral

Healthcare professionals should consider interventions to improve oral intake to patients who can swallow safely and who are:

- malnourished (BMI <18.5-20 kg/m² and unintentional weight loss >5% within the previous 3-6 months) or
- at risk of malnutrition (eaten very little for >5 days and or unlikely to eat more than very little amounts for the next 5 days).

Patients with any of the obvious or less obvious indicators for dysphagia (Table 3) should be referred to healthcare professionals with specialist training in the diagnosis, assessment and management of swallowing disorders for example speech and language therapists, gastroenterologists, radiologists, neurologists, specialist nurses. [D(GPP)]

Table 3: Obvious and less obvious indicators for dysphagia

Obvious Indicators	Less Obvious Indicators	
Patient reports difficulty and/ or painful chewing and/ or swallowing.	Change in respiration pattern	
Regurgitation of undigested food stuffs	Unexplained temperature spikes	
Difficulty controlling food and/ or liquid in the mouth	Wet voice quality	
Drooling	Tongue fasciculation (may be indicative of motor neurone disease)	
Hoarse voice	Xerostomia	
Coughing and/ or choking before, during, or after swallowing	Heartburn	
Globus sensation	Change in eating – for example, eating slowly or avoiding social occasions	
Nasal regurgitation	Frequent throat clearing	
Feeling of obstruction	Recurrent chest infections	
Unexplained/ involuntary weight loss	Atypical chest pain	

Enteral

Healthcare professionals should consider enteral tube feeding in patients who have a functional, tube accessible gastrointestinal tract and who despite the use of oral interventions if appropriate, still have an inadequate or unsafe oral intake and are:

malnourished (BMI <18.5 kg/m² and unintentional weight loss >10% within the previous 3-6 months or BMI <18.5-20 kg/m² and unintentional weight loss >5% within the previous 3-6 months)

and/ or

 at risk of malnutrition (eaten very little for >5 days and or unlikely to eat more than very little amounts for the next 5 days).

Parenteral

Healthcare professionals should consider parenteral nutrition in patients who have a non-functional and /or inaccessible gastrointestinal tract such that they cannot be adequately fed by other means and are:

- malnourished (BMI< 18.5 kg/m² and unintentional weight loss> 10% within the previous 3-6 months, or
 - at risk of malnutrition (eaten very little for > 5 days and or unlikely to eat more than very little amounts for the next 5 days).

What to give

Health care professionals who are appropriately skilled and trained and have knowledge of nutritional requirements and nutrition support (dietitians, pharmacists) should ensure that the total nutrient intake (that is from any food, oral fluid, oral supplements, enteral feeds and IV fluid/PN) accounts for:

- energy, protein, fluid, electrolyte, mineral and micronutrients needs,

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- activity levels and the underlying clinical condition.
- metabolic instability, risk of refeeding problems
- how much nutrition support is being delivered and the potential of poor tolerance of feeds
- the likely duration of nutrition support.

Patients who meet the criteria in Table 4 should be considered to be at very high risk of refeeding problems.

Table 4: Criteria for determining patients at risk of refeeding problems Patient has one or more of the following:

BMI <16 kg/m²

of 262

unintentional weight loss >15%

very little nutritional intake for >10 days

low levels of potassium, phosphate or magnesium prior to feeding

Nutrition support in adults: full guideline DRAFT (August 2005)

Page 46

Or patient has two or more of the following:

BMI <18.5 kg/m²

weight loss >10%

very little nutritional intake for >5 days

a history of alcohol abuse or drugs including insulin, chemotherapy, antacids or diuretics

Monitoring

Healthcare professionals involved in the provision of nutrition support should ensure that there is a review of the indications for, route of and goals of nutrition support daily or twice weekly until the patient is stabilised on nutrition support. Patients receiving long term support should have a similar review every 3-6 months until nutrition support is no longer required. [D(GPP)]

1.14.2 Clinical practice recommendations

Recommendations are graded A, B, C, D or D (GPP) according to the level of evidence of effectiveness that they are based upon.

Organisation of nutrition support

- 1.14.2.1 All healthcare workers in hospital and the community who are directly involved in patient care should receive training in:
 - the importance of nutrition (for patients)
 - the indications for nutrition support and its delivery (routes, mode of access, prescription)
 - when and where to seek expert advice on nutrition support [D(GPP)]
- 1.14.2.2 Healthcare professionals should ensure that patients in hospital and the community who require nutrition support are

Nutrition support in adults: full guideline DRAFT (August 2005) Page 47 of 262

provided with coordinated multi-disciplinary care. This should include close liaison between clinician responsible, pharmacists, dietitians, specialist nutrition and district nurses, patients, carers, caterers, GPs and other allied healthcare professionals as appropriate (for example speech and language therapists). [D (GPP)]

- 1.14.2.3 Healthcare professionals should ensure hospitals and care homes provide:
 - food and fluid of adequate quantity and quality in an environment conducive to eating
 - appropriate support (for example modified eating aids) to those patients who can potentially chew and swallow but who are unable to feed themselves. [D (GPP)]
- 1.14.2.4 All hospitals should consider the employment of at least one specialist nutrition support nurse to:
 - coordinate ward based training, as appropriate
 - ensure that hospital protocols optimise nutritional care and minimise complications are followed, and
 - co-ordinate care within hospital and the community. [D (GPP)]
- 1.14.2.5 Trusts should have a Nutrition Steering Committee to ensure that all patients' nutritional needs are met using nutrition support as appropriate in the safest and most cost-effective manner. Members should include senior representation from Trust management, catering, dietetics, nursing and the nutrition support team and should work within the Governance framework. [D(GPP)]

Nutritional assessment and screening

1.14.2.6 Nutritional assessment and screening should be carried out by healthcare professionals with appropriate training and skills to

Nutrition support in adults: full guideline DRAFT (August 2005) Page 48 of 262

help generate the confidence of patients and enable accurate data collection. [D (GPP)]

- 1.14.2.7 All hospital inpatients on admission and all outpatients at their first clinic appointment should be screened for the presence or risk of malnutrition. Screening should be repeated weekly for inpatients and as indicated clinically for outpatients. Departments who identify groups of patients with low risk of malnutrition may opt-out of screening for those groups although opt-out decisions should follow an explicit process via the local clinical governance structure involving experts in nutrition support. [D(GPP)]
- 1.14.2.8 All residents or patients in care homes should be screened for the presence or risk of malnutrition on admission and whenever there is clinical concern (for example patients with fragile skin, poor wound healing, apathy, wasted muscles, poor appetite, altered taste sensation, impaired swallowing, altered bowel habit, loose fitting clothes, or prolonged intercurrent illness). [D(GPP)]
- 1.14.2.9 Patients on initial registration at general practice and where there is clinical concern should be screened for risk of or existing malnutrition (for example patients with fragile skin, poor wound healing, apathy, wasted muscles, poor appetite, altered taste sensation, impaired swallowing, altered bowel habit, loose fitting clothes, or prolonged intercurrent illness). Screening should also be considered at other opportunities (for example health checks, flu injections). [D(GPP)]
- 1.14.2.10 All screening should be undertaken using a tool that includes BMI, percentage weight loss and consideration of the time over which nutrient intake has been reduced and/or the likelihood of future impaired nutrient intake (for example the Malnutrition Universal Screening Tool, 'MUST'). [D(GPP)]

Indications

- 1.14.2.11 Nutrition support should be considered in patients when:
 - the patient has eaten very little amounts for the last 5 days or more, or
 - the patient is very unlikely to eat more than very little amounts for the next 5 days or more (whatever current BMI or history of weight loss), or
 - the patient's BMI is < 18.5 kg/m², or
 - the patient has unintentionally lost >10% body weight within the previous 3-6 months, or
 - the patient has a BMI < 20 kg/m² with unintentional weight loss >5% within the previous 3–6 months, or
 - the patient has poor absorptive capacity, is catabolic and/or has high nutrient losses and or has a condition that increases their nutritional needs for example hyper mobility.[D(GPP)]
- 1.14.2.12 Healthcare professionals should ensure that cultural, ethical and legal issues are considered when any decisions regarding the nutrition support of patients are made. [D(GPP)]

For ethical considerations of providing nutrition support see guidance issued by the General Medical Council (available from www.gmc-uk.org) and the Department of Health guidelines – Reference guide to consent for examination or treatment (2001) (available from www.dh.gov.uk).[D(GPP)]

For issues addressing patient competence and consent see guidance issued by the General Medical Council (available from www.gmc-uk.org) and the Department of Health guidelines – Reference guide to consent for examination or treatment (2001) (available from www.dh.gov.uk).[D(GPP)]

1.14.2.13 Healthcare professionals involved in the provision of nutrition support should ensure that there is a review of the indications for, route of and goals of nutrition support daily or twice

Nutrition support in adults: full guideline DRAFT (August 2005) Page 50 of 262

weekly until the patient is stabilised on nutrition support and or every 3-6 months and/or until nutrition support is no longer required.[D(GPP)]

- 1.14.2.14 Healthcare professionals should ensure that patients having nutrition support along with their carers are kept fully informed about their treatment and have access to appropriate information and/or the opportunity to discuss diagnosis and treatment options.[D(GPP)]
- 1.14.2.15 Information on nutrition support should be provided in formats, languages and ways that are suited to an individual's requirements. Consideration should be given to the cognitive ability, gender, physical needs, culture, ethnicity and stage of life of the individual. [D(GPP)]

Prescription of nutrition support

- 1.14.2.16 Healthcare professionals who are appropriately skilled and trained and have knowledge of nutritional requirements and nutrition support (dietitians, pharmacists) should ensure that the total nutrient intake (that is from any food, oral fluid, oral supplements, enteral feeds and IV fluid/PN) accounts for:
 - energy, protein, fluid, electrolyte, mineral and micronutrients needs,
 - activity levels and the underlying clinical condition
 - · metabolic instability, risk of refeeding problems
 - how much nutrition support is being delivered and the potential of poor tolerance of feeds
 - the likely duration of nutrition support.[D(GPP)]
- 1.14.2.17 For patients who are clinically stable, the suggested nutritional prescription for total intake (that is from any food, oral fluid, oral supplements, enteral feeds and IV fluid/PN) should have:
 - 20-30 kcal/kg/day total energy (including that derived from protein)
 - 1 1.5g protein/kg/day.
 - 30-35 ml fluid/kg (with allowance for extra losses from drains, fistulae etc. and extra input from other sources for example IV drugs) and
 - considered the need for additional electrolytes, minerals and micronutrients in patients with pre-existing deficits, high losses or increased demands.[D(GPP)]
- 1.14.2.18 The prescription must be reviewed at each stage of the patient's illness and great care must be taken when:
- using food fortification which tends to supplement energy and/or protein without adequate micronutrients and minerals
- using feeds and supplements that are apparently complete but do not meet all daily micronutrient and mineral needs unless they are also meeting full energy needs.

- using pre-mixed PN bags that have not had tailored additions from pharmacy.[D(GPP)]
- 1.14.2.19 Patients requiring enteral or parenteral nutrition support who are seriously ill or injured should have an initial prescription devised that cautiously introduces nutrition support at 50% or less of normal energy and protein requirements according to metabolic and gastrointestinal tolerance.[D(GPP)]
- 1.14.2.20 Patients who are severely malnourished (for example BMI <18.5kg/m² and/or unintentional weight loss > 10% in previous 3-6 months) and those with very little intake for > 5 days should have nutrition support introduced at a maximum of 20 kcal/kg/day for the first 2 days, gradually increasing to meet estimated needs by 4-6 days.[D(GPP)]
- 1.14.2.21 Patients who meet the criteria in Table 5 should be considered to be at very high risk of refeeding problems.[D(GPP)]

Table 5: Criteria for determining patients at risk of refeeding problems

Patient has one or more of the following:

 $BMI < 16 \text{ kg/m}^2$

Unintentional weight loss > 15%

Very little nutritional intake for > 10 days

Low levels of potassium, phosphate or magnesium prior to feeding

Or patient has two or more of the following:

 $BMI < 18.5 \text{ kg/m}^2$

Weight loss > 10%

Very little nutritional intake for > 5 days

A history of alcohol abuse or drugs including insulin, chemotherapy, antacids or diuretics

Nutrition support in adults: full guideline DRAFT (August 2005) Page 53 of 262

- 1.14.2.22 Patients at very high risk of refeeding problems (Table 13) should be looked after by healthcare professionals who are appropriately skilled and trained and have expertise knowledge of nutritional requirements and nutrition support to ensure that the prescription devised considers:
- start nutrition support at a maximum of 10 kcal/kg/day, increasing levels slowly to meet or exceed full needs by 5 to 10 days.
- use only 5 kcal/kg/day in extreme cases (for example BMI < 14 kg/m² or negligible intake for >15 days) and monitor cardiac rhythm continually in these patients and any others who already have or develop any cardiac arrhythmias.
- restore circulatory volume and monitor fluid balance and overall clinical status closely.
- provide immediately before and during the first 10 days of feeding thiamine 100 mg q.d.s, vitamin B co strong 1 b.d. (or full dose daily IV vitamin B preparation if necessary) and a balanced multivitamin/trace element supplement 1 o.d.
- provide oral, enteral or IV supplements of potassium (likely requirement 2- 4 mmol/kg/day), phosphate (likely requirement 0.3 -0.6 mmol/kg/day) and magnesium (likely requirement 0.2-0.4 mmol/kg/day) unless pre-feeding plasma levels are high. Pre-feeding correction of low plasma levels is unnecessary.[D(GPP)]

Monitoring

- 1.14.2.23 Healthcare professionals involved in the provision of nutrition support should ensure that there is a review of the indications for, route of and goals of nutrition support at least twice weekly until the patient is stabilised on nutrition support. Patients receiving long term support should have a similar review every 3-6 months until nutrition support is no longer required.[D(GPP)]
- 1.14.2.24 Patients having nutrition support in hospital should be monitored by health care professionals with the relevant competencies in nutritional monitoring (for example nurse, dietitian, physician and laboratory specialists).[D(GPP)]

- 1.14.2.25 Healthcare professionals should consider the protocols for nutritional, anthropometric and clinical monitoring (Table 6) for patients on nutrition support in hospital. [D(GPP)]
- 1.14.2.26 Healthcare professionals should consider the protocols for laboratory monitoring (Table 7) of patients on nutrition support in hospital. Table 7 is specifically applicable to patients receiving parenteral nutrition. It could also be selectively applied to patients receiving enteral or oral nutrition support especially if patients are unstable or are at risk of refeeding syndrome. The frequency and extent of these observations may need adapted for patients who are acutely ill or metabolically unstable.[D(GPP)]
- 1.14.2.27 Patients having parenteral nutrition support in the community need regular expert assessment and monitoring. This should be carried out by home care nutrition nurse specialists and/or by experienced hospital teams (initially at least weekly), using observations marked* in table 5. In addition they should be monitored at a specialist hospital clinic at least every 3-6 months, more frequently during the early months of HPN, when the full range of tests in Table 5 and Table 7 should be performed. Some of the clinical observations may be checked by patients or carers daily.[D(GPP)]
- 1.14.2.28 Patients having oral and/ or enteral nutrition support in the community should be monitored by health care professionals with the relevant competencies in nutritional monitoring (for example community nurse, dietitian and GP). This group of patients should be monitored every 3-6 months and/or if there is any change in their clinical condition since their last review. A limited range of observations and tests should be performed selected from table 5 and 6. Some of the clinical observations may be checked by patients or carers daily. If clinical progress is satisfactory, laboratory tests are rarely required. [D(GPP)]
- 1.14.2.29 Where long-term nutritional support is required patients and/or carers should be trained to recognise and respond to adverse changes in both their well-being and in the management of their nutritional delivery system. [D(GPP)]

Table 6: Hospital protocol (and community protocol*) for Nutritional, Anthropometric and Clinical Monitoring for patients receiving nutrition support by oral, enteral and/or parenteral routes.

Parameter	Frequency	Rationale
Nutritional		
Nutrient intake from oral, enteral or parenteral nutrition (including any change in conditions that are affecting food intake) *	Daily initially, reducing to 2x/week when stable, and then monthly for long term feeding in the community	To ensure that patient is receiving nutrients to meet requirements and that current method of feeding is still the most appropriate. To allow alteration of feed/diet as indicated by monitoring
Actual volume of feed delivered *	Daily initially, reducing to 2x/week when stable	To ensure that patient is receiving correct volume of feed. To allow troubleshooting of any problems
Fluid balance charts (enteral		To ensure patient is not/is not becoming over/under hydrated
and parenteral)	Daily initially, reducing to 2x/week when stable	
Anthropometric		
Weight*	Daily if concerns re fluid balance otherwise weekly reducing to monthly	To assess ongoing nutritional status, determine whether nutritional goals are being achieved and take into account both body fat and muscle
BMI*	Start of feeding and then monthly	
Mid arm circumference*	Monthly- in patients where weight cannot be obtained or is difficult to interpret	
Triceps skinfold thickness	Monthly- in patients where weight cannot be obtained	

Nutrition support in adults: full guideline DRAFT (August 2005) of 262

Parameter	Frequency	Rationale	
	or is difficult to interpret		
GI function			
Nausea/vomiting*	Daily initially reducing to 2x/week	To ensure tolerance of feed	
Diarrhoea*	Daily initially reducing to 2x/week	To rule out any other causes of diarrhoea and then assess feeding	
Constipation*	Daily initially reducing to 2x/week	Rule out other causes of constipation and then assess feed	
Abdominal distension	As necessary	Assess tolerance of feed	
Enteral tube – nasally inserted			
Tube position (pH <5.5 using pH paper)*	Before each feed begins	To ensure tube in correct position	
Nasal erosion*	Daily	To ensure tolerance of tube	
Fixation (is it secure)*	Daily	Help prevent tube becoming dislodged	
Is tube in working order (all pieces intact, tube blocked/kinked)*	Daily	Ensure tube is in working order	
Tube - gastrostomy or jejunostomy			

Nutrition support in adults: full guideline DRAFT (August 2005) Page 57 of 262

Parameter	Frequency	Rationale
Stoma site*	Daily	To ensure site not infected/red no signs of gastric leakage
Tube position (length at external fixation) (gastrostomy)*	Daily	To ensure tube has not migrated from/into stomach and external overgranulation
Tube rotation (gastrostomy only)*	Weekly	Prevent internal over granulation
Balloon water volume (balloon retained gastrostomies only)*	At insertion	To prevent tube falling out
Exact small bowel position (jejunostomy)	Daily	Confirmation of initial position
Parenteral nutrition Line site*	Daily	Signs of infection/inflammation
Skin over position of line tip (peripherally fed patients)*	Daily	Signs of thrombophlebitis

Parameter	Frequency	Rationale
Clinical condition		
General condition (including skin condition)*	Daily	To ensure that patient is tolerating feed and that feeding and route continue to be appropriate
Temperature/blood pressure	Daily initially	Sign of infection/fluid balance
Drug therapy*	Daily initially reducing to monthly when stable	Appropriate preparation of drug (to reduce incidence of tube blockage). To prevent/reduce drug nutrient interactions
Long/short term goals		
Are goals being met*	Daily initially reducing to 2x/week and then monthly?	To ensure that feeding is appropriate to overall care of patient
Are goals still appropriate*		

 Table 7: Hospital protocol for laboratory monitoring patients on nutrition support

Parameter	Frequency	Rationale	Interpretation
Sodium, potassium, urea, creatinine	Baseline. Daily till stable. Then 1-2X weekly.	Assessment of renal function, fluid status, and Na and K status	Interpret with knowledge of fluid balance and medication. Urine Na may be helpful in complex cases with gastrointestinal fluid loss.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 59 of 262

Parameter	Frequency	Rationale	Interpretation
Glucose	Baseline 1-2X daily (or more if required) till stable Then weekly	Glucose intolerance is common	Good glycaemic control is necessary
Magnesium, phosphate	Baseline. Daily if risk of refeeding syndrome. 3X weekly till stable Then weekly.	Depletion is common and under recognised	Low concentrations indicates poor status
Liver function tests	Baseline 2X weekly till stable Then weekly	Abnormalities common during IVN	Complex. May be due to sepsis, other disease or nutritional intake
Calcium, albumin	Baseline. Then weekly.	Hypocalcaemia or hypercalcaemia may occur	Correct measured serum calcium concentration for albumin. Hypocalcaemia may be secondary to Mg deficiency. Low albumin reflects disease not protein status
Prealbumin	Baseline Then weekly	Short half-life marker of protein status	Affected by APR Especially useful in HPN
C-reactive protein	Baseline 2-3X weekly till stable	Assists interpretation of protein, trace element and vitamin results	Trend of results is important
Zinc, copper#	Baseline Then every 2-4 weeks, depending on results	Deficiency common, especially when increased losses	Patients most at risk when anabolic. APR causes Zn ↓, and Cu ↑

Nutrition support in adults: full guideline DRAFT (August 2005) Page 60 of 262

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Parameter	Frequency	Rationale	Interpretation
Selenium#	Baseline if risk of depletion. Further results dependent on baseline	Se deficiency likely in severe illness and sepsis, or long term nutrition support	APR causes Se↓. Long term status better assessed by glutathione peroxidase
Full blood count and MCV	Baseline 1-2X weekly till stable Then weekly	Anaemia due to iron or folate deficiency is common	Effects of sepsis may be important. Iron status difficult if APR (Fe↓, ferritin↑)
Folate, B12#	Baseline Then every 2-4 weeks	Folate deficiency is common	Serum folate/B12 sufficient, with FBC
Manganese*§	Every 3-6 months if on HPN	Excess provision to be avoided- more likely if liver disease	Red blood cell or whole blood better measure of excess than plasma
25-OH Vit D*§	6 monthly if on long- term support	Low if house-bound	Requires normal kidney function for effect
Bone densitometry*§	On starting HPN Then every 2 years	Metabolic bone disease diagnosis	Together with lab tests for metabolic bone disease

Tests marked with § are primarily required for patients on parenteral nutrition in the community.

Tests marked with # are rarely required in patients having enteral nutrition (in hospital or in the community), unless there is cause for concern.

Oral nutrition support

1.14.2.30 Indications for oral nutrition support

Healthcare professionals should consider interventions to improve oral intake to patients who can swallow safely and who are:

- malnourished (BMI <18.5 -20 kg/m² and unintentional weight loss >5% within the previous 3-6 months), or
- at risk of malnutrition (eaten very little for >5 days and/or unlikely to eat more than very little amounts for the next 5 days). [A]
- 1.14.2.31 Healthcare professionals should aim to ensure that the overall nutrient intake of oral nutritional interventions offered to patients contain a balanced mixture of protein energy, vitamins and minerals.[D(GPP)]
- 1.14.2.32 For patients where there is concern about the adequacy of micronutrient intake, a complete oral multi vitamin and mineral supplement providing the reference nutrient intake for all vitamins and trace elements should be considered by healthcare professionals with the relevant competencies in nutrition support who are able to determine the nutritional adequacy of a patient's dietary intake. [D(GPP)]

Oral nutrition support for surgical patients

- 1.14.2.33 Pre- and post-operative oral nutrition support should be considered for malnourished surgical patients (BMI < 18.5 kg/m² and weight loss>10% within the previous 3-6 months or BMI 18.5-20 kg/m² and weight loss > 5% within the previous 3-6 months. [B]
- 1.14.2.34 Healthcare professionals can provide post caesarean or gynaecological surgical patients some oral intake within 24 hours of surgery. [A]

Patients with dysphagia

1.14.2.35 Patients with any of the obvious or less obvious indicators for dysphagia (Table 20) should be referred to healthcare

Nutrition support in adults: full guideline DRAFT (August 2005) Page 62 of 262

professionals with specialist training in the diagnosis, assessment and management of swallowing disorders for example speech and language therapists, gastroenterologists, radiologists, neurologists, specialist nurses. [D(GPP)]

Table 8: Obvious and less obvious indicators for dysphagia

Obvious indicators	Less obvious indicators
Patient reports difficulty and/ or painful chewing and/ or swallowing.	Change in respiration pattern
Regurgitation of undigested foodstuffs	Unexplained temperature spikes
Difficulty controlling food and/ or liquid in the mouth	Wet voice quality
Drooling	Tongue fasciculation (may be indicative of motor neurone disease)
Hoarse voice	Xerostomia
Coughing and/or choking before, during, or after swallowing	Heartburn
Globus sensation	Change in eating – for example, eating slowly or avoiding social occasions
Nasal regurgitation	Frequent throat clearing
Feeling of obstruction	Recurrent chest infections
Unexplained/involuntary weight loss	Atypical chest pain

1.14.2.36 Healthcare professionals should recognise that patients with acute and chronic neurological conditions and those who have undergone surgery or radiotherapy to the upper aero-digestive tract, are at high risk of developing dysphagia. [D(GPP)]

- 1.14.2.37 When managing patients with dysphagia, healthcare professionals with relevant competencies in swallowing assessment/management should consider:
 - risk/benefits of the feeding options for each individual (oral for example modified consistency and or enteral nutrition support)

factors listed in Table 21. [D(GPP)]

Table 9: Factors to be considered before any modification on nutrition and hydration methods

Recurrent chest infections

Mobility

Dependency on others for assistance to eat

Perceived palatability and appearance of food/drink for the patient

Level of alertness

Compromised physiology

poor oral hygiene

Compromised medical status

Metabolic and nutritional requirements

Vulnerability (for example immuno- compromised?)

Co-morbidities

- 1.14.2.38 For patients with dysphagia, healthcare professionals with relevant experience in swallowing problems and drug administration should perform a drug review to ascertain if the current drug formulation, route and timing of administration remain the most appropriate and without contraindications for either the feeding regimen or drug therapy.[D(GPP)]
- 1.14.2.39 Healthcare professionals with the relevant competencies in swallow assessment/management should regularly monitor and reassess patients having modified diets until the patient is stabilised.[D (GPP)]

Enteral tube feeding

Indications for enteral nutrition support

1.14.2.40 Healthcare professionals should consider enteral tube feeding in patients who have a functional, tube accessible gastrointestinal tract and who despite the use of oral

Nutrition support in adults: full guideline DRAFT (August 2005) Page 64 of 262

interventions if appropriate, still have an inadequate or unsafe oral intake and are:

malnourished (BMI < 18.5 kg/m² and unintentional weight loss >10% within the previous 3-6 months or BMI < 18.5 -20 kg/m² and unintentional weight loss > 5% within the previous 3 to 6 months),

and /or

- at risk of malnutrition (eaten very little for >5 days and or unlikely to eat more than very little amounts for the next 5 days). [D(GPP)]
- 1.14.2.41 Elective enteral tube feeding should not be given to patients unless it is either in the context of a clinical trial or they present with the indications for enteral feeding:
- a functional, tube accessible gastrointestinal tract and an inadequate or unsafe oral intake, and
- malnourished (BMI < 18.5 kg/m² and unintentional weight loss > 10% within the previous 3 to 6 months or BMI < 18.5 -20 kg/m² and unintentional weight loss > 5% within the previous 3 to 6 months), and/or
- at risk of malnutrition (eaten very little for > 5 days and or unlikely to eat more than very little amounts for the next 5 days). [A]

Enteral nutrition support for surgical patients

- 1.14.2.42 Malnourished surgical patients (BMI < 18.5 kg/m² and unintentional weight loss > 10% within the previous 3-6 months) who are due to undergo major abdominal procedures should be considered for pre-operative enteral tube feeding.
 [B]
- 1.14.2.43 General surgical patients who are expected to resume normal oral intake within 5 days should not have enteral tube feeding within 48 hours post-surgery outside the context of a clinical trial unless they have a functional, tube accessible gastrointestinal tract and an inadequate or unsafe oral intake and:
- malnourished (BMI < 18.5 kg/m² and unintentional weight loss > 10% within the previous 3- 6 months or BMI < 18.5 -20 kg/m² and unintentional weight loss > 5% within the previous 3-6 months)

and / or

- at risk of malnutrition (eaten very little for > 5 days and or unlikely to eat more than very little amounts for the next 5 days).[A]
- 1.14.2.44 Healthcare professionals should consider enteral tube feeding in post surgical patients who have a functional, tube accessible gastrointestinal tract and an inadequate or unsafe oral intake and:
- malnourished (BMI < 18.5 kg/ m^2 and unintentional weight loss > 10% within the previous 3-6 months or BMI < 18.5 -20 kg/ m^2 and unintentional weight loss > 5% within the previous 3-6 months)

and /or

• at risk of malnutrition (eaten very little for >5 days and or unlikely to eat more than very little amounts for the next 5 days). [D(GPP)]

Enteral route of access

- 1.14.2.45 General medical, surgical and intensive care patients should be fed via a tube into the stomach unless there is upper gut dysfunction. [A]
- 1.14.2.46 Patients with upper gut dysfunction (or an inaccessible upper GI tract) should be considered for post-pyloric (duodenal /jejunal) feeding. [D(GPP)]
- 1.14.2.47 Gastrostomy feeding should be considered in patients likely to need long-term (4 weeks) enteral tube feeding. [D(GPP)]
- 1.14.2.48 PEG tubes which have been placed without apparent complications can be used four hours after insertion. [A]

Patients with dysphagia

1.14.2.49 In the acute setting for example following stroke, patients unable to swallow safely or take sufficient energy and nutrients orally, should have an initial 2-4 week trial of nasogastric tube

Nutrition support in adults: full guideline DRAFT (August 2005) Page 66 of 262

feeding. Healthcare professionals with the relevant competencies in nutrition support and swallow assessment/management should assess the prognosis and the appropriateness of future options for feeding.[A]

Enteral mode of delivery

- 1.14.2.50 For patients being fed into the stomach, either bolus or continuous methods should be considered, taking into account patient preference, convenience and drug administration.[B]
- 1.14.2.51 For patients in intensive care, nasogastric tube feeding should usually be delivered continuously over 16-24 hours daily.

 Where insulin administration is required it is safe and more practical to administer feeding continuously over 24 hours.

 [D(GPP)]

Enteral feeding and motility agents

- 1.14.2.52 For patients in intensive care with delayed gastric emptying who are not tolerating enteral feeding a motility agent should be considered unless there is suspicion of gastrointestinal obstruction or a pharmacological cause. [A]
- 1.14.2.53 Patients in other acute care settings who have delayed gastric emptying and are not tolerating enteral feeding should also be offered a motility agent unless there is suspicion of gastrointestinal obstruction or a pharmacological cause. [D(GPP)]
- 1.14.2.54 If patients have delayed gastric emptying which severely limits feeding into the stomach, despite the use of motility agents, post-pyloric ETF and/or PN will need to be considered. [D(GPP)]

Management of enteral feeding tubes

1.14.2.55 Patients requiring enteral tube feeding should have the enteral feeding tube inserted by healthcare professionals with the relevant competencies in passing and managing enteral tubes (or by trainees under their direct supervision). [D(GPP)]

Nutrition support in adults: full guideline DRAFT (August 2005) Page 67 of 262

- 1.14.2.56 The position of all NG tubes should be confirmed after placement and before each time of use by aspiration and pH paper (with X-ray if necessary) as per the advice from the National Patient Safety Agency (NPSA 2005). Local protocols should address the clinical criteria (for example unchanged length of tube, absence of any apparent ETF related complications) which permit ETF to proceed when the ability to make repeat checks of the tube position are limited by inability to aspirate the tube or the checking of pH is invalid because of gastric acid suppression. [D(GPP)]
- 1.14.2.57 The initial placement of post-pyloric tubes requires an abdominal X-ray with protocol agreed clinical checks before repeated use. [D(GPP)]

Parenteral nutrition support

Indications for parenteral nutrition support

- 1.14.2.58 Healthcare professionals should consider parenteral nutrition in patients who have a non-functional and /or inaccessible gastrointestinal tract such that they cannot be adequately fed by other means and are:
- malnourished (BMI < 18.5 kg/m² and unintentional weight loss > 10% within the previous 3-6 months), or
- at risk of malnutrition (eaten very little for >5 days and/or unlikely to eat more than very little amounts for the next 5 days).

Prescription of parenteral nutrition

1.14.2.59 The introduction of PN should be progressive, usually starting at a maximum of 50% of estimated needs with close monitoring. Parenteral nutrition can be withdrawn once patients are tolerating adequate nutrition orally or enterally and whose nutritional status is stable. Withdrawal should be planned and stepwise with a daily review of the patient's progress.[D(GPP)]

- 1.14.2.60 PN should be stopped when the patient is established on adequate oral and/or enteral support. There is no minimum appropriate length of time for duration of PN and even stopping after only 1 or 2 days, should not infer that it was started unnecessarily.[D(GPP)]
- 1.14.2.61 Patients prescribed standardised PN should have their nutritional requirements determined by healthcare professionals with the relevant competencies in the prescription of nutrition support before selection of a particular parenteral nutrition product. The addition of vitamins and trace elements is always required and occasionally additional electrolytes and other nutrient supplements. Additions must be made under appropriate pharmaceutically controlled environmental conditions before administration. [D (GPP)]

Parenteral nutrition support for surgical patients

- 1.14.2.62 For surgical patients who have limited gut function and who are already severely malnourished (that is BMI < 18.5 kg/m² and have unintentional weight loss > 10% within the previous 3–6 months) elective supplementary pre- and/ or post-operative PN should be considered. [B]
- 1.14.2.63 Peri-operative supplementary parenteral nutrition should not be given to surgical patients who are neither severely malnourished (BMI > 18.5, no history of weight loss > 10%) nor at particular risk of malnourishment (have had some food intake during last 5 days and are likely to have some food intake within 5 days). [B]
- 1.14.2.64 In the presence of inadequate intestinal tolerance ETF should be supported with or replaced by PN which is equally safe if undertaken by experts. [B]

Parenteral nutrition route of access

1.14.2.65 Patients having PN in hospital can have a peripherally inserted central catheter (PICC) as an alternative to a centrally placed central venous catheter. A free dedicated lumen in a multi-

lumen centrally placed catheter can also be used for in hospital PN.[B]

- 1.14.2.66 Administration of PN via a peripheral venous catheter can be considered for patients who are likely to require short term PN (<14 days) who have no need for central access for other reasons. Attention to pH, tonicity and long term compatibility of the PN admixture should be considered to avoid stability or administration problems. [B]
- 1.14.2.67 Tunnelling subcutaneous catheters is recommended for long term used (> 14 days). [D(GPP)]
- 1.14.2.68 Tunnelling catheters is not recommended for short term use (14days). [D(GPP)]

Parenteral nutrition mode of delivery

- 1.14.2.69 Continuous administration of parenteral nutrition should be offered as the preferred method for infusion in most severely ill patients who require this method of nutrition support.[B]
- 1.14.2.70 Cyclical delivery of PN should be considered when using peripheral venous canola with planned routine catheter change.[B]
- 1.14.2.71 A gradual change from continuous to cyclical PN administration should be considered in patients requiring PN support for periods of more than 2 weeks. [D(GPP)]

Management of catheter use for parenteral nutrition

1.14.2.72 Healthcare professionals competent in catheter placement should be responsible for placement of catheters and should be aware of the importance of monitoring and managing these safely. For guidance on prevention of infections when placing, monitoring and managing catheters refer to the NICE Infection Control guideline. [D(GPP)]

Nutrition support in adults: full guideline DRAFT (August 2005) Page 70 of 262

Nutrition support in the community

- 1.14.2.73 All patients on enteral tube feeding in the community should be supported by coordinated multidisciplinary care, which includes input from dietitians and district, care home or homecare company nurses and other allied healthcare professionals (for example speech and language therapists) as appropriate. Close liaison with patients, carers and GPs regarding diagnoses, arrangements and potential problems is essential. [D(GPP)]
- 1.14.2.74 Patients being discharged into the community on enteral tube feeding and/or their carers should receive an individualised care plan which includes a monitoring plan. Patients should also receive training and information from healthcare professionals with the relevant competencies in nutrition support (specialist nutrition nurses and dietitians) on:
- the management of their enteral feeding delivery systems and their enteral feeding regime, outlining all procedures related to setting up feeds, using feed pumps, the likely risks and methods for troubleshooting common problems and be provided with an instruction manual (and visual aids where appropriate).
- both routine and emergency telephone numbers to contact a healthcare professional who understands the needs and potential problems of patients on HETF
- the arrangements for the delivery of equipment, ancillaries and feed with appropriate contact details for any homecare company involved. [D(GPP)]
- 1.14.2.75 All patients having parenteral nutrition in the community should be supported by co-ordinated multidisciplinary care, which includes input from specialist nutrition nurses, dietitians and district and/or homecare company nurses. Close liaison with patients, carers and GPs regarding diagnoses, arrangements and potential problems is essential. [D(GPP)]
- 1.14.2.76 Patients being discharged into the community on parenteral nutrition and/or their carers should receive an individualised care plan which includes a monitoring plan. Patients should also receive training and information from healthcare

professionals with the relevant competencies in nutrition support (specialist nutrition nurses, pharmacists and dietitians) on:

- the management of their parenteral nutrition delivery systems and their feeding regime, outlining all procedures related to setting up feeds, using feed pumps, the likely risks and methods for troubleshooting common problems and be provided with an instruction manual (and visual aids where appropriate).
- routine and emergency telephone numbers to contact a healthcare professional with the relevant competencies (nutrition nurse, pharmacist)
- the arrangements for the delivery of equipment, ancillaries and feed with appropriate contact details for any homecare company involved [D(GPP)]
- 1.14.2.77 Healthcare professionals should ensure that patients and/or carers of patients having enteral tube feeding or parenteral nutrition in the community:
- are kept fully informed and have access to appropriate sources of information in formats, languages and ways that are suited to an individual's requirements. Consideration should be given to cognition, gender, physical needs, culture and stage of life of the individual.
- have opportunity to discuss diagnosis, treatment options and relevant physical, psychological and social issues
- are given contact details for relevant support groups, charities and voluntary organizations. [D(GPP)]

1.14.3 Research recommendations

The guideline group made a number of recommendations for research in areas where evidence is lacking. They selected 5 of these that were considered to be the highest priority. These are:

1.14.3.1 What are the benefits of a nutritional screening programme (using a simple tool such as 'MUST') compared to not screening patients in; a) primary care (attending GP clinics), b) care homes c) hospital inpatients d) hospital outpatients in terms of determining the number of patients at risk of malnutrition,

complications, survival, length of stay, quality of life and cost effectiveness?

There is no clear evidence available as to whether screening is really beneficial or how it should be carried out. With the lack of evidence the GDG have considered in detail this problem and have instead carefully developed consensus statements to support recommendations for screening. As a priority it is important that we determine the need for screening and intervention in the community.

1.14.3.2 Further research is required to identify which components of nutrition monitoring are clinically and cost effective.

There is no clear evidence available in to the long and short term benefits of clinical monitoring in terms of prevention of complications and survival. With the lack of evidence the GDG have considered in detail this problem and have instead carefully developed the guidance for monitoring by expert clinical practice and consensus opinion.

1.14.3.3 What are the benefits of patients (in hospital or the community, including older people) identified as high risk of malnutrition by a screening tool such as 'MUST' being offered either oral sip feeds compared to a) dietary modification and or food fortification, or b) dietary modification and or food fortification and dietary counselling in terms of determining complications, survival, length of hospital stay, quality of life and cost effectiveness?

This is an essential recommendation for research since there is insufficient evidence on the benefits of intervention used for oral nutrition support in particular the benefits of often first line treatment e.g. food fortification and or dietary counselling. It is essential to know this so that the indications on who to treat can be further supported.

1.14.3.4 What are the benefits to patients in hospital identified as at high risk of malnutrition by a screening tool such as 'MUST' being offered either a) complete oral sip feeds b) combined micro and macronutrient supplements or b) micronutrient supplementation alone compared to placebo in terms of survival, hospital admissions, quality of life and cost effectiveness?

This is an essential recommendation for research since there is insufficient evidence on the benefits of intervention using oral nutrition support and/or

Nutrition support in adults: full guideline DRAFT (August 2005) Page 73 of 262

micronutrients but indications that such interventions might decrease complications, mortality and lengths of stay. Results will clarify indications on who to treat and the best means of doing so.

1.14.3.5 Further research is required to ascertain whether an educational intervention (e.g. 3 one week modular courses, over 6 months) for all healthcare professionals, in particular medical and nursing staff, would impact on patient care (i.e. length of hospital stay, frequency of GP visits, complications and quality of life) compared to no formal education?

It is known that health care professionals in both the hospital and community setting have a poor knowledge of nutrition. This is partly due to receiving a minimal amount of education in nutrition during the undergraduate training. It is therefore essential to determine whether an organised nutrition support education programme to health care professionals would improve the choice made about nutrition support and the consequent care of patients prescribed nutrition support.

2 Malnutrition and the principles of nutrition support

2.1 Introduction

The purpose of this guideline is to present evidence and guidance related to nutrition support but in view of the problems related to studies of nutritional intervention (described in section 1.12), the Guideline Development Group (GDG) agreed to base some of the recommendations on principles derived from understanding the causes and effects of malnutrition in patients. This chapter covers these issues.

2.2 The causes of malnutrition

The main causes of malnutrition can be categorised under four headings (summarised in Table 10):

- impaired intake;
- impaired digestion and or absorption;
- altered metabolic nutrient requirements; and
- · excess nutrient losses.

The relative importance of each class of problem varies and multiple factors often occur simultaneously. Physical factors, usually associated with illness, are the predominant cause of malnutrition in UK adults, although psychosocial issues have significant effects on dietary intake in some groups (e.g. the socially isolated, the bereaved, poor quality diets in low income groups and some older subjects). Since malnutrition both predisposes to disease (Table 10) and is simultaneously an outcome of disease, patients may enter a downward spiral of ill-health due to malnutrition-disease interactions.

Table 10: Factors contributing to disease related malnutrition

Problem	Cause					
Impaired intake	Poor appetite: illness (a major and common cause); pain/nausea when eating; depression/anxiety; food aversion; medication; drug addiction					
	Inability to eat: diminished consciousness; confusion; weakness or arthritis in the arms or hands; dysphagia; vomiting; painful mouth conditions, poor oral hygiene or dentition; restrictions imposed by surgery or investigations. Lack of food: poverty; poor quality diet at home, in hospital or					

Nutrition support in adults: full guideline DRAFT (August 2005) Page 75 of 262

	in care homes; problems with shopping and cooking
Impaired digestion &/or absorption	Medical and surgical problems effecting stomach, intestine, pancreas and liver
Altered requirements	Increased or changed metabolic demands related to illness, surgery, organ dysfunction, or treatment
Excess nutrient losses	Gastrointestinal losses: vomiting; diarrhoea; fistulae; stomas; losses from nasogastric tube and other drains. Other losses: e.g. skin exudates from burns

2.3 The effects of malnutrition

Malnutrition detrimentally effects physical function, psychosocial well-being and the outcome of disease. It can affect every system and tissue of the body 194,343 , see Table 11.

Table 11: Some physical and psycho-social effects of malnutrition

Adverse effect	Consequence				
Impaired immune responses	Predisposes to infection and impairs recovery when infected				
Impaired wound healing	Surgical wound dehiscence, anastamotic breakdowns, development of post-surgical fistulae, failure of fistulae to close, increased risk of wound infection and un-united fractures. All can then lead to prolonged recovery from illness, increased length of hospital stay and delayed return to work				
Reduced muscle strength and fatigue	Inactivity, inability to work effectively, and poor self care. Abnormal muscle (or neuromuscular) function may also predispose to falls or other accidents				
Reduced respiratory muscle strength	Poor cough pressure, predisposing to and delaying recovery from chest infection. Difficulty weaning malnourished patients from ventilators				
Inactivity, especially in bed bound patient	Predisposes to pressure sores and thromboembolism, and muscle wasting				

Nutrition support in adults: full guideline DRAFT (August 2005) Page 76 of 262

Adverse effect	Consequence				
Water and electrolyte disturbances	Malnourished individuals are usually depleted in whole body potassium, magnesium and phosphate, while simultaneously overloaded in whole body sodium and water. They also have reduced renal capacity to excrete a sodium and water load. This leads to vulnerability to re-feeding syndrome (see section 6.6) and iatrogenic sodium and water overload.				
Impaired thermoregulation	Hypothermia and falls, especially in older people				
Vitamin and other deficiencies	Specific vitamin deficiency states e.g. scurvy and vitamin related re-feeding risks e.g. Wernike-Korsakoff syndrome (see section 6.6.4). Mineral deficiencies include iron deficiency anaemia, and magnesium deficiency, which can cause tetany (see also above for electrolyte disturbances). Trace elements can be a cause of a range of deficiencies ²⁹⁸ .				
Menstrual irregularities/ame norrhoea	Infertility and osteoporosis				
Impaired psychosocial function	Even when uncomplicated by disease, patients who are malnourished may experience apathy, depression, self-neglect, hypochondriasis lack of self esteem, poor body image, possible confusion about slow recovery, lack of interest in food, loss of libido and deterioration in social interactions 194,343. Malnutrition may also affect behaviour and attitude.				

2.4 The prevalence of malnutrition

There are many different anthropometric, clinical and biochemical criteria that have been used to assess malnutrition and these have resulted in widely varying reports of its prevalence. One of the simplest criteria is current weight status (e.g. body mass index; BMI). The proportion of underweight adults (BMI<20 kg/m²) in the UK varies considerably according to care setting: 10-40% in hospitals and care homes; \leq 5% in the general population at home, and >10% in those at home with chronic diseases of the lung and gastrointestinal tract, or those who have had surgery in the previous 6 weeks. The 'Malnutrition Universal Screening Tool' (MUST)⁹¹, which incorporates both current weight status and unintentional weight loss, has identified more than 10% of the general population aged 65 years and over as being at medium or high risk of malnutrition aged 65 years and over as being at medium or high risk of malnutrition aged 65 years and over as being at medium or high risk is seen in 10-60% depending on medical condition and patients' age. Similar very high prevalence's of nutritional risk are seen in residents of care homes but although most malnutrition is found in the community (>95%), most malnutrition related expenditure occurs in

Nutrition support in adults: full guideline DRAFT (August 2005) Page 77 of 262

hospital^{9,87}. However, both care settings make a substantial contribution to total costs.

The prevalence of individual nutrient deficiencies is also disturbing, especially in older subjects. For example, in people aged 65 years and over 110, folate deficiency affects 29% of those who are "free living" (8% in severe form) and 35% of those in institutions (16% in severe form). Similarly, vitamin C deficiency in such people affects 14% of those who are free living (5% in a severe form) and 40% of those in institutions (16% in severe form). Nutrient deficiencies and protein-energy malnutrition commonly coexist 343.

2.5 Principles underlying intervention

The difficulties inherent in nutritional support mean that there is little hard evidence to assist with decisions on how and when to treat patients who are either malnourished or at risk of becoming so. However, sensible approaches can be derived from understanding 3 types of observations:

- Cross-sectional studies suggest that nutritionally related problems are likely to occur in individuals who are thin or who have recently lost weight^{91,343,344} e.g. those with BMIs of <20 kg/m² and especially <18.5 kg/m² and/or those who have recently lost >5% of their usual body weight, especially those who have lost >10%.
- 2. Studies in healthy volunteers show that measures such as muscle function^{213,343} decline within a few days of complete starvation, and after more than 5 -7 days of little or no intake there is significant detriment in several bodily functions including many of those listed in Table 11. These ill effects reverse promptly with the provision of adequate feeding.
- 3. Studies in malnourished patients show rapid functional benefits when adequate feeding is provided. These changes can occur well before the weight lost has been regained (e.g. malnourished patients have low collagen deposition rates in surgical wounds but show improved deposition within days of receiving nutritional support³⁸¹).

With these observations in mind, good nutrition should benefit both those who are already overtly malnourished in terms of BMI or recent unintentional weight loss *and* those who are developing nutritional risks by having eaten little or nothing for be likely to eat little or nothing for over 5 days. In addition, nutrition support can often provide simple direct benefits by:

- Keeping patients who are eating inadequately, alive for long enough for specific medical or surgical interventions to take effect.
- Making malnourished patients feel better, improving their ability to cope with ill-health.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 78 of 262

- Maintaining strength through patients' illnesses so that their recuperation is shortened and they are less susceptible to further problems.
- Providing long-term support for those patients with chronic inability to eat, drink or absorb adequately.

The principles above underlie many of the recommendations proposed in these Guidelines. They are also in keeping with physical, psychological and social improvements that occur during repletion 194.

3 Organisation of Nutrition Support

3.1 Introduction

Patients requiring nutritional support need help from a range of health care professionals including dietitians, pharmacists, laboratory specialists, nurses, care assistants, speech and language therapists, occupational therapists, physiotherapists, GPs and hospital doctors. It is therefore important that all healthcare workers involved in direct patient care should appreciate the value of providing their patients with adequate nutrition and be familiar with the possibilities for providing nutrition support if needed. The composition and organisation of multidisciplinary teams for nutrition support will differ in community, care homes and hospital settings.

3.2 Nutrition support in the community

All healthcare professionals should try to ensure that coordinated nutritional care is provided for patients with or at risk of malnutrition in the community. A multi-disciplinary 'community nutrition team' approach is valuable, comprising dietitians, district nurses and care home staff with other allied healthcare professionals such as speech and language therapists, physiotherapists and occupational therapists as necessary. The team should then work with patients, relatives, carers, caterers, and GPs to prevent or treat malnutrition as appropriate. They should also develop protocols and care pathways for nutrition support, along with educational initiatives to ensure that all healthcare professionals understand the importance of nutrition in patient care.

Although guidance on the provision of meals in care homes is beyond the scope of these Guidelines, it is clear that care homes should provide adequate quantities of good quality food if the use of unnecessary nutrition support is to be avoided. The food should be served in an environment conducive to eating, with help given to those patients who can potentially eat but who are unable to feed themselves.

Patients having home enteral tube feeding or home parenteral nutrition have particularly complex needs with demands for a coordinated supply of feeds and ancillaries, and the need for regular expert review (see Chapter 11).

Although the GDG were unaware of any RCTs examining the benefits of introducing community nutrition support teams, observational work has suggested benefit e.g. audits following the introduction of expert review for home ETF patients have suggested overall cost savings related to identification of significant numbers of such patients whose condition had improved enough to allow them to return to normal or modified oral intake.

3.3 Nutrition support in Hospital

Nutrition support in adults: full guideline DRAFT (August 2005) Page 80 of 262

The organization of Nutrition Support in hospital needs to ensure that *all* patients' nutritional needs are met whenever possible. This requires coordinated activity by catering, dietetic departments and multi-disciplinary nutrition support teams (NSTs), working with all ward-based nurses and care assistants. Other allied healthcare professionals such as speech and language therapists, occupational therapists and physiotherapists may also need to be involved. The GDG agree with recommendations made by BAPEN (BAPEN1994) and the Royal College of Physicians in London³⁰⁵ that such coordination is best achieved by hospitals having a Nutrition Steering Committee with members which include senior representation from Trust management, catering, dietetics, nursing and the nutrition support team. The Committee should work within the Governance framework, reporting directly to the Chief Executive or Trust Board.

The different components of the hospital organization which deal with providing adequate nutrition for patients have differing roles:

3.3.1 Catering

There are numerous good reasons for hospitals to provide adequate quantities of good quality food, of which one is the need to limit unnecessary use of nutrition support. The food should also be served in an environment conducive to eating, with help given to those who can potentially eat but who are unable to feed themselves. These issues are given proper consideration in the Government 'Better Hospital Food'²⁵⁷ and 'Protected Mealtimes' ²⁵⁸.

3.3.2 Dietitians

Although there are no relevant RCTs, dietitians are clearly central to the provision of nutrition support for patients who cannot derive enough nourishment from food. Dietitians are involved in nutritional screening and assessment, as well as with the provision of supplementary nutrition through oral, enteral and parenteral routes. All hospitals should therefore ensure that patients who are either at risk of or have malnutrition should have access to a dietitian if necessary.

The relatively small number of dietitians in most hospitals, means that some of their roles must be delegated to other ward staff. The dietitians therefore need to develop hospital protocols and care pathways on nutrition support, and to participate in the nutritional education of the entire clinical workforce. The aim should be that all hospital healthcare professionals should understand the importance of nutrition in patient care and the means available to provide it safely and effectively.

3.3.3 Ward Nurses

Although there are no relevant scientific studies, all ward nurses should be fully aware of the importance of patients meeting their nutritional needs and should understand the likely benefits and risks of nutrition support by oral, enteral and parenteral routes. Furthermore, nurses looking after patients other than those explicitly excluded from nutritional screening (section 4.14) will often need to undertake the screening process and to instigate associated care pathways.

3.3.4 Specialist nutrition support nurses

Many hospitals employ specialist nurses or nurse consultants to take responsibility for ensuring that nutritional support is delivered as safely and effectively as possible. Such nurses will train other healthcare professionals, will monitor adherence to protocols for enteral and parenteral nutrition and will usually coordinate the nutritional care of patients in hospitals and in the community.

3.3.5 Nutrition support Teams

The aim of a hospital NST is to ensure that specialised nutrition support is given safely and effectively to those patients who need it. The NST should be formally recognised and should comprise dietitians, nutrition nurses, pharmacists and clinicians with good biochemistry and microbiology laboratory support. NST clinicians are often gastroenterologists, GI surgeons or intensivists or chemical pathologists with a specific interest in nutritional problems but whatever their background, they should have also received specific training in nutrition support.

Hospital NSTs may take on total responsibility for the nutritional care of patients, particularly those on PN, or act in an advisory (consultative) role. The potential advantages of NSTs include:

- reduction of unnecessary treatments
- prevention of complications (mechanical, infective and metabolic)
- pharmaceutical advice on stability and compatibility of drugs and PN regimens
- production or support of existing guidelines
- education and training of other staff, patients and carers
- audit/research
- acting as advocates for patients

 point of contact for patients and carers, especially for those on home parenteral nutrition (HPN) or home enteral tube feeding (HETF) (see Chapter 11)

The scale of these benefits is open to debate, and we therefore conducted a review of studies investigating these issues, recognising while doing so, and the many difficulties inherent in conducting RCTs on service interventions.

3.4 Methods

Our review included randomised and non-randomised controlled trials, since we were aware that this type of question is not easily addressed by controlled trials. The studies included patients cared for by a NST and patients receiving the standard regimen used in the care setting without an NST. In the intervention arm patients had to be receiving nutrition support (oral, ETF or PN excluding home nutrition support) and had to have nutritional management from a NST composed of two or more relevant health care professionals. In the comparison arm patients had no intervention from nutrition support teams.

3.4.1 Studies considered for this review

The literature search identified two RCTs^{178,178,320} and four non-randomised comparative studies: two on ETF^{49,289} and two on PN ^{108,190} one of which was a systematic review ¹⁰⁸ including 11 studies (Table 87,Table 88,Table 89). All studies were set within hospitals. A number of studies were excluded due to poor methodological quality, the main reason being the studies had no control group.

3.5 Clinical evidence

3.5.1 Randomised controlled trials

One RCT included 212 patients at nutritional risk¹⁷⁸ (Table 89). Three Danish hospitals participated in the study. The NST consisted of a nurse and a dietitian. Patients were randomised to receive nutrition support managed by the NST (n= 108) or by usual departmental procedures (n= 104). The NST provided motivation for patients and staff, detailed a nutritional plan, assured delivery of prescribed food and gave advice on ETF and PN when appropriate.

The primary outcome was length of stay considered to be sensitive to nutritional support. When a patient fulfilled the following three criteria, hospital stay was no longer considered to be sensitive to nutritional support:

patient is able to manage toilet visit without assistance

Nutrition support in adults: full guideline DRAFT (August 2005) Page 83 of 262

- absence of fever (temperature < 38°C)
- patient is without intravenous access

Other outcomes reported were total length of stay with a maximum of 28 days (LOS₂₈), minor and major complications and quality of life (QoL).

There were no statistically significant differences between the two groups in any of the outcomes. In a subgroup analysis, patients with complications but no operation had shorter length of stay sensitive to nutritional support (p=0.015) and shorter overall LOS₂₈ (p=0.028) if managed by the NST. The other RCT included 101 patients referred and accepted for a PEG³²⁰ (NST group n= 47, Control group n= 54) (Table 88). The NST consisted of a nurse and a dietitian. Patients were followed up for 12 months. The team provided weekly visits while in acute hospital and at least monthly after discharge, regular liaison with ward and primary care professionals and counselling to patients and carers including telephone contact for support. There were no statistically significant differences between the two groups in mortality, complications, time to removal of PEG, LOS or readmissions. For QoL there was an improvement in the social functioning element of the SF36 with NST group over control group (p=0.05). There were no differences in other elements of the SF36.

3.5.2 Non-randomised controlled trials

3.4.2.1 Enteral tube feeding

Two studies from the same American university teaching hospital looked at the effect of a NST in surgical, medical and ICU patients who were started on ETF support (n= 101²⁸⁹; n= 102⁴⁹). The comparative group were concurrent controls managed by their primary physician (Table 87).

In both studies patients in the NST group had fewer untreated metabolic complications (p<0.05) such as hyperglycaemia (p<0.05) and hypophosphataemia (p<0.05). More NST group patients also attained adequate feeding (p<0.05) One study²⁸⁹ reported fewer total complications (pulmonary, mechanical, GI and metabolic) in the NST group (p<0.05) but in the other study⁴⁹ the difference was not significant. Neither study found significant differences in mortality.

3.4.2.2 Parenteral Nutrition

One systematic review¹⁰⁸ looked at the effect of a NST in patients receiving PN (Table 88). The review included 11 studies but there was a lot of heterogeneity in study methodology, patients included, the members and roles of the NSTs and outcome measures and length of follow up. In four of the studies the NST groups were compared with concurrent controls^{76,109,120,361} whilst in seven the NST groups were compared with historical patients^{65,112,160,171,266,287,364}. Sample sizes in the studies were

Nutrition support in adults: full guideline DRAFT (August 2005) Page 84 of 262

generally small ranging from 28 to 285 and five studies had unequal sample sizes between the groups. Both medical and surgical patients were included.

In most studies the NST was composed of a physician, pharmacist, nurse and a dietitian. Two studies included a gastroenterologist^{109,112}, another included a biochemist¹⁰⁹ and another surgeon²⁸⁷. In some studies the NST provided a consultative service whilst in others it assumed total responsibility for the nutritional management of the patient.

Due to the heterogeneity of the studies it was not possible to pool the results, however, a general summary of outcomes reported is provided below:

Catheter related complications:

- There were no significant differences in mechanical complications between the groups although there was a trend towards fewer pneumothoraces in the NST group.
- Most studies reported no significant differences in septic complications between the groups. However a retrospective study¹⁹⁰ which reported data on 54 medical and surgical patients who received PN before the NST was formed, compared with 75 who received PN after, found that patients in the NST group had significantly fewer incidents of catheter related sepsis: 29% compared to 71% (p<0.05) (Table 89). Due to the way that this clinical question was defined, the effect of a nutrition support nurse on patient outcomes was not specifically considered. However, the GDG were aware of findings from several observational studies^{51,103,104,133,172,192} that have demonstrated much reduced rates of catheter related sepsis following the introduction of specialist nutrition nurses in a variety of hospital settings. *Metabolic complications:*
- NST groups had significantly fewer metabolic complications in five studies^{76,109,112,120,364}.

Mortality

 Most studies reported no significant differences in mortality but the retrospective study¹⁹⁰ which reported lower catheter sepsis rates also reported lower mortality in the NST managed patients: 24% compared to 43% (p<0.05).

3.6 Cost effectiveness evidence

It has been hypothesised that NSTs can achieve cost savings through:

- Reduced complications associated with PN such as catheter-related sepsis and metabolic disturbance
- Reduced use of inappropriate PN

Nutrition support in adults: full guideline DRAFT (August 2005) Page 85 of 262

- · Reduced length of stay
- Reduced PN wastage
- Use of lower cost materials

We found a number of studies that evaluated the cost of nutrition support teams(Table 90 and Table 91). One was based on an RCT³²⁰ and five were based on comparisons of cohorts^{1,65,190,364,375}. Two studies were excluded because the NST existed during the control period and therefore the nature of the comparison was unclear ^{68,263}. One study was excluded because it was poorly reported and used an obscure method of controlling for severity ¹⁵⁰. A further eight studies were not included because they used a hypothecated comparison arm^{18,102,126,242,243,262,303,324} and two were excluded because they reported total costs only and the denominator was not stated ^{22,182}.

One RCT³²⁰ evaluated the follow-up of patients after insertion of a PEG (as reported in section 3.5.1 above). All hospital and community care costs were measured over 12 months. There were (non-significant) incremental cost savings per patient of £3,538 (95% CI: -£2,790, £9,847) but there were no apparent differences in complication rates.

A US evaluation based on a prospective cohort study ⁶⁵ compared automatic referral to NST with ad hoc referral for patients who were on PN for at least two days. They estimated hospital pharmacy and biochemistry costs although NST costs were not included. They found incremental cost *savings* (p=0.41): £930 vs £1100.

A retrospective cohort study ³⁷⁵ evaluated NSTs in the management of patients referred for serious burns compared with physician management. They found hospital costs *savings* (£9,300 vs. £12,700) but the statistical significance is unclear. There were statistically significant reductions in minor complications but no differences in major complications.

A second US retrospective cohort study ³⁶⁴ compared an NST (metabolic support service) consultation with no NST consultation for inpatients beginning PN. For both cohorts they estimated avoidable PN charges using the ASPEN guidelines. They found incremental cost *savings* (the statistical significance of which was not clearly reported): £180 vs. £540. And there was a substantial reduction in complications: 34% vs. 66% (p=0.004). However, it is possible that patients referred to NST could be very different to those not referred and it is unclear who was deciding which costs were avoidable. NST costs were also not included.

A UK-based retrospective cohort study ¹⁹⁰ estimated cost savings of £227 per patient referred for PN due to prevention of catheter-related sepsis (cost of staff time and bed occupancy costs not included). Substantial cost savings were also estimated through the avoidance of unnecessary PN (£777 per patient referred). However this does not take into account the observation that total PN days were increased, and the authors were unable to determine the

Nutrition support in adults: full guideline DRAFT (August 2005) Page 86 of 262

extent to which this was due to the presence of the NST or due to changing workload and practices within the hospital. Nor did the study estimate the health gain associated with this increase in PN usage.

A UK study estimated cost savings from a reduced incidence of catheter-related sepsis attributable to the presence of an NST. Using the aggregated infection rate from seven cohort studies, they estimated cost savings of between £24 (best case scenario) and £70 (worst case) per patient receiving PN.

3.7 Conclusion

As expected for studies relating to service interventions, those identified by our review were of limited quality in terms of the scientific rigour of their design and all were small and heterogenous. Nevertheless, the evidence suggests that NSTs decrease complications and costs through reductions in unnecessary treatments and prevention of complications.

3.8 Recommendations

- 3.7.1.1 All healthcare workers in hospital and the community who are directly involved in patient care should receive training in:
 - the importance of adequate nutrition (for patients)
- the indications for nutrition support and its delivery (routes, mode of access, prescription)
- when and where to seek expert advice on nutrition support [D(GPP)]
- 3.7.1.2 Healthcare professionals should ensure that patients in hospital and the community who require nutrition support are provided with coordinated multi-disciplinary care. This should include close liaison between clinician responsible, pharmacists, dietitians, specialist nutrition and district nurses, patients, carers, caterers, GPs and other allied healthcare professionals as appropriate (for example speech and language therapists). [D (GPP)]

- 3.7.1.3 Healthcare professionals should ensure hospitals and care homes provide:
 - food and fluid of adequate quantity and quality in an environment conducive to eating
 - appropriate support (for example modified eating aids) to those patients who can potentially chew and swallow but who are unable to feed themselves. [D (GPP)]
- 3.7.1.4 All hospitals should consider the employment of at least one specialist nutrition support nurse to:
 - coordinate ward based training, as appropriate
 - ensure that hospital protocols optimise nutritional care and minimise complications are followed, and
 - co-ordinate care within hospital and the community [D (GPP)]
- 3.7.1.5 Trusts should have a Nutrition Steering Committee to ensure that all patients nutritional needs are met using nutrition support as appropriate in the safest and most cost-effective manner. Members should include senior representation from Trust management, catering, dietetics, nursing and the nutrition support team and should work within the Governance framework. [D(GPP)]
- 3.7.2 Research recommendations
- 3.7.2.1.1 Further research is required to ascertain whether an educational intervention (e.g. 3 one week modular courses, over 6 months) for all healthcare professionals, in particular medical and nursing staff, would impact on patient care (i.e. length of hospital stay, frequency of GP visits, complications and quality of life) compared to no formal education?

It is known that health care professionals in both the hospital and community setting have a poor knowledge of nutrition. This is partly due to receiving a minimal amount of education in nutrition during the undergraduate training. It is therefore essential to determine whether an organised nutrition support

Nutrition support in adults: full guideline DRAFT (August 2005) Page 88 of 262

DRAFT FOR SECOND CONSULTATION

education programme to health care professionals would improve the choice made about nutrition support and the consequent care of patients prescribed nutrition support.

Nutrition support in adults: full guideline DRAFT (August 2005) F of 262

4 Nutritional assessment and 'screening'

4.7 Nutritional assessment

Early identification of patients who are nutritionally depleted (or likely to become so) is vital if you are to provide help and achieve the most effective use of resources. Although biochemical measurements can contribute to nutritional assessment, none are always a reliable measure of nutritional risk e.g. a low serum albumin is almost always a marker of an acute phase response or saline overload rather than a marker of malnutrition. There is therefore no alternative to measurements of weight and height, along with other anthropometric measures in specialist circumstances. These measurements are then used in conjunction with consideration of the following:

- Has the patient been eating a normal and varied diet in the last few weeks?
- Has the patient experienced intentional or unintentional weight loss recently? Obesity or fluid balance changes and oedema may mask loss of lean tissue. Rapid weight loss is a concern in <u>all</u> patients whether obese or not.
- Can the patient eat, swallow, digest and absorb enough food safely to meet their likely needs?
- Does the patient have an unusually high need for all or some nutrients?
 Surgical stress, trauma, infection, metabolic disease, wounds,
 bedsores or history of poor intake may all contribute to such a need.
- Does any treatment, disease, physical limitation or organ dysfunction limit the patient's ability to handle the nutrients needed to meet current or future requirements?
- Does the patient have excessive nutrient losses through vomiting, diarrhoea, surgical drains etc.?
- Does a global assessment of the patient suggest under nourishment?
 Low body weight, loose fitting clothes, fragile skin, poor wound healing, apathy, wasted muscles, appetite, taste sensation, altered bowel habit.
 Discussion with relatives may be important.
- In the light of all of the above, can the patient meet all of their requirements by voluntary choice from the food available?

Considering all the above takes time and expertise and so simple, repeatable non-expert screening tools have been developed to identify those in need of more careful assessment.

4.8 Why and how to screen

Several studies have found that malnutrition is widespread among hospital inpatients and common in some community settings ^{91,345}. Many screening tools have been developed to help identify such individuals ^{106,181} and given the high prevalence of malnutrition and lack of proper management of patients in various settings, routine nutritional 'screening' should result in early identification of patients who might have otherwise been missed.

Nutritional screening in this context is not a stand alone procedure since the measurement of height and weight are arguably useful clinical measurements which provide a reliable baseline for reference in future episodes of care - to enable the clinician to reliably document changes in weight with intercurrent acute illness or chronic illness. Thus although clinicians must ask patients whether their height and weight can be measured, and where this is declined the patient's wishes must be respected, it is probably not necessary for the normal requirements of screening to be met (e.g. formal consent, and explanation of different possible pathways of care that might result from measurement). Thus although screening as discussed in this document refers to combined clinical assessment and screening for risk of malnutrition, to avoid confusion, and since the term nutritional 'screening' is already widely used, we will simply refer to nutritional 'screening'.

If patients agree to 'screening', then the outcome should be documented - including as appropriate consideration of nutritional assessment to 'diagnose' malnourishment, intervention to combat malnourishment, and timelines for review and or re measurement - and the care plan agreed. It thus may help in establishing reliable pathways of care for patients with malnutrition which could include provision of support, advice for junior clinicians, access to dietitians, provision of adequate follow-up, and attention to continuity of care across sector boundaries (e.g. malnourished patients discharged to the community).

Routine assessment of weight and height in hospitals as well as in high-risk groups in the community has been recommended by many expert panels 51,211,227,305,330. However, despite these efforts and publicity, recent studies suggest that weight and height of patients are still not systematically recorded in hospitals, making it difficult to estimate BMI, change in weight and risk of malnutrition⁵⁷. It is also known that many nutritional screening tools were developed with no reference to defined methodological criteria 11,181 Recently, however, an easy to use, valid nutritional screening tool with clear criteria, the 'Malnutrition Universal Screening tool' (MUST) was developed 91 and this or an equivalent has been widely recommended in an attempt to improve quality of nutritional care in hospitals and other care settings² MUST can be used for the screening of both malnutrition and obesity. MUST has limitations – for example the measurement of height may not always be possible in order to calculate BMI - and other tools are available 106,181 nevertheless it is easy to use, has simple training requirements (under 1 hour) and has had some validation 91.

Introducing any programme, however, can invoke costs to health systems (personnel time and treatment costs) and problems for patients (e.g. because of false negatives, false positives, and side effects from potential treatments). It is therefore important to try and assess the effectiveness of nutritional 'screening' similar to other areas of care ³⁰⁸.

A nutritional screening programme refers to the application of a screening tool in a group of patients or apparently healthy individuals, for whom the level of malnutrition risk is unknown, in order to establish the level of risk.

4.9 Methods

In view of the above, a systematic review of evidence for the benefits of screening for malnutrition was conducted, taking care to distinguish between screening and assessment (as discussed previously, assessment is more detailed and targets patients already considered to be 'at risk' of malnutrition, whilst screening targets patients for whom the risk of under-nourishment is unknown). In practice, however, the line between the two is often blurred and so careful attention is needed when examining the relevant literature. Furthermore, nutritional screening can be offered as a stand alone intervention or as part of a wider strategy (e.g. a multi-component screening and/or interventional strategy for quality improvement). Such a 'multiple screening and intervention package' has been reported in primary care settings for older people.

4.9.1 Studies considered for this review

The systematic review aimed to examine the (cost) effectiveness of nutritional screening in improving quality of care (professional practice) and patient outcomes compared with usual care.

Because of a perceived lack of good quality evidence it was decided a priori that all experimental and quasi-experimental studies in which nutritional screening is compared with a control intervention (e.g. usual care) would be eligible for inclusion in the review. In line with the guideline scope, studies from the hospital and community setting were considered eligible.

4.10 Clinical evidence

Three primary studies were considered eligible for inclusion (Table 28). The studies were heterogeneous in their designs, settings, interventions and outcomes. Therefore, no quantitative synthesis was conducted.

The first study, a cluster randomised trial, had been conducted in a US primary care setting²⁴⁷. The intervention practices offered screening for eight ailments (including malnutrition) to patients older than 70 years on their first visits to the practices. The study found participating physicians were

Nutrition support in adults: full guideline DRAFT (August 2005) Page 92 of 262

receptive to the intervention; but it did not result in any improvement in detection rate, nutritional intervention rate or patients' quality of life. However, the study was underpowered and there were concerns about the quality of the screening tool used in the study.

The other two studies had been conducted in hospitals. One UK controlled study offered nutritional screening to patients admitted to two hospital wards and used a further two wards as controls¹⁸⁵. The control wards received usual care. The mean age of the hospitalised patients was 67. As a result of the intervention, patients' weight recording in the intervention wards increased from 26% to 72% while it decreased in the control wards. The study observed no change in meal-time observation for the 'at risk' patients, and referral to the dietitians decreased in both intervention and control wards. The study did not report patient outcomes. This study suffered from weak design and lack of measurement of appropriate outcomes.

The third study was conducted in three hospitals in the Netherlands³⁰⁷. The intervention was screening patients older than 60 years for malnutrition (using the MNA-sf), dysphagia and dehydration followed by immediate treatment, including menu modification or supplements. The intervention was offered in one hospital and the other two acted as controls. The study reported statistically significant weight gain and reduction in hospital acquired infection rate in the intervention hospital. It observed no change in pressure ulcer rates and length of hospital stay. The study concluded that targeted nutritional screening improved quality of care for older patients. For some of the outcomes (e.g. length of stay, hospital infection rate) the study did not report the 'before' rates.

4.11 Cost-effectiveness evidence

Only one of the above studies evaluated cost or cost-effectiveness³⁰⁷. The study found a significant reduction in complications and a significant weight gain in the intervention arm (Table 29 and Table 30). In their base case they found that the weight gain was achieved at a cost of £39 per kg gained. As a sensitivity analysis, hospital costs associated with length of stay were included and the result was that screening was cost-saving; however, length of stay was highly variable and not statistically significant. Alternatively, the worst case scenario suggested a cost of £369 per kg gained.

It is difficult to judge whether this represents good value for money since weight gain is not easily converted into patient outcomes and since there is no accepted threshold of cost per kg gained and the impact on health-related quality of life is unclear. Cost-effectiveness modelling on this topic could provide a clearer answer and could utilise broader evidence on the effectiveness of oral nutritional interventions. An original model was therefore developed for these guidelines to explore the cost-effectiveness of malnutrition screening and intervention.

4.11.1 Cost-effectiveness model

We conducted a cost-utility analysis, which we undertook from the perspective of the NHS and personal social services. Expected costs and health outcomes (quality-adjusted life-years) were calculated using decision analysis, with life expectancies being estimated by life-table analysis. Full details are given in Appendix Five: Cost-Effectiveness Analysis of Malnutrition Screening.

A screening strategy ('Screen') was compared with a strategy of ward nurses selecting patients for oral nutrition support using oral nutritional supplements with later dietetic input if this was unsuccessful ('Nurse'), and with a strategy of no oral nutrition intervention ('Don't Treat'). The target population chosen for the base case was <u>older inpatients</u>. This population was chosen because it is known to have a high prevalence of malnutrition and because the majority of RCTs evaluating oral nutrition interventions have focused on this group. We also conducted a sensitivity analysis to explore how the cost-effectiveness of screening varies for <u>other inpatient populations</u>.

Screening of <u>older inpatients</u> was more effective but more costly than the other two strategies. The Nurse strategy was excluded due to extended dominance, that is to say that not only was it less effective than screening but also compared with Don't treat it had a higher cost per QALY gained. The incremental cost per QALY gained for Screen compared with Don't Treat was £7,500. This would suggest that screening is cost-effective when compared to a threshold of £20,000 per QALY gained. We conducted one-way sensitivity analyses on each of the model's parameters. In none of the scenarios was Nurse the optimal strategy. The Screen strategy was no longer cost-effective compared with Don't Treat only when:

- * the mortality relative risk was high (i.e. the relative risk reduction attributable to oral nutrition support was small), or
- * the duration of the intervention was long (without a commensurate increase in health gain)

The observation that screening of older inpatients would increase hospital costs (rather than creating net cost savings) is consistent with the findings of the one published cost-effectiveness analysis of malnutrition screening described above³⁰⁷. That study showed that hospital costs might be reduced if length of stay is reduced. However, they did not find a significant reduction in length of stay and our meta analysis of the effects of oral nutrition support (Chapter 8) do not indicate significant reductions in length of stay either

Table 12 shows a two-way sensitivity analysis that indicates the cost-effectiveness for Screen versus Don't Treat, when the population characteristics of malnutrition risk and mortality are varied. The red (dark) shaded cells indicate the combination of assumptions where Screen would NOT be cost-effective, when compared to a threshold of £20,000 per QALY gained. So for example, with an acute background mortality of 1.5%, a prevalence of malnutrition of 4% would be enough to make screening cost-effective. This is on the basis that the *relative* risk reduction associated with oral nutrition support is the same for all groups; all data and assumptions used

Nutrition support in adults: full guideline DRAFT (August 2005) Page 94 of 262

are detailed in Appendix Five: Cost-Effectiveness Analysis of Malnutrition Screening.

Table 12: Cost-effectiveness (cost per QALY gained) of screening inpatients, by malnutrition risk and baseline mortality

Patients at moderate or	All-cause mortality in 60 days from admission								
high malnutrition risk	1.0%	1.5%	2.0%	2.5%	3.0%	3.5%	4.0%		
1%	67,600	46,300	35,600	29,200	24,900	21,900	19,600		
2%	40,100	27,900	21,800	18,100	15,700	13,900	12,600		
3%	30,900	21,700	17,100	14,400	12,600	11,300	10,300		
4%	26,300	18,600	14,800	12,500	11,000	9,900	9,100		
5%	23,500	16,800	13,500	11,400	10,100	9,100	8,400		
6%	21,700	15,600	12,500	10,700	9,500	8,600	7,900		
7%	20,400	14,700	11,900	10,200	9,000	8,200	7,600		
8%	19,400	14,000	11,400	9,800	8,700	7,900	7,400		
9%	18,600	13,500	11,000	9,500	8,400	7,700	7,200		

The model's base case assumptions were deliberately conservative in the following ways. We assumed that the risk reduction observed in the trials did not continue beyond the observation period. Also, we assumed that a proportion of patients would have enteral tube-feeding, even though this guideline does not advocate tube-feeding, except where oral nutrition is not possible. As part of the Screen strategy we included the cost of nurse time for monitoring and assisting patients to eat, whereas it could be argued that these activities should already be practiced as part of basic standards of care.

There are a few assumptions that might bias the model in favour of screening. The level of compliance achieved and clinical effect observed in the trials might be greater than that achievable in normal clinical practice, where protocols might be less rigorously enforced and patients less well selected. Certainly, it has been observed that the wastage of oral nutritional supplements in NHS hospitals can be very high 135, but this might well be reduced if proper screening protocols led to better selection of patients and more rigorous application of interventions.

In our model, we also estimated that the cost per patient of training and quality assurance was rather low; however, the published cost-effectiveness analysis³⁰⁷ based on a real intervention showed these costs to be rather high because they were averaged over only 140 patients. We would argue that such costs can be kept low if screening is conducted at a hospital-wide level, and would urge implementers to take this into consideration.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 95 of 262

4.11.2 Transferability to other settings

We believe that the model reflects with a reasonable level of accuracy the costs and benefits of screening, given the particular intervention strategies specified and the populations covered by the clinical trials included. However, with alternative strategies or alternative settings/populations the cost-effectiveness could be quite different.

The nutrition intervention that was costed in our model comprised of oral nutritional supplements, nurse time and dietitian time (and tube-feeding for a small minority of patients). If alternative intervention strategies are used the cost-effectiveness could be different – less labour-intensive interventions might be less costly but they might also be less effective.

In general practice, screening could be less cost-effective than in hospital if patients at risk are more likely to be identified without the use of a screening tool because their co-morbidities are known to practice staff or if the incidence of malnutrition is lower than in hospital. Furthermore, the paucity of evidence about risk reduction, and the likelihood that risk reduction from intervention would be less in a lower risk population makes it even more difficult to assess. In the community, oral nutritional supplements would also be purchased at the full market price rather than the heavily discounted hospital price.

Similar arguments are likely to apply in care homes, and residents in such settings may also be less amenable to intervention or to risk reduction from intervention (e.g. those with multiple and severe co morbidities). In addition, screening may be less cost-effective if the life expectancy of patients is low therefore the potential benefits from intervention are less. There are also increased costs of care with added days of life, which ought to be considered in the evaluation of cost-effectiveness, along with improvements in quality of life.

Evidence that typical patients in the community and nursing home may possibly benefit less for intervention (and hence less from screening) comes from the three studies using more typical patients in the community - the elderly malnourished, often in a nursing home setting ^{87,204,385}. The estimates from these studies suggest a benefit from supplements of increased weight but no mortality benefit, in contrast to the net overall mortality benefit identified by the meta-analysis.

Due to the difficulty of the generalising the evidence from hospital settings to primary care settings, our recommendations for primary care centre more around opportunistic clinical management rather than a systematic screening programme - hence we advocate baseline 'screening' at registration with the practice or care home, and then with subsequent clinical concern.

4.11.3 Conclusions

Using the evidence from the literature and expert opinion, we found that malnutrition screening in <u>older hospital inpatients</u> is likely to be cost-effective, although there is still some uncertainty, given the broad confidence intervals

Nutrition support in adults: full guideline DRAFT (August 2005) Page 96 of 262

for the clinical effects associated with oral nutrition support. Screening is also likely to be cost-effective for other inpatient groups, except where malnutrition risk and acute background mortality are very low. The cost-effectiveness of screening in other settings is harder to determine.

4.12 Consensus development methods

Because of weaknesses in the methodologies and designs of the identified studies, no firm conclusion could be made and the cost-effectiveness model also highlighted uncertainties in the value of screening. The group therefore conducted a consensus development exercise to utilise the expertise of the GDG for making recommendations.

We used a modified Delphi approach for consensus development^{33,252}. It comprised three stages: two rounds of Delphi questionnaire surveys (plus an in-group discussion meeting), and then a nominal group technique meeting. It was decided a priori that if 80% of the members agreed on a recommendation, then the consensus had been achieved. After each Delphi round, the results were quantitatively summarised and fed back to the group in meetings. The views expressed in the surveys were anonymised and presented to all the members. In the nominal group technique meeting, all the members expressed their views, in rounds, about all potential recommendations. Final votes were obtained privately. The results of the consensus development exercises demonstrated the existence of consensus for all four pre-defined settings.

4.13 Impact of nutritional assessment on the patient

Patient representatives on the GDG recognised the importance of nutritional assessment and screening as being in the patient's interest. Good communication skills and a non-judgemental attitude by healthcare professionals will help to create a suitable environment in which the patient will feel comfortable to be open and provide accurate and helpful information.

Aspects of nutritional assessment and routine measurements of weight, height and other anthropometric measurements may be perceived by the patient as an invasion of personal space and information. Healthcare professionals should be aware of this and respect the patient's dignity: this information should be documented and stored both for future reference and to minimise unnecessary repetition.

4.14 Recommendations for nutrition screening

4.14.1.1 Nutritional assessment and screening should be carried out by healthcare professionals with appropriate training and skills

Nutrition support in adults: full guideline DRAFT (August 2005) Page 97 of 262

to help generate the confidence of patients and enable accurate data collection. [D(GPP)]

- All hospital inpatients on admission and all outpatients at their first clinic appointment should be screened for the presence or risk of malnutrition. Screening should be repeated weekly for inpatients and as indicated clinically for outpatients. Departments who identify groups of patients with low risk of malnutrition may opt-out of screening for those groups although opt-out decisions should follow an explicit process via the local clinical governance structure involving experts in nutrition support. [D(GPP)]
- 4.14.1.3 All residents or patients in care homes should be screened for the presence or risk of malnutrition on admission and whenever there is clinical concern (for example patients with fragile skin, poor wound healing, apathy, wasted muscles, poor appetite, altered taste sensation, impaired swallowing, altered bowel habit, loose fitting clothes, or prolonged intercurrent illness). [D(GPP)]
- 4.14.1.4 Patients on initial registration at general practice and where there is clinical concern should be screened for risk of or existing malnutrition (for example patients with fragile skin, poor wound healing, apathy, wasted muscles, poor appetite, altered taste sensation, impaired swallowing, altered bowel habit, loose fitting clothes, or prolonged intercurrent illness). Screening should also be considered at other opportunities (for example health checks, flu injections). [D(GPP)]
- 4.14.1.5 All screening should be undertaken using a tool that includes BMI, percentage weight loss and consideration of the time over which nutrient intake has been reduced and/or the likelihood of future impaired nutrient intake (for example the Malnutrition Universal Screening Tool, 'MUST'). [D(GPP)]

4.15 Research recommendations

4.15.1.1 What are the benefits of a nutritional screening programme (using a simple tool such as 'MUST') compared to not screening patients in; a) primary care (attending GP clinics), b) care homes c) hospital inpatients d) hospital outpatients in terms of determining the number of patients at risk of malnutrition, complications, survival, length of stay, quality of life and cost effectiveness?

There is no clear evidence available as to whether screening is really beneficial or how it should be carried out. With the lack of evidence the GDG have considered in detail this problem and have instead carefully developed consensus statements to support recommendations for screening. As a priority it is important that we determine the need for screening and intervention in the community.

5 Indications for nutrition support

5.1 Introduction

Food and nutrition intake is fundamental to good health and resistance to disease. There is a positive duty at common law to care for and provide such treatment as is in the patient's best interests and to take such reasonable steps as are necessary to preserve life. Where nutrition as food and fluid (including nutrition support) is necessary to preserve life, the duty of care will normally require the supply of such nutrition or nutrition support. There will be circumstances in which the provision of nutrition or nutrition support is not clinically indicated or where risks trying to provide nutrition outweigh the potential benefits. Prolonging life will usually be in the best interests of a patient provided that the treatment is not excessively burdensome or disproportionate to the expected benefits.

In the majority of cases, adequate nutrition can be achieved by providing good food, as long as care is taken to ensure that the appropriate consistency of food is used and physical help with eating is provided when necessary. In hospitals, it is also important that meals are not missed and that restrictions on intake related to investigations or surgical procedures are minimized.

Nutrition support involves the provision of nutrition beyond that provided by normal food intake using oral supplementation, or enteral tube feeding(ETF) and parenteral nutrition (PN). The overall aim of nutrition support is to try to ensure that total nutrient intake (food + nutrition support) provides enough energy, protein, fluid and micronutrients to meet all the patients' needs. When feasible, it should be given via the gastrointestinal (GI) tract, which is generally effective and relatively inexpensive. The following methods can be used:

- · Modified food and menus
- Food fortification
- Proprietary oral nutritional supplement
- Enteral tube feeding (ETF)

Feeding via the GI tract is also relatively safe although there are some risks if ETF is needed (Chapter 9).

If the GI tract cannot be accessed or there is either partial or complete intestinal failure (e.g. with obstruction, ileus, extensive surgical resection or malabsorption), some or all of a patient's nutritional needs may be met using an intravenous infusion of parenteral nutrition (PN). This entails risks (Chapter 10 Parenteral nutrition) and costs but should always be considered if it is the only way to feed a patient effectively.

5.2 Methodology

Decisions on when and to whom nutrition support should be offered can be difficult and require careful consideration. Oral, enteral and parenteral methods of nutrition support are not mutually exclusive and although we carried out a number of reviews on the benefits and risks of oral, enteral and parenteral interventions, the literature does not yield data that provide hard evidence on the indications for nutrition support for the reasons outlined in Section 1.12. The GDG therefore used their expert knowledge of clinical practice to agree by informal consensus the general guidance on indications for oral, enteral and or parenteral nutrition support (although more specific guidance in circumstances where there is an evidence base is given in the individual chapters or oral, enteral and parenteral feeding). The GDG agreed that consideration of the following is needed when making decisions on the need for nutrition support:

- The extent to which the patient is meeting their nutritional needs through ordinary eating and drinking.
- The length of time that intake has been inadequate and/or is likely to remain inadequate.
- The patient's current nutritional status in terms of BMI, recent unintentional weight loss and evidence of any specific nutrient deficiencies.
- The patient's current medical conditions
- Whether nutrition support will serve the patient's best interests in terms of both clinical outcomes and quality of life, and all relevant ethical and legal issues
- The potential methods available to provide nutrition support and whether these would entail any clinical risks.

Difficulties arise when trying to define fixed criteria on instigating nutrition support since the first of three factors above are infinitely variable. Support may thus be needed in patients who have had a mild nutritional deficit for a prolonged period, a complete deficit for a short period, or anything in between.

5.3 Appropriate Nutrition Support and ethical/legal issues

The provision of nutrition support is not always appropriate. Decisions on withholding or withdrawing nutrition support can be difficult. Decisions which involve the withholding or withdrawing of nutrition support require a consideration of both ethical and legal principles (both at common law and statute including the Human Rights Act 1998). It is important to note:

 it is a general legal and ethical principle that valid consent must be obtained before starting treatment for a patient. A health professional who does not respect this principle may be liable both to legal action by the patient and action by their professional body.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 101 of 262

- to give valid consent the patient needs to understand in broad terms the nature and purpose of the treatment;
- every person is presumed to have capacity unless and until that presumption is rebutted;
- no one is able to consent to or refuse treatment on behalf of another competent adult where that adult cannot consent for himself;
- the competent adult has the absolute right to decide what treatment he does
 or does not wish to receive even where refusal may result in the death of the
 patient;
- where the patient lacks the capacity to make a decision for himself, the law requires a doctor to provide such treatment and care as are in the patient's best interests:
- best interests;
 'best interests' are not confined to 'medical best interests' and are not necessarily the same as the wishes of the patient;
- in considering what is in the 'best interests' of the patient the doctor should consult with family and carers and take their views into account in the decision making process;
- in respect of those patients detained under the Mental Health Act 1983, healthcare professionals should not make the assumption that such patients lack the capacity to consent and as with all other patients, an assessment should be undertaken as to whether or not such patients retain the capacity to consent to the treatment under consideration;
- regard should be had to communication difficulties with the help of relatives, carers, interpreters and speech and language therapists;
- patient autonomy and the right to self determination do not extend to the patient insisting on receipt of a particular treatment regardless of its nature;
- a distinction has to be drawn between those cases where a patient's life can
 be prolonged indefinitely by treatment or provision of nutrition, but only at a
 cost of great suffering and those cases where the 'incompetent' patient is in
 the final stages of life and although treatment would prolong the dying
 process, this would be at the cost of comfort and dignity;
- each case must be considered individually and decisions as to the provision, withholding or withdrawal of nutrition reached objectively;
- decision involving the withholding and withdrawal of treatment can be
 particularly difficult and at times contentious and in these circumstances
 consideration should be given the GMC guidance 'Withholding and
 Withdrawing Life-prolonging Treatments: Good Practice in Decision-making'
 and legal advice sought if appropriate.

Additionally:

- if an illness is regarded as being in the terminal phase and the treatment plan is to provide only compassionate and palliative care, an artificial supply of nutrients or fluid need only be given to relieve symptoms and such provision should not necessarily be used to prolong survival;
- in cases where the benefits of specialised nutrition or fluid support are in doubt, a planned 'time-limited' trial may be useful; and
- treatment plans for patients should include decisions on fluid and/or nutrient provision, especially when there are either existing or possible future deficits in fluid or nutrient intake.

5.4 Rationale for recommendations

Since it is impossible to make firm recommendations to cover all circumstances, decisions on instigating nutrition support should ideally involve individuals with expertise in clinical nutrition such as dietitians, specialist nutrition nurses, and pharmacists and clinicians with relevant training (see Chapter 3). There are many malnourished patients in both hospital and community settings and hence it is important that all healthcare professionals understand the importance of malnutrition and its treatment in patient care. This guideline therefore provides broad recommendations on when to consider active nutritional intervention based on the principles outlined in Chapter 2, combined with consideration of the ethical and legal principles involved.

5.4.1 Recommendations

- 5.4.1.1 Nutrition support should be considered in patients when:
- the patient has eaten very little amounts for the last 5 days or more,
 or
- the patient is very unlikely to eat more than very little amounts for the next 5 days or more (whatever current BMI or history of weight loss), or
- the patient's BMI is $< 18.5 \text{ kg/m}^2$, or
- the patient has unintentionally lost > 10% body weight within the previous 3-6 months, or
- the patient has a BMI < 20 kg/m², with unintentional weight loss >
 5% within the previous 3-6 months,or
- the patient has poor absorptive capacity, is catabolic and/or has high nutrient losses and or has a condition that increases their nutritional needs for example hypermobility. [D GPP)]

For specific guidance on when oral, enteral and parenteral nutrition support may be required please see the recommendations in chapters 8, 9 and 10.

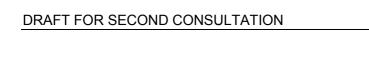
For ethical considerations of providing nutrition support see guidance issued by the General Medical Council (available from www.gmc-uk.org) and the Department of Health guidelines – Reference guide to consent for examination or treatment (2001) (available from www.dh.gov.uk). [D(GPP)]

For issues addressing patient competence and consent see guidance issued by the General Medical Council (available from www.gmc-uk.org) and the Department of Health guidelines – Reference guide to consent for examination or treatment (2001) (available from www.dh.gov.uk). [D(GPP)]

- 5.4.1.2 Healthcare professionals involved in the provision of nutrition support should ensure that there is a review of the indications for, route of and goals of nutrition support daily or twice weekly until the patient is stabilised on nutrition support and or every 3-6 months and/or until nutrition support is no longer required. [D(GPP)]
- 5.4.1.3 Healthcare professionals should ensure that patients having nutrition support along with their carers are kept fully informed about their treatment and have access to appropriate information and/or the opportunity to discuss diagnosis and treatment options. [D(GPP)]
- 5.4.1.4 Information on nutrition support should be provided in formats, languages and ways that are suited to an individual's requirements.

 Consideration should be given to the cognitive ability, gender, physical needs, culture, ethnicity and stage of life of the individual. [D(GPP)]

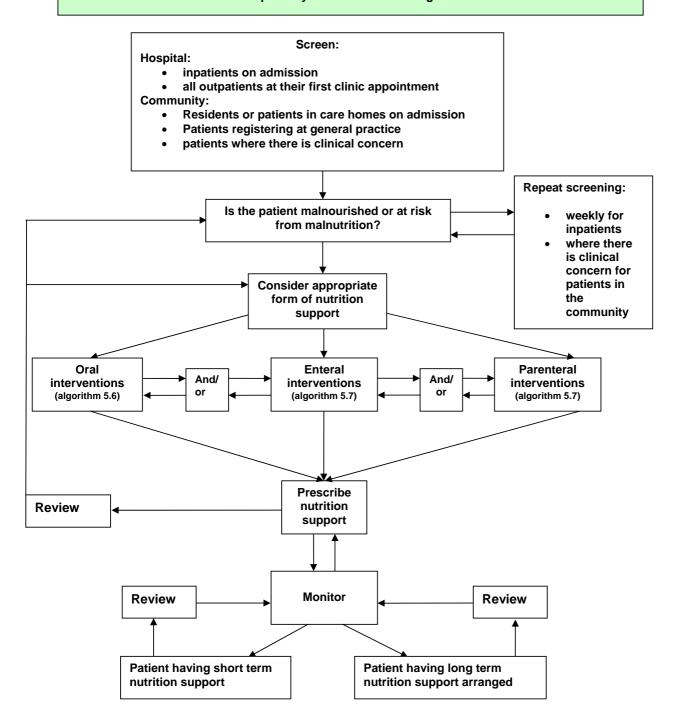
These recommendations have been incorporated into the algorithms in Sections 5.5, 5.6 and 5.7.



5.5 Patient Pathway Algorithm

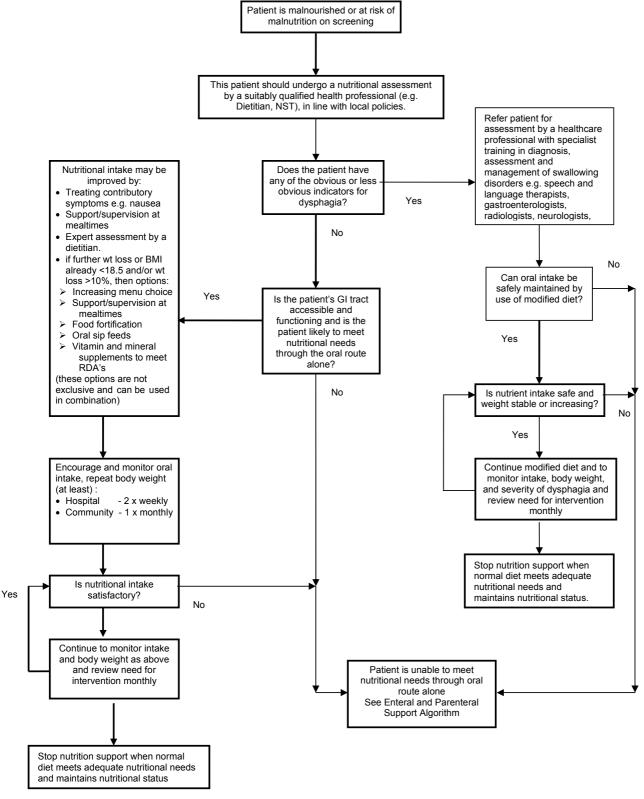
At all stages of care:

- · Consider cultural, ethical and legal issues of providing nutrition support
- · Provide patients and/ or carers with information about their treatment
- Ensure that there is a care pathway with clear treatment goals



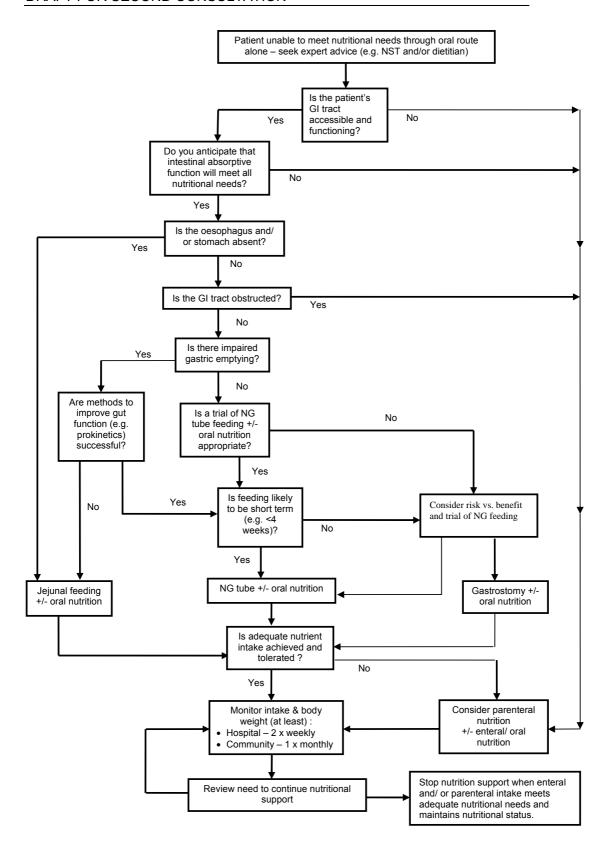
Nutrition support in adults: full guideline DRAFT (August 2005) Page 106 of 262

5.6 Oral Algorithm



Nutrition support in adults: full guideline DRAFT (August 2005) Page 107

5.7 Enteral and Parenteral Algorithm



Nutrition support in adults: full guideline DRAFT (August 2005) Page 109 of 262

6 What to Give

6.1 Background

Individual patients' nutritional needs vary with their current and past nutritional history and the nature of their condition. It is therefore essential to estimate nutritional requirements before instigating nutritional support. Since either inadequate or excessive macronutrient or micronutrient provision can be harmful, recommendations on appropriate levels would ideally be based on large studies comparing the effects of different levels of feeding on clinical outcomes e.g. complications, length of stay, and mortality. However, relatively few such studies have been published and hence the recommendations in this part of the guideline were proposed by a number of GDG members who have expertise in this area and a knowledge of other widely accepted levels of feeding including those recommended by BAPEN³⁹ and The PEN Group³⁵³. These accepted levels evolved over several decades from studies of metabolic rate and nitrogen balance along with measurements of electrolyte and micronutrient status in both healthy volunteers and patients. Nevertheless, members of the GDG have concerns about some aspects of current practice, particularly the potential over provision of nutrition in early feeding of severely ill or injured patients (see Section 4.1.3).

6.2 General Principles

The overall aim when devising a prescription, whether for oral, enteral or parenteral nutrition, is to provide the patient with their complete requirements via single or combined routes. The prescription of any supplementary nutrition support by enteral or parenteral routes should therefore account for any current oral intake from food and/or oral nutritional supplements.

The usual approach to estimating nutritional needs is to estimate energy requirements from calculations of basal metabolic rate (using equations accounting for age, sex and body weight) with the addition of increments to allow for any physical activity and increases in metabolism caused by illness and feeding itself (see Section 5.3). Protein requirements are estimated from body weight with additional increments dependent on likely metabolic stress and hence catabolism. A prescription is then devised to meet the estimated energy and protein requirements. This can then be exceeded if body weight recovery is indicated or less can be given if weight loss would be beneficial or there are concerns about a patient's ability to tolerate the feed in terms of refeeding risks (see Section 6.6) or metabolic instability (see Section 5.4). In all patients, likely micronutrient, electrolyte and fluid needs must also be met, taking into account any unusual demands or losses.

The aims and objectives of nutritional support should be clearly defined at each stage of the patient's illness with nutritional support tailored accordingly e.g. limitation but not prevention of lean tissue loss in acutely ill patients, maintenance in stable patients who still have increased catabolism, and anabolism in patients once the catabolic phase has passed. Requirements and

Nutrition support in adults: full guideline DRAFT (August 2005) Page 110 of 262

prescription must therefore be regularly reviewed to account for changes in activity levels, goals of treatment, clinical condition and care setting.

In patients requiring long-term nutrition support, it is useful to decide on a 'target weight' and to make adjustments to the level of nutrition provided in order to achieve it. The target weight may sometimes be lower than an optimal 'healthy' weight since the latter may be impossible or inappropriate to achieve in ill patients (especially those with gastrointestinal dysfunction). Occasionally, the target weight may be higher than that considered optimal for health since it is not always reasonable to expect severe weight reduction in obese patients with illness and eating problems.

6.3 Calculating requirements

6.3.1 Energy

A number of equations are available to calculate basal metabolic rate (BMR) e.g. Schofield 1985³¹⁷ to which increments are added to account for increased energy requirements caused by the metabolic stress of disease and variations in activity levels etc. Tables summarising these increments are used by experts in nutrition support to tailor requirements to individual patients needs and those recommended by the PEN Group³⁵³. They include guidance on the special requirements for different patient groups such as the obese. For most patients, however, 20-30 kcal/kg/day is likely to be adequate although patients who are severely malnourished or severely ill might need to commence feeding at lower levels (Section 6.6) and patients who have reached an anabolic state may have greater requirements.

The energy delivered by nutrition support is not only derived from metabolism of the carbohydrate and fat content of the feed but also, unless the patient is anabolic, from metabolism of an amount of protein at least equivalent to all that provided within the feed. It is therefore inappropriate in most cases of nutrition support to consider matching estimated energy requirements from 'non-protein energy' content of feeds, whatever the route of administration.

6.3.2 Protein

For most patients in both acute and community settings, 1g/kg/day will provide sufficient protein (corresponding to approximately 0.15g N from amino acids in intravenous nutrition). However in situations of metabolic stress, requirements may be higher although the GDG would not recommend the provision of levels greater than 1.25 g/kg/day (0.2gN/kg).

6.3.3 Fluid

Fluid needs are usually a total of 30 - 35 ml/kg body weight in both the acute and community setting with allowance for extra losses from drains, fistulae etc. All sources of fluid must be considered to stop over-prescription in patients receiving enteral/parenteral feeds including any oral intake and other intravenous sources especially the large amounts of fluid given with some intravenous drugs. This is a particular problem for surgical patients since excess fluid and sodium is a common cause of oedema, prolonged ileus and other complications.

6.3.4 Electrolytes and minerals

Most standard oral and enteral feeds contain enough electrolytes and minerals to meet the daily requirements of sodium, potassium, calcium, magnesium and phosphate, but only if the patient is having enough of the feed to meet all their energy needs. Since many patients are either receiving less than full nutrition from these products or have pre-existing deficits, high losses or increased demands, additional provision is often required. However, care is needed to avoid excessive provision in some patients e.g. those with renal or liver impairment. Some specialized feeds are designed specifically for patients with low total energy needs to provide adequate electrolytes, vitamins and minerals in lower total calories.

Pre-mixed PN bags contain very variable amounts of electrolyte and minerals and care is needed to avoid giving PN with either inadequate or excessive electrolyte and/or mineral content.

6.3.5 Micronutrients

Micronutrients are required for the prevention or correction of deficiency states and maintenance of normal metabolism and anti-oxidant status. As with electrolytes and minerals, most standard oral and enteral feeds contain enough vitamins and trace elements to ensure that needs are met if the patient is taking enough feed to meet their daily energy needs. However, since this is often not the case, further balanced micronutrient supplementation may be required especially in those with pre-existing deficits, poor absorption, increased demands or high losses. Food fortification with both high-energy foodstuffs (e.g. cream or butter) or commercial products need to be used with particular caution since they usually contain very low and unbalanced levels of micronutrients.

Premixed PN bags invariably contain inadequate levels of some micronutrients and therefore need additions to be made prior to administration. The provision of PN without adequate micronutrient content must be avoided.

6.3.6 Fibre

Oral and enteral feeds with added fibre should be considered for those on long term supplementary feeding.

6.4 Concerns with prescribing levels

- Although the levels of feeding suggested in Section 4.1 and 4,2 are similar to those previously advocated by many expert groups, they may result in high levels of energy and protein being prescribed for patients who are severely ill. This concerned members of the GDG since severe illness is associated with 'metabolic instability' and poor tolerance of feeding and a number of clinical observations and studies raise the possibility that such high levels of early feeding can cause problems. The observations include: feeding at levels above actual requirements (hyper-alimentation), advocated widely during the early development of PN, had adverse effects on clinical outcome.
- The very high, early energy requirements seen in the severely ill often decline swiftly so that initial estimates of nutritional needs can rapidly become over-estimates.
- Most trials showing benefit from short-term nutrition support, do so despite 'too little nutrition' being given for 'too short a time' for the benefit to accrue from maintaining or improving body energy and protein stores¹⁷³
- Higher levels of feeding increase oxygen consumption and carbon dioxide production and hence may worsen respiratory failure 12,13.
- Severely ill patients are often insulin resistant and so high levels of feeding will produce relative hyperglycaemia. This is of particular concern since a large intensive care trial demonstrated outcome benefits from tight blood glucose control³⁶⁹.
- Although studies have shown that higher levels of protein provision (e.g. 1.5g protein/kg/day) may reduce net lean tissue loss, they have not shown better clinical outcomes. Furthermore, very high levels of protein provision (e.g. 2g protein/kg/day) do not yield additional lean tissue sparing.
- The amino acids (AAs) needed for synthesis of acute-phase proteins differ from those provided in either food or commercially available nutrition support products which generally meet the needs for normal synthesis of structural and transport proteins etc. Generous nitrogen provision may therefore lead to an excess of free AAs which are potentially 'toxic' unless they are either oxidised or metabolism is diverted away from acute phase protein synthesis into more 'normal' pathways.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 113 of 262

- High protein and or/high energy feeding has been shown to increase mortality in animal models of sepsis (e.g. Peck et al. 1989²⁸³)
- The mortality of very malnourished, oedematous, severely ill adults in refeeding camps following famine has been shown to be increased by high protein provision compared to those receiving low protein diets (e.g. Collins et al, 1998⁶⁹) as has that of children (Scherbaum et al, 2000³¹⁵).

Meeting the high estimates of nutritional needs during early feeding of the severely ill may therefore cause problems and the practice of cautious introduction of nutrition support (e.g. at 50% of calculated requirement) is now widespread. The GDG therefore made the following recommendations.

6.5 Recommendations

- 6.5.1.1 Healthcare professionals who are appropriately skilled and trained and have knowledge of nutritional requirements and nutrition support (dietitians, pharmacists) should ensure that the total nutrient intake (that is from any food, oral fluid, oral supplements, enteral feeds and IV fluid/PN) accounts for:
 - energy, protein, fluid, electrolyte, mineral and micronutrients needs,
 - activity levels and the underlying clinical condition.
 - · metabolic instability, risk of refeeding problems
 - how much nutrition support is being delivered and the potential of poor tolerance of feeds
 - the likely duration of nutrition support. [D(GPP)]
- 6.5.1.2 For patients who are clinically stable, the suggested nutritional prescription for total intake (that is from any food, oral fluid, oral supplements, enteral feeds and IV fluid/PN) should have:
 - 20-30 kcal/kg/day total energy (including that derived from protein)
 - 1–1.5g protein/kg/day.

- 30-35 ml fluid/kg (with allowance for extra losses from drains, fistulae etc. and extra input from other sources for example IV drugs) and
- considered the need for additional electrolytes, minerals and micronutrients in patients with pre-existing deficits, high losses or increased demands. [D(GPP)]
- 6.5.1.3 The prescription must be reviewed at each stage of the patient's illness and great care must be taken when:
 - using food fortification which tends to supplement energy and/or protein without adequate micronutrients and minerals
 - using feeds and supplements that are apparently complete but do not meet all daily micronutrient and mineral needs unless they are also meeting full energy needs.
 - using pre-mixed PN bags that have not had tailored additions from pharmacy. [D(GPP)]
- 6.5.1.4 Patients requiring enteral or parenteral nutrition support who are seriously ill or injured should have an initial prescription devised that cautiously introduces nutrition support at 50% or less of normal energy and protein requirements according to metabolic and gastrointestinal tolerance. [D(GPP)]

6.6 Re-feeding Problems

6.6.1 Background

Re-feeding problems encompass life-threatening acute micronutrient deficiencies, fluid and electrolyte imbalance, and disturbances of organ function and metabolic regulation that may result from over-rapid or unbalanced nutrition support. They can occur in any severely malnourished individuals but are particularly common in those who have had very little or no food intake, even including overweight patients who have eaten nothing for protracted periods.

The problems arise because starvation causes adaptive reductions in cellular activity and organ function accompanied by micronutrient, mineral and electrolyte deficiencies. Abnormalities in malnourished individuals may therefore include:

- · deficiencies of vitamins and trace elements;
- whole body depletion of intracellular potassium, magnesium and phosphate;
- increased intracellular and whole body sodium and water;
- low insulin levels and a partial switch from carbohydrate metabolism to ketone metabolism to provide energy.
- Impaired cardiac and renal reserve with decreased ability to excrete an excess salt and water load.
- Abnormalities of liver function

Giving nutrients and fluid to malnourished patients will reverse these changes but in doing so leads to an increase in demands for electrolytes and micronutrients, and a simultaneous shift of sodium and water out of cells. Overrapid or unbalanced nutrition support can therefore precipitate acute micronutrient deficiencies and dangerous changes in fluid and electrolyte balance.

The problems of refeeding are less likely to arise with oral feeding since starvation is usually accompanied by a loss of appetite, however care should be taken in the prescription of oral nutrition supplements particularly in the area of eating disorders. Enteral tube or PN feeding can precipitate re-feeding problems since excessive feeding levels can be achieved easily and exaggerated if the products do not include adequate vitamins, phosphate or electrolytes.

The two widely recognized problems of re-feeding are those of the classical 'Re-Feeding Syndrome' and the 'Wernicke-Korsakoff Syndrome'. Since the nature of refeeding precludes randomised trials of treatment, recommendations are derived from expert opinion.

6.6.2 The classical 'Re-Feeding Syndrome'

6.6.2.1 Clinical description

'Re-Feeding Syndrome' occurs on feeding when a range of life-threatening clinical and biochemical abnormalities arise:

- Cardiac failure, pulmonary oedema and dysrhythmias
- Acute circulatory fluid overload or circulatory fluid depletion
- hypophosphataemia
- hypokalaemia

Nutrition support in adults: full guideline DRAFT (August 2005) Page 116 of 262

- hypomagnesaemia and occasionally hypocalcaemia
- hyperglycaemia

Any severely malnourished patient (e.g. BMI <18.5 kg/m², unintentional weight loss >10% in 3-6 months) and or a patient of any nutritional status who has had very little food for >5 days is at some risk of re-feeding problems. Nutrition support should therefore be introduced at a maximum of 20 kcal/kg/day or 50% of requirements (there is no evidence for either of these, but I feel that 20kcal/kg often comes out at quite a lot) for the first 2 days, gradually increasing to meet estimated needs by 4 - 6 days with close clinical and biochemical monitoring. However, much greater care is needed in some patients, indeed life-threatening problems are particularly seen in patients meeting any of the following criteria:

- BMI <16 kg/m²
- weight loss within 3 6 months of >15%,
- very little or no nutrient intake for >10 days
- low levels of potassium, phosphate or magnesium prior to any feeding.

Patients with two or more of the following lesser criteria are also at high refeeding risk:

- BMI <18.5 kg/m²
- weight loss >10% in 3-6 months
- very little or no intake for >5 days
- A history of alcohol abuse or some drugs including insulin, chemotherapy, antacids or diuretics

6.6.3 Clinical management of patients at high re-feeding risk

Patients at high risk of re-feeding syndrome should be fed at very low levels for the first few days with generous provision of thiamine and other B group vitamins, along with a balanced multi-vitamin and trace element supplement (since they are likely to have multiple deficits that cannot be met by low level oral, enteral or parenteral intake).

Most high re-feeding risk patients also need generous supplementation of potassium, magnesium and phosphate from the onset of feeding *unless* blood levels are already high (this may be the case in patients who have renal impairment). It is important to appreciate that patients with normal pre-feeding levels of potassium, magnesium and phosphate can still be at high risk, and

Nutrition support in adults: full guideline DRAFT (August 2005) Page 117 of 262

that many of those with high plasma levels will still have whole body depletion and may therefore need supplementation as re-feeding progresses and renal function improves.

The GDG do not agree with previous recommendations from some groups e.g. The PEN Group³⁵³ that all feeding should be withheld in patients with low levels of potassium, magnesium or phosphate until these have been corrected. The rationale underlying this disagreement is that since the vast majority of the deficits are intracellular, they cannot be corrected without commencing low-level energy provision. Any reassurance gained from pre-feeding correction of plasma levels is therefore unlikely to reflect significant changes in whole body status or significant reduction in risks.

6.6.4 The Wernike-Korsakoff syndrome

6.6.4.1 Clinical description

The Wernike-Korsakoff syndrome is caused by acute thiamine deficiency when re-feeding of malnourished patients precipitates increased thiamine demand as starving cells switch back to carbohydrate metabolism. The syndrome of acute neurological abnormalities comprises of one or more of the following:

- apathy and disorientation
- nystagmus, opthgalmoplegia or other eye movement disorders
- ataxia
- severe impairment of short-term memory often with confabulation.

It is seen particularly frequently in alcoholics who may have low liver stores of thiamine. It can also occur in any patient with chronic vomiting including those with hyperemesis gravidarum and gastric outlet obstruction.

6.6.4.2 Clinical management

Patients should be managed as for "re-feeding syndrome" with particularly high doses of daily thiamine and other B vitamins intravenously for 3 days (e.g. pabrinex 1 + 2 o.d + oral thiamine 100mg every 6hrs + Vitamin B Co strong 1 b.d.). The eye signs and impairment of consciousness usually resolve but the loss of short-term memory may be permanent.

6.6.5 Other re-feeding syndromes

Other re-feeding issues may occur that are less easily characterized on clinical or biochemical grounds. Some experts believe that these may arise in less obviously malnourished patients when significant metabolic stress, redirection

Nutrition support in adults: full guideline DRAFT (August 2005) Page 118 of 262

of metabolic processes or organ dysfunction acutely alters fluid distribution and the levels/demands of vitamins and electrolytes.

6.7 Recommendations

- 6.7.1.1 Patients who are severely malnourished (for example BMI < 18.5 kg/m² and/or unintentional weight loss > 10% within the previous 3-6 months) and those with very little intake for > 5 days should have nutrition support introduced at a maximum of 20 kcal/kg/day for the first 2 days, gradually increasing to meet estimated needs by 4-6 days. [D(GPP)]
- 6.7.1.2 Patients who meet the criteria in Table 13 should be considered to be at very high risk of refeeding problems. [D(GPP)]

Table 13: Criteria for determining patients at risk of refeeding problems Patient has one or more of the following:

BMI < 16 kg/m^2

Unintentional weight loss > 15%

Very little nutritional intake for > 10 days

Low levels of potassium, phosphate or magnesium prior to feeding

Or patient has two or more of the following:

BMI <18.5 kg/m2

Weight loss >10%

Very little nutritional intake for > 5 days

A history of alcohol abuse or drugs including insulin, chemotherapy, antacids or diuretics

6.7.1.3 Patients at very high risk of refeeding problems (Table 13) should be looked after by healthcare professionals who are appropriately skilled and trained and have expertise

Nutrition support in adults: full guideline DRAFT (August 2005) Page 119 of 262

knowledge of nutritional requirements and nutrition support to ensure that the prescription devised considers:

- start nutrition support at a maximum of 10 kcal/kg/day, increasing levels slowly to meet or exceed full needs by 5 to 10 days.
- use only 5 kcal/kg/day in extreme cases (for example BMI < 14 or negligible intake for > 15 days) and monitor cardiac rhythm continually in these patients and any others who already have or develop any cardiac arrhythmias.
- restore circulatory volume and monitor fluid balance and overall clinical status closely
- provide immediately before and during the first 10 days of feeding thiamine 100 mg q.d.s, vitamin B co strong 1 b.d. (or full dose daily IV vitamin B preparation if necessary) and a balanced multi-vitamin/trace element supplement 1 o.d.
- provide oral, enteral or IV supplements of potassium (likely requirement 2 –4 mmol/kg/day), phosphate (likely requirement 0.3-0.6 mmol/kg/day) and magnesium (likely requirement 0.2-0.4 mmol/kg/day) unless pre-feeding plasma levels are high. Pre-feeding correction of low plasma levels is unnecessary. [D(GPP)]

6.8 Recommendations for research

6.8.1.1 Further research investigating the optimal levels of energy and nitrogen provision using clinical endpoints is needed.

7 Monitoring nutritional support

7.1 Introduction

The main objectives of monitoring nutritional support are:

- 1. To ensure nutritional support is provided safely, and to detect and treat clinical complications as early and effectively as possible.
- 2. To assess the extent to which nutritional objectives have been reached.
- 3. To alter the type of nutritional support, or the components of the regimen, to improve its effectiveness and to minimise or prevent metabolic complications.

To achieve these objectives monitoring protocols (Table 14 and Table 15) which integrate a variety of observations and measurements, are required. These will usually include:

- Basic clinical observations (temperature, pulse, oedema)
- Observations specifically relating to the feeding technique and its possible complications
- Measures of nutritional intake (appetite, oral food intake and total intake, gastrointestinal function).
- Weight
- Fluid balance charts (in hospital)
- Laboratory data
- Outcome factors (complications, improvements in aspects of nutritional status, length of stay)

The type and frequency of monitoring will depend on the nature and severity of the underlying disease state, whether previous results were abnormal, the type of nutrition support used, the setting of the nutritional care, and the expected duration of nutritional support.

Laboratory tests usually involve analyses of serum or plasma, but may also require tests on whole blood or blood cellular components. Tests of urinary loss are rarely required (although urinary sodium may be useful in patients with complex electrolyte problems). Most tests are non- specific, and abnormalities can be caused by factors other than the nutritional component of interest, and especially by aspects of the disease process. Care must therefore be exercised in interpretation of results, particularly when patients are subject to the effects of the Acute Phase Response (APR), or Systemic Inflammatory Response Syndrome (SIRS) such as after surgery, trauma or infection, in the critically ill, or if they have a chronic inflammatory disease state.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 121 of 262

7.2 Methods

We conducted a literature search to identify studies that looked at the impact of monitoring nutritional support compared with no monitoring. Since no trials that prospectively investigated the diagnostic efficacy or cost- effectiveness of monitoring could be identified, we conducted a survey within the GDG to try to identify current best practice. The recommendations on monitoring provided here were then developed by members of the GDG with specific clinical expertise in this area and were agreed by the GDG using informal consensus.

The above approach recognises that the guidelines for monitoring patients on nutrition support given in Table 14 and Table 15 will need to be agreed by local Nutrition Support Teams or other experts in nutritional care, and that final protocols will therefore vary depending upon local clinical experience and local availability of particular tests. They will also be modified in individual cases according to clinical progress of the patient.

7.3 Recommendations

- 7.3.1.1 Healthcare professionals should ensure that there is a review of the indications for, route of and goals of nutrition support at least twice weekly until the patient is stabilised on nutrition support. Patients receiving long term support should have a similar review every 3-6 months until nutrition support is no longer required. [D(GPP)]
- 7.3.1.2 Patients having nutrition support in hospital should be monitored by health care professionals with the relevant competencies in nutritional monitoring (for example nurse, dietitian, physician and laboratory specialists). [D(GPP)]
- 7.3.1.3 Healthcare professionals should consider the protocols for nutritional, anthropometric and clinical monitoring (Table 14) for patients on nutrition support in hospital. [D(GPP)]

- 7.3.1.4 Healthcare professionals should consider the protocols for laboratory monitoring (Table 15) of patients on nutrition support in hospital. Table 15 is specifically applicable to patients receiving parenteral nutrition. It could also be selectively applied to patients receiving enteral or oral nutrition support especially if patients are unstable or are at risk of refeeding syndrome. The frequency and extent of these observations may need adapted for patients who are acutely ill or metabolically unstable. [D(GPP)]
- 7.3.1.5 Patients having parenteral nutrition support in the community need regular expert assessment and monitoring. This should be carried out by home care nutrition nurse specialists and/or by experienced hospital teams (initially at least weekly), using observations marked* in table 5. In addition they should be monitored at a specialist hospital clinic at least every 3-6 months, more frequently during the early months of HPN, when the full range of tests in Table 14 and Table 15 should be performed. Some of the clinical observations may be checked by patients or carers daily. [D(GPP)]
- 7.3.1.6 Patients having oral and/or enteral nutrition support in the community should be monitored by health care professionals with the relevant competencies in nutritional monitoring (for example community nurse, dietitian and GP). This group of patients should be monitored every 3-6 months and/or if there is any change in their clinical condition since their last review. A limited range of observations and tests should be performed selected from table 5 and 6. Some of the clinical observations may be checked by patients or carers daily. If clinical progress is satisfactory, laboratory tests are rarely required. [D(GPP)]
- 7.3.1.7 Where long-term nutritional support is required patients and or carers should be trained to recognise and respond to adverse changes in both their well-

being and in the management of their nutritional delivery system. [D(GPP)]

Table 14: Hospital protocol (and community protocol*) for Nutritional, Anthropometric and Clinical Monitoring for patients receiving nutrition support by oral, enteral and/or parenteral routes.

Parameter	Frequency	Rationale
Nutritional		
Nutrient intake from oral, enteral or parenteral nutrition (including any change in conditions that are affecting food intake) *	Daily initially, reducing to 2x/week when stable, and then monthly for long term feeding in the community	To ensure that patient is receiving nutrients to meet requirements and that current method of feeding is still the most appropriate. To allow alteration of feed/diet as indicated by monitoring
Actual volume of feed delivered *	Daily initially, reducing to 2x/week when stable	To ensure that patient is receiving correct volume of feed. To allow troubleshooting of any problems
Fluid balance charts (enteral and parenteral)	Daily initially, reducing to 2x/week when stable	To ensure patient is not/is not becoming over/under hydrated
Anthropometric		
Weight*	Daily if concerns re fluid balance otherwise weekly reducing to monthly	To assess ongoing nutritional status, determine whether nutritional goals are being achieved and take into account both body fat and muscle
BMI*	Start of feeding and then monthly	

Nutrition support in adults: full guideline DRAFT (August 2005) of 262

Parameter	Frequency	Rationale	
Mid arm circumference*	Monthly- in patients where weight cannot be obtained or is difficult to interpret		
Triceps skinfold thickness	Monthly-in patients where weight cannot be obtained or is difficult to interpret		
GI function			
Nausea/vomiting*	Daily initially reducing to 2x/week	To ensure tolerance of feed	
Diarrhoea*	Daily initially reducing to 2x/week	To rule out any other causes of diarrhoea and then assess feeding	
Constipation*	Daily initially reducing to 2x/week	Rule out other causes of constipation and then assess feed	
Abdominal distension	As necessary	Assess tolerance of feed	
Enteral Tube – nasally inserted			
Tube position (pH <5.5 using pH paper)*	Before each feed begins	To ensure tube in correct position	

Nutrition support in adults: full guideline DRAFT (August 2005) Page 125 of 262

Parameter	Frequency	Rationale
Nasal erosion*	Daily	To ensure tolerance of tube
Fixation (is it secure)*	Daily	Help prevent tube becoming dislodged
Is tube in working order (all pieces intact, tube blocked/kinked)*	Daily	Ensure tube is in working order
Tube-gastrostomy or jejunostomy Stoma site*		To ensure site not infected/red no signs of
Storia site	Daily	gastric leakage
Tube position (length at external fixation) (gastrostomy)*	Daily	To ensure tube has not migrated from/into stomach and external overganulation
Tube rotation (gastrostomy only)*	Weekly	Prevent internal over granulation
Balloon water volume (balloon retained gastrostomies only)*	At insertion	To prevent tube falling out
Exact small bowel position (jejunostomy)	Daily	Confirmation of initial position

Nutrition support in adults: full guideline DRAFT (August 2005) Page 126 of 262

Parameter	Frequency	Rationale
Parenteral nutrition		
Line site*	Daily	Signs of infection/inflammation
Skin over position of line tip (peripherally fed patients)*	Daily	Signs of thrombophlebitis
Clinical condition		
General condition (including skin condition)*	Daily	To ensure that patient is tolerating feed and that feeding and route continue to be appropriate
Temperature/blood pressure	Daily initially	Sign of infection/fluid balance
Drug therapy*	Daily initially reducing to monthly when stable	Appropriate preparation of drug (to reduce incidence of tube blockage). To prevent/reduce drug nutrient interactions
Long/short term goals		
Are goals being met*	Daily initially reducing to 2x/week and then monthly?	To ensure that feeding is appropriate to overall care of patient

Nutrition support in adults: full guideline DRAFT (August 2005) Page 127 of 262

Parameter	Frequency	Rationale
Are goals still appropriate*		

Table 15: Hospital protocol for laboratory monitoring for patients on nutrition support

Parameter	Frequency	Rationale	Interpretation
Sodium, potassium, urea, creatinine	Baseline. Daily till stable. Then 1-2X weekly.	Assessment of renal function, fluid status, and Na and K status	Interpret with knowledge of fluid balance and medication .Urine Na may be helpful in complex cases with gastrointestinal fluid loss.
Glucose	Baseline 1-2X daily (or more if required) till stable Then weekly	Glucose intolerance is common	Good glycaemic control is necessary
Magnesium, phosphate	Baseline. Daily if risk of refeeding syndrome. 3X weekly till stable Then weekly.	Depletion is common and under recognised	Low concentrations indicates poor status
Liver function tests	Baseline 2X weekly till stable Then weekly	Abnormalities common during IVN	Complex. May be due to sepsis, other disease or nutritional intake
Calcium, albumin	Baseline. Then weekly.	Hypocalcaemia or hypercalcaemia may occur	Correct measured serum calcium concentration for albumin. Hypocalcaemia may be secondary to Mg deficiency. Low albumin reflects disease not protein status
Prealbumin	Baseline Then weekly	Short half life marker of protein status	Affected by APR Especially useful in HPN
C-reactive	Baseline	Assists interpretation of protein, trace	Trend of results is

Nutrition support in adults: full guideline DRAFT (August 2005) Page 129 of 262

Parameter	Frequency	Rationale	Interpretation
protein	2-3X weekly till stable	element and vitamin results	important
Zinc, copper#	Baseline Then every 2-4 weeks, depending on results	Deficiency common, especially when increased losses	Patients most at risk when anabolic. APR causes Zn ↓, and Cu ↑
Selenium#	Baseline if risk of depletion. Further results dependent on baseline	Se deficiency likely in severe illness and sepsis, or long term nutrition support	APR causes Se↓. Long term status better assessed by glutathione peroxidase
Full blood count and MCV	Baseline 1-2X weekly till stable Then weekly	Anaemia due to iron or folate deficiency is common	Effects of sepsis may be important. Iron status difficult if APR (Fe↓, ferritin↑)
Folate, B12#	Baseline Then every 2-4 weeks	Folate deficiency is common	Serum folate/B12 sufficient, with FBC
Manganese*§	Every 3-6 months if on HPN	Excess provision to be avoided- more likely if liver disease	Red blood cell or whole blood better measure of excess than plasma
25-OH Vit D*§	6 monthly if on long- term support	Low if house-bound	Requires normal kidney function for effect
Bone densitometry*§	On starting HPN Then every 2 years	Metabolic bone disease diagnosis	Together with lab tests for metabolic bone disease

Tests marked with § are primarily required for patients on parenteral nutrition in the community.

Tests marked with # are rarely required in patients having enteral nutrition (in hospital or in the community), unless there is cause for concern.

7.4 Research Recommendations

The following research recommendation was proposed:

Nutrition support in adults: full guideline DRAFT (August 2005) Page 130 of 262

7.4.1.1 Further research is required to identify which components of nutrition monitoring are clinically and cost effective.

There is no clear evidence available in to the long and short term benefits of clinical monitoring in terms of prevention of complications and survival. With the lack of evidence the GDG have considered in detail this problem and have instead carefully developed the guidance for monitoring by expert clinical practice and consensus opinion.

8 Oral Nutrition Support

8.1 Introduction

Options for oral nutrition support should be considered for any patients taking inadequate food and fluid to meet their requirements, unless they cannot swallow safely or have inadequate gastrointestinal function. Oral options include dietary counselling to facilitate the addition of ingredients high in energy and/or protein (e.g. butter, cream, milk, sugar); adaptation of meal structures (e.g. 3 meals plus 3 snacks); and the use of proprietary oral nutritional supplements such as nutritionally complete pre-packed drinks or vitamin/mineral tablets.

Proprietary oral nutritional supplements can be prescribed for conditions laid down under Borderline substance guidance. Levels of electrolytes in oral and enteral feeds are governed by the EC Directive for Foods for Special Medical Purposes (1999/21/EC) There is also a category of 'disease related malnutrition' which covers a lot of the patients requiring ONS.

The aim of oral nutritional supplements is to improve the patient's overall food and fluid intake in order to improve clinical outcomes. It is important that the total intake from normal food plus the additional measures provides a balanced mix of energy, protein and micronutrients.

Dietary counselling and nutritional supplements may both be used to increase nutrient intake either individually or in combination. Dietary counselling has potential advantages in that it offers greater variety, can be tailored to individual needs and may be associated with lower costs to the health service. It has therefore been suggested that it should precede the use of nutritional supplements is simple and many are available on prescription although a number of studies have highlighted problems with compliance ^{189,251,280}. It is not known whether these two methods of nutritional support are complimentary to one another.

We conducted a number of reviews to investigate the clinical and nutritional effects of one or more oral interventions along with a review to identify patients' views on some of these interventions. Patient in all settings were included but there was insufficient evidence to make separate recommendations for each setting. However, it is likely that if oral nutritional interventions provide overall benefit for malnourished patients, these benefits will occur regardless of the setting in which the nutritional intervention is given. All diagnoses were also included in the reviews but only three areas were identified with enough specific studies to warrant separate sections in this chapter: surgery, pancreatitis and dysphagic patients. T

Page 132

8.2 Oral nutritional interventions versus standard care in malnourished patients

8.2.1 Studies considered for this review

Since effects of oral nutritional interventions are likely to be most evident in patients who are malnourished or at risk of malnourishment, we only aimed to review studies undertaken in such groups in both hospital and community settings (Table 31) Ideally, the studies included would have used the same or similar definitions for malnutrition and nutritional risk but unfortunately inclusion criteria were variable and in some cases unclear. Consequently, we included any study in which it appeared likely from either the reported criteria or the clinical setting that at least 50% of all participants would have had a BMI less than or equal to 21kg/m², unintentional weight loss of 5% in recent months, or not been able to eat or been unlikely to eat for more than five days.

8.2.2 Clinical evidence for oral nutritional supplements versus standard care in malnourished patients

The review identified 38 RCTs^{10,19,23,26,31,36,63,80,86}-88,119,122,162,196,204,206,208,215,236,238,269,278,279,288,291,292,294,310,314,352,357,370-372,380,382,385

that looked at the effectiveness of using an oral nutritional supplementation. These included studies giving supplements alone and in combination with dietary counselling. The supplements investigated were a combination of proprietary complete supplements (complete supplements contain a balanced mixture of protein, energy, vitamins and minerals), homemade supplements and incomplete supplements (incomplete supplements do not contain a complete balance of nutrients).

8.2.2.1 Oral nutritional supplements alone versus standard care

Thirty RCTs compared patients who received oral nutritional interventions with patients who received standard care/no intervention 19,26,36,63,80,86-88,122,162,196,204,206,208,215,236,238,269,288,292,294,310,314,352,357,370-372,382,385. There was no

form of dietary advice in either arm. The most frequently reported outcomes were: death, anthropometric measurements (such as weight change), length of hospital stay, wound healing or complications, quality of life and functional status.

Twenty studies ^{19,36,63,80,86,87,122,162,196,206,208,236,288,292,314,352,357,371,372,385} reported mortality. Although most of the studies showed lower mortality rates in the supplemented group no individual study showed a significant difference. However, a meta-analysis (Table 16) of these studies showed a significant reduction in mortality for the proprietary complete supplements with no significant difference for homemade or incomplete supplements (although only three small studies reported mortality this type of intervention).

Nutrition support in adults: full guideline DRAFT (August 2005) Page 133 of 262

Eighteen studies provided information on weight change ^{26,63,87,122,162,196,204,215,236,238,269,288,310,314,357,370,372,385}. Six showed a significant weight change in favour of the supplemented group ^{63,236,238,269,288,385}, although in one of these it was only evident in a severely malnourished subgroup ²⁸⁸. The other studies showed no significant difference in weight change.

Fifteen of the eighteen included studies with enough data to incorporate into a meta-analysis \$^{26,63,87,122,162,204,236,269,288,310,314,357,370,372,385}\$ The meta-analysis showed that those taking proprietary complete supplements \$^{63,87,122,236,269,288,357,370,372,385}\$ had significant weight gains whereas homemade or incomplete supplements \$^{26,162,204,310,314}\$ only showed a non-significant weight change in favour of supplements.

Change in BMI as an outcome was reported in 5 studies^{63,204,294,382,385}. Two ^{63,385} documented significant change favouring the supplemented group, one reported that the majority of participants in both groups showed improved or maintained BMI but did not document the change ²⁹⁴, one reported a significant increase in BMI of men that were supplemented compared to male controls but no significant differences for women ³⁸² and the last showed no significant difference in any groups ²⁰⁴. Other anthropometric measurements such as Triceps skin fold (TSF), Mid-arm muscle circumference (MAC), were not reported consistently in studies although where significant differences were shown they favoured the intervention groups.

Ten studies provided data on length of stay^{80,87,122,162,288,292,310,357,371,382}. One showed a significant reduction in the supplemented group⁸⁰, two showed no significant difference between groups^{288,292}, and seven did not report the significance. Our meta-analysis (Appendix Six: Meta-Analyses Oral versus Standard Care) showed no significant difference overall for either complete proprietary supplements or non-complete/homemade supplements.

Functional outcomes reported differed from study to study but where benefit was identified, it favoured the supplemented group.

Energy and/or protein intake was higher in the supplemented group in some studies 36,122,196,215,238,310,370 and where significant benefit was identified it was in favour of the intervention. No study demonstrated a better intake in the control for this outcome.

Complications were reported in six studies 36,80,122,292,310,357 . All showed fewer complications in the supplemented group, the difference was significant in two studies 36,292 .

8.2.2.2 Oral nutritional supplements plus dietary counselling versus standard care

Three studies compared oral supplements plus dietary counselling with standard care^{31,278,279}. All three of these showed a weight gain in the supplement plus dietary counselling group compared to the standard care group, the gain was significant in two of these studies^{278,279}. Two studies

Nutrition support in adults: full guideline DRAFT (August 2005) Page 134 of 262

reported data on energy intake with one showing no difference between the groups³¹ and the other showing a significant increase in the supplemented group²⁷⁹.

8.2.2.3 Oral nutritional supplements plus dietary counselling versus dietary counselling

The review identified five RCTs^{10,23,119,291,380} that compared oral supplements plus dietary counselling with dietary counselling alone (although dietary counselling is not necessarily standard care). There was no significant difference in mortality for the three studies reporting this outcome ^{10,23,119}. The same three studies also reported weight change with only one of them showing a significant difference²³, this was in favour of the supplemented group.

Length of stay was reported for two studies^{23,380}, both reported shorter lengths of stay in the control group than the supplemented group but neither showed a significant difference. Beattie et al²³ also reported complications, the supplement group had significantly fewer than the control group.

8.2.3 Meta-analysis summary of oral vs. standard care

Our meta-analysis (Appendix Six: Meta-Analyses Oral versus Standard Care) looked into four commonly reported outcomes for oral nutritional supplementation. It demonstrated that their use leads to statistically significant increases in weight and statistically significant reductions in complications and mortality. There was no significant effect on length of hospital stay although some caution is required when interpreting both weight change and length of stay data. In one study ²⁶, we had to approximate mean weight change from median weight change, and estimate the standard deviation using the weighted mean of standard deviations in the other studies. Similar approaches were needed for lengths of stay data in four studies ^{80,122,288,357}.

Table 16: Summary of meta-analysis of oral intervention vs. standard care

	No. patients (Intervention/ standard care)	Pooled effect [95% CI]	P value from test for heterogeneity
Mortality reported in 25 studies 10,19,23,36,63,80,86,87,1 19,122,162,204,206,208,236,278,279 ,288,292,314,352,357,371,372,385	1388/1480	RR (fixed) 0.82 [0.69, 0.98]	
Length of stay (days)		WMD (fixed)	0.63

 Length of stay (days)
 682/667
 WMD (fixed)

 reported in 12 studies
 -0.43 [-1.65, 0.80]

Nutrition support in adults: full guideline DRAFT (August 2005) Page 135 of 262

23,80,87,122,162,288,292,310,357,3 71,380,382			0.004
Complications reported in 7 studies ^{23,36,80,122,292,310,357}	462/543	RR (fixed) 0.73 [0.63, 0.85]	0.27
Weight gain (kg) reported in 21 studies ^{23,26,31,63,87,119,122,16} 2,204,236,269,278,279,288,291,310, 314,357,370,372,385	557/550	WMD (random) 1.21 [0.70, 1.71]	0.0001

8.2.4 Cost effectiveness of oral nutritional supplementation

We found one UK and one French study that compared the cost of oral nutrition support with standard care using data extracted from specific RCTs (Studies on the use of support in surgical patients rather than generally malnourished patients are dealt with separately – see section 8.6). Both studies were performed on patients in the community although in one case patients had just been discharged from hospital and in both cases hospital admissions or readmissions were costed outcomes.

The UK study was a cost-effectiveness analysis ⁸⁷ was based on an RCT to determine whether nutritional supplementation reduced health care costs and improved quality of life in older malnourished patients post-discharge. They found no significant difference in quality of life of patients although, the short course of the intervention (8 weeks) made it relatively unlikely that improvements would be evident. Patients in the oral supplement arm had significantly increased cost (£3034 vs. £1854) due to longer lengths of stay for those who needed readmission to hospital, even though the increases in length of stay were not significant. The reasons for the increased length of stay were neither clear nor discussed in the paper. However, although it is possible that they were a result of the intervention, a misbalance between trial arms (although baseline characteristics of the patients were similar) or chance within the small study with varied diagnoses seems more likely.

The French study also evaluated the resource and cost implications of using supplements in older patients⁹. It was based on a prospective comparison of patient cohorts with one cohort in a region with high rates of oral nutritional supplement prescription compared to another cohort in a region with low prescription rates. Patients in the high frequency arm had a significantly improved MNA scores, reduced numbers of admissions (in contrast to Edington 2004) but no significant reduction in costs. There was no significant difference in mortality and other patient outcomes, such as quality of life were not recorded.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 136 of 262

In addition to the above, we also examined an unpublished report ⁹³ that estimated the cost impact of oral nutritional supplements from an NHS perspective using two separate analyses related to lengths of stay or complication rates. These were extracted by meta-analysis from selected RCTs. The report found relatively few studies in the community on which to base any estimates of cost impact and the majority of relevant RCTs identified in hospital settings, were in surgical patients and did not necessarily focus on patients that were malnourished. Both the length of stay and complication rate showed that the use of oral nutrition supplements led to reduced in hospital costs. However, specific additional costs associated with administering and monitoring the supplements were not included, the bed day costs used did account for associated nursing time etc. However, the studies did not claim to be full cost-benefit analyses and they do not account for potential additional NHS costs of care related to added weeks of life in any seriously ill patients and, furthermore, the differences in length of stay reported in this study do not concord with either our meta-analysis or that in the Cochrane review ²⁴¹ (neither of which show significant reductions in length of stay with oral nutrition supplements).

We also estimated the cost-effectiveness of oral nutrition support in older inpatients in our model of their use within the context of a malnutrition screening programme (Section 4.11.1). This suggested that screening followed by intervention using sip feeds would be cost-effective using the base case assumptions although the results were sensitive to relatively small changes in some of the model's parameters.

8.2.4.1 Conclusions

Overall, although the studies identified were small with marked heterogeneity in study populations and outcomes, they do show improved outcomes for malnourished patients given oral nutrition supplements. These benefits were somewhat inconsistent but our meta-analysis (Appendix Six: Meta-Analyses Oral versus Standard Care) shows that the use of oral nutrition supplements in such patients leads to statistically significant improvements in body weight along with reductions in complications and mortality. Economic modelling of the use of oral nutrition supplements within the context of a screening programme undertaken in elderly hospital patients also suggests probable cost-effectiveness in terms of cost per QALY <£20,000. However, available RCTs provide too little information and are too underpowered to define these costs with confidence.

8.2.5 The influence of care setting for oral nutritional supplementation

As stated in the introduction to this section, too few RCTs on the effects of on oral nutrition support in the community were identified to make separate recommendations for different patient settings. Furthermore, we did find some evidence which suggests that caution is needed in extrapolating to typical

Nutrition support in adults: full guideline DRAFT (August 2005) Page 137 of 262

malnourished groups in the community from the evidence within hospital studies. Three RCTs ^{87,204,385} examined the benefits of oral nutrition support in typical elderly malnourished patients in community settings (rather than community studies on more unusual populations such as those with locally advanced cancer or alcoholic liver disease). These studies suggested a benefit from supplements in terms of increased weight but did not confirm the net mortality benefit in this setting that was identified by our meta-analysis. However, overall the paucity of evidence from community studies make it very difficult to be confident in any real differences related to setting and/or patient population, and more detailed larger studies are required.

8.2.6 Patient's satisfaction with nutritional supplements

A literature search conducted to identify patient's views on nutrition support retrieved four studies which looked at patients' preferences for nutritional supplements ^{85,146,232,332}.

In one US study ³³² 20 patients and 20 staff members of a large teaching hospital rated a variety of brands of liquid nutritional supplements. Each participant sampled four brands of vanilla product and four brands of an alternate flavour (either chocolate or strawberry, based on their personal preference). The first round of sampling was blinded (participants did not know the brand of the supplements) and in the second round the brand was disclosed. The results of the study indicated that staff member ratings of acceptability were lower (in some cases significantly lower) than ratings given by patients. In general, staff member acceptability ratings did not change significantly once the brand name was known. Patient acceptability ratings appeared to be impacted to a much greater degree by knowing brand name; significant increases were seen in four ratings.

Another study ⁸⁵ also looked at differences in preferences of oral nutritional supplements between patients and dietitians. There were significant differences between patients and dietitians in their evaluation of 7 of their 13 products.

The palatability of sip-feed nutritional supplements and other high-energy foods to older medical inpatients was assessed in one study ¹⁴⁶. 49 malnourished subjects rated the taste of a previously selected sip-feed supplement and five other high-energy foods: cheese biscuit, plain potato crisps, chocolate, cherry-flavored cereal bar and stout beer. Subjects rated the taste of sip-feeds as favourable as all other offered foods, with the exception of stout beer which had a lower rate.

Another study ²³² examined whether sip-feeds are less preferred and less likely to be selected than other energy-dense foods in healthy elders; and whether eating alone further reduces intake relative to eating in a social setting.

Twenty-one healthy older adults (aged 60-79) were included. Subjects rated six different flavours of sip-feed (three fruit juice flavours: apple, orange and fruit punch and three milkshake flavours: vanilla, strawberry and chocolate) and then rated the pleasantness of the taste of the flavour against five other energy-

Nutrition support in adults: full guideline DRAFT (August 2005) Page 138 of 262

dense familiar foods/drinks (cheese cracker, cereal bar, potato chip, chocolate button, and beer). Two drinks, two salty foods, and two sweet foods were offered to the participants. Intake was measured when participants ate alone or in a group. Pleasantness ratings were made on a 7-point Likert scale, where 1 represented 'extremely unpleasant' and 7 represented 'extremely pleasant'.

The results from the study showed that the mean pleasantness of sip-feeds was above neutral (rating of 4) in all but one case (chocolate). Sip-feeds were rated as the third most pleasant (5.0 +/- 0.3). The participants' favourite flavours of sip-feeds compared well with other more familiar foods and were selected as part of a snack. Snack intake increased by 60% when consumed in a group setting compared with eating alone.

8.2.6.1 Conclusions

Patients found sip feeds an acceptable form of nutritional support.

8.3 Dietary advice versus standard care

8.3.1 Studies considered for this review

One systematic review ¹⁷ and one RCT¹¹⁴ investigated the impact of dietary advice. The purpose of dietary advice given by a dietitian or health care professional was to provide instruction on modifying food intake (e.g. food fortification, meal plan adaptation) to improve nutritional intake. 'No dietary advice' as used in this context meant patients received no other specific oral intervention.

Two of the sub-group comparisons were of interest; dietary advice versus no advice and dietary advice plus supplements (if required) versus no advice and no supplements.

8.3.2 Clinical evidence for dietary advice versus no dietary advice

The review considered 5 RCTs including 888 older people, cancer and Crohn's disease patients (Table 32). However, only three of these studies reported outcomes of interest; mortality, hospital admission, nutritional status and clinical function. No significant difference was found for mortality at six months (two studies), hospital admission (one study), weight change and BMI (one study) or measures of clinical function (one study).

8.3.3 Clinical evidence for dietary advice plus oral nutritional supplements (if required) versus no dietary advice and no oral nutritional supplements

The Baldwin et al. review ¹⁷ also compared patients receiving dietary advice plus sip feeds (if required) with those receiving no advice and no sip feeds (Table 32). Seven RCTs including 665 cancer, surgical and chronic obstructive pulmonary disease patients were contained within the review although, only two provided data on the outcomes of interest which were mortality and change in nutritional status. The separate small RCT ¹¹⁴ also looked at this comparison although it also included a third, normal weight group of patients, which we did not include in our analysis.

No significant differences for any of the outcomes were found in either the systematic review ¹⁷ or the small RCT ¹¹⁴.

8.3.4 Patient's satisfaction with dietary advice

We performed a literature search to assess patient's views on dietary advice which identified two studies: one conducted in Canada ³⁶³ and the other in Australia ¹⁰⁷. The studies included hospitalised patients for a minimum stay of 5 days ³⁶³ (n=55) and acute hospital patients ¹⁰⁷ (n=49). Patients consumed a therapeutic diet and used dietary counselling during their hospital stay. A survey questionnaire was used to evaluate patients' satisfaction with four components of dietary counselling. One study ³⁶³ looked at the following components:

- knowledge: "patient's perception of the dietitian's knowledge of his or her medical condition, dietary therapy, and food composition of meals served in the hospital."
- cognitive communication skills: "dietitian's use of simple language in verbal and written communications and in answering patient's questions"
- affective communication skills: "interpersonal qualities of the dietitian (e.g., courtesy, warmth, and attentiveness) that help build a positive relationship with the patient"
- facilitation skills: "dietitian customization of the diet, inclusion of the patient in decision making, and dispensation of advice to the patient about adapting the diet after discharge from the hospital"

The other study ¹⁰⁷ assessed the following elements:

- Staff interpersonal skills: These included staff communication skills and understanding of patients' needs.
- Nutrition supplements: Temperature, taste, smell and appearance of nutritional supplements

Nutrition support in adults: full guideline DRAFT (August 2005) Page 140 of 262

- Perceived health benefits of nutrition care: Effect of dietary advice on patient's health
- Staff presentation skills: These included whether staff were polite, courteous and friendly.

The result from the studies indicated that staff facilitation skills, knowledge ³⁶³ and interpersonal skills ¹⁰⁷ were the most important factors of patient satisfaction with dietary advice.

8.3.4.1 Conclusions

Staff facilitation skills were the most important determinant of patients' satisfaction with dietary advice.

8.3.5 Cost-effectiveness evidence for dietary advice

No study reporting cost or cost-effectiveness of dietary advice was found.

8.3.6 Conclusions

We were unable to demonstrate any evidence of effect for dietary advice but studies were too small and heterogeneous to allow any conclusions. Many also failed to report outcomes of interest and there is no relevant economic evidence

8.4 Oral nutritional supplements versus dietary advice

8.4.1 Studies considered for this review

We looked for studies that compared one type of oral nutrition support with another, for example three meals per day versus six meals per day, snacks or dietary advice to improve nutritional status versus sip feed, sip feed versus placebo multivitamin pills, in malnourished patients or patients at risk of malnutrition (Table 33). One systematic review and one RCT met the inclusion criteria. The systematic review compared the effects of dietary advice to no advice or other oral interventions ¹⁷, and the RCT compared dietary advice with oral supplements and also standard care ²⁹⁴.

8.4.2 Clinical evidence for dietary advice or snacks versus oral nutritional supplements

We identified one systematic review ¹⁷ which included 4 RCTs covering 173 older, HIV and cystic fibrosis patients, and one additional RCT ²⁹⁴ that included 111 colorectal cancer patients undergoing radiotherapy treatment, compared dietary advice or snacks with sip feeds. The Ravasco RCT ²⁹⁴ included patients

Nutrition support in adults: full guideline DRAFT (August 2005) Page 141 of 262

regardless of nutritional status but did provide some results for 42 patients considered malnourished. The reported outcomes were mortality, hospital admission, nutritional status, nutritional intake and clinical function.

There was no significant difference in mortality at three months (5 studies), hospital admission (1 study), or measures of clinical function at three months (1 study investigating older people living at home). Energy intake at three months was significantly greater in the sip feed group compared to the dietary advice group (4 studies) and although there were variable effects on weight change, the systematic review reported significantly greater gains in the sip fed patients.

8.4.3 Cost-effectiveness evidence

No study reporting cost or cost-effectiveness was found.

8.4.4 Conclusions

Oral nutritional supplements may be more effective in increasing energy intake and increasing weight than dietary advice but studies have been too small to determine whether there are any differences in terms of mortality or clinical outcome, and there is little or no information on cost effectiveness.

Since oral nutritional supplements presumably produce clinical benefits through increased nutrient intake, a similar increase in nutrient intake achieved by dietary means, should lead to similar clinical benefits. It therefore seems logical that, until further evidence is available, people with weight loss secondary to illness should either be managed by referral to a dietitian or by staff using protocols drawn up by dietitians with referral as necessary.

8.5 Recommendations

- 8.5.1.1 Healthcare professionals should consider interventions to improve oral intake to patients who can swallow safely and who are:
 - malnourished (BMI < 18.5 -20 kg/m² and unintentional weight loss >5% within the previous 3-6 months), or
 - at risk of malnutrition (eaten very little for > 5 days and or unlikely to eat more than very little amounts for the next 5 days). [A]

8.5.1.2 Healthcare professionals should aim to ensure that the overall nutrient intake of oral nutritional interventions offered to patients contain a balanced mixture of protein energy, vitamins and minerals. [D(GPP)]

8.6 Oral nutrition support in surgical patients

8.6.1 Introduction

Many surgical patients are malnourished prior to their operation. During the period leading up to diagnosis, the underlying problem (especially if gastrointestinal) may cause deterioration in nutritional status and in some patients, coincidental illness or psycho-social issues also contribute. To add to these nutritional risks, many investigations used to diagnose surgical problems, require patients to be 'nil by mouth'.

Following surgery, any pre-operative problems can worsen. Many patients have some degree of intestinal failure, usually due to ileus and most also have variable catabolic responses with increased or changed nutrient demands. Some have abnormal nutrient losses via drains, stomas etc.

In view of the above, there are always some surgical patients with an undoubted need for temporary nutrition support (e.g. those with prolonged but potentially reversible intestinal failure due to post-operative complications such as sepsis, anastamotic leaks, or GI fistulae, will need it until recovery). There will also be occasional patients who end up with irreversible intestinal failure due to extensive gut resection etc., and these may need long-term enteral tube feeding or parenteral nutrition (see Chapter 11). In the majority of surgical cases, however, the need for nutrition support is less definite. Nevertheless, they might benefit from its elective use. Pre-operative nutrition support might reduce risks of infection or poor wound healing, whilst early post-operative intervention might limit the nutritional risks arising from the standard practice of keeping patients 'nil by mouth' for several days (with a view to protecting gastro-intestinal anastamoses and allowing any ileus to resolve). Furthermore, there is some evidence that early post-operative engagement of the GI tract might reduce the metabolic effects of injury and limit infections caused by the spread of gut organisms to other parts of the body. We therefore reviewed studies of oral nutrition interventions around the time of surgery.

8.6.2 Methodology

We conducted literature searches to identify studies on the 'elective' use of nutritional support around the time of surgery. The studies identified were grouped to examine the possible benefits under the following circumstances:

 Pre-operative oral nutrition support versus no additional pre-operative supplementary nutrition (i.e. normal hospital diet, placebo drink, fasting or simple IV fluids)

Nutrition support in adults: full guideline DRAFT (August 2005) Page 143 of 262

- Pre- and post-operative oral nutrition support vs. no additional nutrition support (i.e. normal hospital diet, placebo drink, fasting or simple IV fluids)
- Pre-operative oral nutrition support versus post-operative oral nutrition support
- Early post-operative oral nutrition (<24 hrs after surgery) versus no additional post -operative nutrition (i.e. normal post-operative fasting with simple IV fluids until clinically-judged return of GI function)

They were also grouped according to the type of surgery undertaken.

8.6.3 Elective pre-operative oral nutrition support versus no preoperative nutritional support

8.6.3.1 Studies considered for this review

We identified 2 RCTs^{219,334} which examined pre-operative oral nutritional supplements versus no pre-operative nutritional support (Table 36).

8.6.3.2 Clinical evidence

One study³³⁴ reported a decrease in postoperative complications following preoperative nutritional supplementation while the other ²¹⁹ reported increased problems.

8.6.4 Elective pre- and post-operative oral nutrition support vs. no nutrition support

8.6.4.1 Studies considered for this review

Two RCTs ^{219,334} were identified (Table 36).

8.6.4.2 Clinical evidence

One RCT ³³⁴ reported a decrease in the total number of postoperative minor complications in patients receiving pre- and post-operative nutrition support (p<0.05) and the fed group also lost significantly less weight than controls (p<0.05), however, the other RCT ²¹⁹ found no significant differences between intervention and control groups. Different systems of classification of complications were used for the studies.

8.6.5 Elective pre-operative oral nutritional support versus postoperative oral nutritional support

8.6.5.1 Studies considered for this review

Two RCTs ^{219,334} were identified (Table 36).

8.6.5.2 Clinical evidence

No significant differences were found in any of the outcomes.

8.6.6 Elective post-operative oral nutrition support versus standard care

8.6.6.1 Post-operative oral nutrition support in GI surgery (at the time of or after return of GI function)

8.6.6.1.1 Studies considered for this review

Six RCT's ^{23,175,176,189,219,292,310,334} (one trial was reported in two studies) compared patients undergoing abdominal surgery who received standard care/no intervention with patients who received oral supplements at or after the return gastrointestinal function judged clinically (Table 37). Two studies included patients undergoing elective and emergency GI surgery ^{174,310}, four studies included patients undergoing elective GI surgery only ^{189,219,292,334} and one study included patients undergoing elective GI and vascular surgery ²³. Three of these studies ^{23,292,310} are also included in the oral vs. standard care section for malnourished patients in general (section 8.2).

8.6.6.1.2 Clinical evidence

Post-operative oral supplements led to significant increase in BMI and mid-arm circumference in 1 study 189 and weight gain in 3 studies 189,292,310 . In one study 189 the intervention group had significantly less complications than the control group (p< 0.05), although in another 334 the difference was only significant for minor complications. Four studies reported no significant difference for wound infections 23,219,292,310 . The only study that reported pneumonia 292 showed a lower incidence in the supplemented group (p<0.02). Quality of life was significantly higher in the intervention group in one study 23 . Postoperative anxiety was reported in one study and showed no significant difference 219 . There were no significant changes in length of stay 219,292,310 or mortality 23,219,292 in the studies reporting these outcomes.

8.6.6.2 Post operative oral nutrition support in orthopaedic Surgery (at the time of or after return of GI function)

A systematic review (8 RCT's) ¹⁴ and 2 additional RCT's ^{50,166} provided data on the effects of elective post-operative oral nutrition support in patients following

Nutrition support in adults: full guideline DRAFT (August 2005) Page 145 of 262

orthopaedic surgery for hip fracture (Table 38). The systematic review reported on mortality, complications, and unfavourable outcomes but potential biases resulting from inadequate sample size, allocation and concealment make the results difficult to interpret.

Pooled data from for 3 RCTs ^{80,145,338} contained in the systematic review demonstrate that oral nutrition supplements led to a statistically significant reduction in adverse outcomes in the supplemented groups including reduced complications (borderline significance). However, none of the studies in the systematic review demonstrated a difference between study groups for functional outcomes and the 2 separate RCTs ^{50,166} did not show any differences in reported outcomes.

8.6.7 Early post-operative oral nutrition (<24 hrs after surgery) versus post-operative 'nil by mouth'.

8.6.7.1 Introduction

Routine practice in most centres is for post-surgical patients to be kept nil by mouth until there are clinical signs of returning GI function e.g. for two to three days after a major abdominal operation. This delayed nutrient intake could have significant consequences on nutritional state and potential recovery but conversely, very early oral intake might cause problems with nausea and vomiting, or leakage from vulnerable anastamoses. We therefore conducted a review to investigate any benefits or harm related to delaying the start of food and fluid intake in post-surgical patients.

8.6.7.2 Studies considered for this review

We identified one systematic review ²¹⁶ that looked at early post-operative feeding (oral or enteral) versus post-operative 'nil by mouth'. The oral studies from this review were included as relevant in this section (enteral tube studies were included in section 8.X.X on post-operative enteral tube feeding) to give a total of 20 RCTs identified in which patients were given oral feeding within 1-24 hours post operatively compared to no nutrition (i.e. intravenous dextrose and/or clear fluids only) until clinical evidence of returning bowel function 32,52,74,105,130,131,140,144,148,201,224,267,277,281,295,299,316,339,342,376. Data were extracted on seven outcomes: vomiting, anastomotic dehiscence, pneumonia, death, intra-abdominal abscess, wound infection and hospital length of stay (LOS) (Table 39, Table 40, Table 41). Where appropriate we pooled the data for these outcomes but we were unable to pool data for LOS as the studies reported this in different units and information needed to convert these units was lacking. Studies fell into two groups, those including patients undergoing general abdominal surgery for gastrointestinal problems, vascular problems of trauma, and those including patients undergoing gynaecological or obstetric surgery. One study of early oral intake in pancreatitis patients who did not undergo surgery is reported separately.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 146 of 262

8.6.7.3 Clinical evidence

8.6.7.3.1 Abdominal surgery patients

We identified eight studies. Six included patients undergoing lower GI surgery ^{32,105,148,267,299,342}, one included patient undergoing lower GI and transabdominal central vascular reconstruction ¹⁴⁴ and one included emergency or elective intra-peritoneal surgery of all types²⁹⁵ (Table 39). A combined analysis of these eight studies showed that patients in the early feeding group had a statistically higher incidence of vomiting compared to patients in the later feeding group. There were no statistically significant differences in any of the other outcomes in this pooled analysis (Table 17 and Appendix Seven). LOS was reported in six studies ^{32,105,144,148,299,342} with no statistically significant differences between groups.

Table 17: Outcomes reported in studies of patients undergoing GI surgery

No. patients (early feeding/late feeding)	RR (fixed) 95% CI
262/261	1.43 [1.07, 1.92]
0.52	
300/294	0.74 [0.27, 2.06]
0.75	
300/294	0.98 [0.32, 3.00]
0.92	
244/245	1.01 [0.14, 7.06]
P=1.0	
350/344	0.62 [0.29, 1.34]
P=0.48	
350/344	1.21 [0.29, 4.96]
P= 0.29	
	feeding/late feeding) 262/261 0.52 300/294 0.75 300/294 0.92 244/245 P=1.0 350/344 P=0.48 350/344

Nutrition support in adults: full guideline DRAFT (August 2005) Page 147 of 262

8.6.7.3.2 Caesarean and gynaecological surgery

We identified twelve studies in this group: seven studies included patients undergoing caesarean section ^{52,130,131,140,201,277,376} and five studies ^{74,224,281,316,339} included patients undergoing gynaecological surgery (Table 40,Table 41). Although pregnancy does not fall within the scope of the guideline the GDG decided to include patients who have undergone caesarian section as these patients are no longer pregnant at the start of oral feeding.

We initially analysed the two surgical groups (caesarean and gynaecology) separately. The results of the analyses showed no significant differences between the groups in vomiting, pneumonia and wound infection in either surgical group. The P value from test for heterogeneity was greater than 0.1 for all outcomes in either surgical group. LOS was reported in 10 studies. The early feeding group spent fewer days in hospital (p< 0.001) in two ^{131,277} out of six studies ^{52,130,131,201,277,376} on caesarean section and four ^{74,281,316,339} out of four studies on gynaecological surgery (p<0.05).

In an analysis there were no statistically significant differences in any of the outcomes extracted (Table 18 and Appendix Seven: Meta-Analyses Oral versus Nil Post Operative Nutrition Support).

Table 18: Outcomes of studies of patients undergoing caesarean and gynaecological surgery

	No. patients (early feeding/late feeding)	RR (fixed) 95% CI
Vomiting (reported in five studies 52,74,201,224,281)	361/395	1.07[0.73, 1.58]
P value from test for heterogeneity	0.71	
Wound infection (reported in five studies ^{74,130,131,281,339}	358/356	0.94 [0.58, 1.52]
P value from test for heterogeneity	0.65	
Pneumonia (reported in 4 studies ^{74,281,316,339})	249/260	0.42 [0.08,2.17]
P value from test for heterogeneity	0.74	

Nutrition support in adults: full guideline DRAFT (August 2005) Page 148 of 262

8.6.8 Cost effectiveness evidence in surgical patients

We identified two studies and two cost analyses which examined the effects of peri-operative oral nutrition support. An RCT (n=152), based in the UK compared four arms (pre-operative, post-operative, peri-operative and no nutritional supplementation) in patients undergoing elective major to moderate lower GI surgery ³³⁴. There were significantly fewer *minor* complications in the intervention arms and no significant differences with respect to major complications. Costs were lower by £300 per patient although this was not significant. The results favour intervention but the trial was inadequately powered.

Another study²⁰⁷ looked at the effect of post-operative oral supplements on complication rates and hospital costs in adult orthopaedic patients, using a cross-over trial. Despite low compliance with the intervention there was a significant reduction in the complication rate in the oral supplemented group (16.6 % vs. 35.1%, p=0.005). There were cost savings from the reductions in both length of stay and specific treatment interventions (£2,068 vs. £2,199) although it was not stated whether this difference was statistically significant.

An unpublished UK-based decision analysis ²⁷⁵ evaluated preoperative assessment, dietary advice and oral intervention (mixture of fortification and/or supplements) versus no preoperative assessment or intervention in patients undergoing GI surgery. Data was elicited from the expert opinion of a sample of NHS consultants. Incremental cost per patient (excluding cost savings due to complications averted) was estimated to be between £17 and £48. They found that preoperative assessment and ONS would be cost saving if averting a complication saves three or more bed-days.

An unpublished report ⁹³ estimated the cost impact of oral nutritional supplements from an NHS perspective using two alternative methods: firstly by costing length of stay (as reported in selected RCTs) and secondly by costing complications (reported in those same RCTs). The RCTs included were mainly in surgical patients but did not all focus on patients that we would categorise as being at risk of malnourishment. For each of the trials, and using both methods, they estimated in hospital cost savings from oral nutrition supplements and although any specific additional costs associated with administering and monitoring the supplements were not included, the bed day costs used did account for associated nursing etc. The studies did not claim to be full cost-benefit analyses and they did not account for the potential additional NHS costs of care in added weeks of life for critically ill patients.

Only one study was found that evaluated the costs (and consequences) of early post-operative oral nutrition versus nil by mouth ⁶. It was performed in Japanese patients undergoing oncological colorectal surgery and reported that early post-operative feeding significantly reduced length of stay and hence medical costs with no significant differences in complication rates. However, the difference in length of stay in this study was much greater than that observed in studies within the clinical review and patients did not appear to be randomized. This, in

Nutrition support in adults: full guideline DRAFT (August 2005) Page 149 of 262

combination with small sample size and considerable variation in the types of surgery included within different arms, gave a large potential for bias. Furthermore, the costs appear to be expressed as medians and hence might not reflect true differences in mean cost and the feeding protocol was based on rice gruel, which may not be replicable in a UK setting.

8.6.9 Conclusions - oral nutrition support in surgical patients

Some surgical patients need nutrition support either pre- and or post-operatively due to the severity of their existing malnourishment or the presence of post-operative complications and hence prolonged delay in recovery of normal food intake. These patients should receive support by the simplest method possible using oral supplements, enteral tube feeding or PN alone or in combination as necessary.

For less malnourished patients, there is little evidence that pre-operative oral nutrition support is of benefit although trials are small and underpowered. A cost-benefit model does suggest that pre-operative oral support might be cost saving for some patient groups but the models were sensitive to assumptions about the number of complications averted. There is some evidence that post-operative oral nutrition supplements, introduced at or after recovery of GI function may reduce some complications in general surgery patients and patients with hip fracture requiring orthopaedic surgery. Once again, however, studies have been small and underpowered. Nutritional principles suggest that giving post-operative oral supplements to more malnourished patients might lead to greater benefits but larger, targeted trials are needed to prove this point.

8.6.10 Rationale for recommendations

There is little evidence that early introduction of oral intake following abdominal surgery is of value although in caesarean or gynaecological surgery patients it is generally well tolerated and may lead to earlier discharge. Larger trials are also needed to confirm this point.

8.7 Recommendations

8.7.1.1 Pre- and post-operative oral nutrition support should be considered for malnourished surgical patients (BMI < 18.5 kg/m² and weight loss > 10% within the previous 3-6 months or BMI18.5 - 20 kg/m² and weight loss > 5% within the previous 3-6 months. [B]

8.7.1.2 Healthcare professionals can provide post caesarean or gynaecological surgical patients some oral intake within 24 hours of surgery. [A]

8.8 Oral nutrition support in pancreatitis patients

Only one study included patients who had clinical features of acute pancreatitis and did not have any surgical procedure ²⁰⁵ (Table 42). Fifty patients were included in the study. Patients in the early feeding group (n=50) were given liquids, such as tea, water and juice, orally without restrictions immediately after admission. Patients in the late feeding group had a nasogastric tube placed in the stomach for suction. Continuous suction was applied and maintained until the tube was removed.

Results were available for mortality and LOS. There were three deaths in the early feeding group and two deaths in the late feeding group. There were no statistically significant differences in LOS.

8.8.1 Conclusion

There is insufficient data to conclude on the benefits of early feeding for pancreatitis patients.

8.9 Oral multivitamin and mineral supplementation in malnourished patients

8.9.1 Introduction

Oral multivitamin and mineral supplements should help individuals who are eating poorly to meet their vitamin and mineral requirements and in some circumstances, apparently healthy people may also have sub-optimal multivitamin/mineral status. In the National Diet and Nutrition Survey, many older individuals living at home and a great many living in residential care were found to have biochemical deficiencies of vitamins or minerals despite the fact that their food supply appeared to contain sufficient amounts. This raises the possibility that vitamin/mineral supplementation might be of value to patients with malnutrition and they might even be of value to individuals who are not overtly malnourished or ill, although the latter fall outside the scope of this guideline.

8.9.2 Clinical evidence

Our review identified RCTs that studied the effects of multivitamins/minerals on patients who were potentially malnourished. The studies included individuals

Nutrition support in adults: full guideline DRAFT (August 2005) Page 151 of 262

who were hospitalised, living in older persons care homes or were HIV infected patients. 127-129,164,284,371. The studies were categorised into two groups according to the type of supplement provided i.e. multivitamin *and* mineral supplement v placebo 127-129 (Table 34) or multivitamin supplement only v placebo 164,284,371 (Table 35).

8.9.3 Multivitamin and mineral v placebo/standard care

8.9.3.2 Studies considered for this review

Four studies were included in this category ^{8,127-129,177} (one study was reported in two papers ^{127,129}). Three studies included older patients in nursing homes and one study included HIV infected patients.

8.9.3.3 Older patients in nursing homes

Two studies with identical methodology included older patients in nursing homes. One was a large multi-centre study¹²⁸ and the other reported in two papers^{127,129} was a study in one of the centres in the multi-centre study but provided additional data. Patients in both studies were randomised into four groups: vitamin group (Vitamins A, C and E) mineral group (zinc, selenium), vitamin and mineral group (vitamins A, C, E and zinc and selenium) and a placebo group (calcium phosphate). Immunological data were reported in the large multi-centre study ¹²⁸.

8.9.3.3.1 Clinical Evidence

No differences were observed in delayed hypersensitivity responses. A subgroup of patients received influenza vaccine towards the end of the two-year supplementation period and the humoral response to the vaccine strain was assessed before and after vaccination. Results overall for the three influenza vaccines showed an improvement in antibody titre in trace element and trace element/vitamin groups relative to placebo or vitamins alone, but the mineral group had significantly higher numbers of serologically protected patients compared to the vitamin, vitamin/mineral, and placebo groups, for one of the three vaccines (p<0.05). The authors concluded that zinc and selenium supplementation improves the humoral response, and that vitamin supplementation led to a weaker response, but chance variation is another explanation.

Infectious morbidity, respiratory and urogenital infections were reported in both of these studies. In the smaller study ^{127,129} (n=81) patients in the mineral and (mineral/vitamin) groups had significantly fewer respiratory and urogenital infections(p<0.01). In the larger multicentre study ¹²⁸ (n=725) no significant difference between the groups was observed. However, there are some limitations with this last result. A subgroup of 140/725 patients in this study

Nutrition support in adults: full guideline DRAFT (August 2005) Page 152 of 262

received influenza vaccine to assess immunological outcomes. Infections were reported for the total number of patients and not extracted for the group that received the vaccine. These two trials ¹²⁷⁻¹²⁹ also reported mortality and both found no significant differences between the groups.

In a further small study in the UK ⁸, a two month period of supplementation with a complete vitamin/trace element mixture was not associated with any significant alteration in antibody response to influenza vaccination.

8.9.3.4 HIV-infected patients

8.9.3.4.1 Studies considered for this review

A single study was identified ¹⁷⁷ which included 481 HIV-infected patients randomised to receive either a high dose multiple micronutrient or a placebo for a period of 48 weeks. Patients were examined clinically 12-weekly and tested for CD4 cell count 24-weekly.

8.9.3.4.2 Clinical Evidence

There were no statistically significant differences in overall mortality or changes in CD4 cell count.

8.9.4 Multivitamin v placebo/standard care

8.9.4.1 Studies considered for this review

Three studies were included in this category ^{164,284,371} and although there was a variation in the content of the intervention supplement, most were composed of vitamins C,+/- A, B and E. One included older long-stay stroke patients ²⁸⁴ and one included acute medical or surgical patients ³⁷¹ (Table 35). The other study ¹⁶⁴ included older medical patients who received in addition to the intervention/placebo either a glucose energy or placebo drink.

8.9.4.2 Clinical Evidence

One study ²⁸⁴ reported changes in absolute number of lymphocytes and T cells sub-types. This showed a significant increase in the intervention group (p<0.05). Mental test score and Barthel score (activity score) were reported in one study ¹⁶⁴ with no significant differences between the groups. Change in body weight was reported in two studies ^{164,284}. In one there was no significant change whilst in the other ²⁸⁴, the supplemented group lost weight compared to placebo p<0.05). There were no significant differences reported for mortality or length of stay ^{164,371} although the findings in the Vlaming study did suggest that length of stay may be shorter in multivitamin supplemented acute hospital patients and if this were the case, it would be a very important finding since the

Nutrition support in adults: full guideline DRAFT (August 2005) Page 153 of 262

intervention is relatively low cost and probably harmless. More research is therefore needed with a large multi--=centre trial to clarify this point. .

(Note: The most commonly reported outcome was biochemical assessment of plasma vitamins and minerals. This data was not extracted.)

8.9.4.3 Cost-effectiveness evidence

We did not find any relevant economic studies.

8.9.4.4 The National Diet and Nutrition Survey

The National Diet and Nutrition Survey presented findings on biochemical indices of nutritional status and nutrient intake in older people living in nursing homes. Results from the survey indicate that although the food supply appears to contain sufficient amounts of vitamins and trace elements, in general the status of vitamins and minerals is poor in this population, suggesting that intake and absorption from food was inadequate. The reasons for this are not clear, but possibilities include the presentation and timing of the food, the need for assistance in eating, changes in absorptive function of the gut, and general medical condition.

8.9.5 Conclusions

There is no evidence to support the routine use of vitamin and mineral supplements in either acute hospitalised patients or older residents of nursing homes. However, in view of the National Diet and Nutrition Survey findings, large scale trials are needed and a vitamin/ mineral supplement may be beneficial in older people when there is concern about the adequacy of total food intake.

8.9.6 Rationale for recommendation

The National Diet and Nutrition Survey has shown biochemical deficiency of vitamins and or minerals is common in older people, particularly those in residential care. Studies to determine whether there is definite benefit of providing vitamin supplements to patients have been inadequate, but balanced micronutrient supplements providing the reference nutrient intake for all vitamins and trace elements, have been shown to improve biochemical deficiencies.

8.10 Recommendation

8.10.1.1 For patients where there is concern about the adequacy of micronutrient intake, a complete oral multi vitamin and mineral supplement providing the reference nutrient intake for all vitamins and trace elements should be considered by healthcare

Nutrition support in adults: full guideline DRAFT (August 2005) Page 154 of 262

professionals with the relevant competencies in nutrition support who are able to determine the nutritional adequacy of a patient's dietary intake. [D(GPP)]

8.11 Nutrition support in patients with dysphagia

8.11.1 Introduction

Dysphagia is the term used to describe any impairment of eating, drinking and swallowing. It is ...' not a disease in itself, but rather a symptom of one or more underlying pathologies...' ²⁰³.. Patients with dysphagia are seen in both hospital and community settings, with varying degrees of severity and impact on individuals' lives. Around 50% of older people with dysphagia living in either nursing homes or attending clinics reported that they ate less, whilst 44% reported weight loss and 41%, anxiety or panic attacks during mealtimes⁹⁰. There is therefore a close link between dysphagia and nutritional compromise. Indeed, one study showed that by offering swallowing therapy to dysphagic patients post stroke, they could improve nutritional parameters ⁹⁶. The cause of dysphagia can be either a single medical problem (e.g. acute cerebral conditions, progressive neurological disorders and trauma, disease or surgery to the mouth, pharynx, larynx or oesophagus ²¹⁴). It can also occur or worsen with conditions such as sepsis, respiratory impairment and cognitive disorders.

If the dysphagia is not diagnosed, it can lead to inadequate food and fluid intake, impaired nutritional status and problems such as chest infections, sepsis, and pneumonia. Avoidance of eating may also lead to social isolation and ultimately dysphagia has a 'high morbidity, mortality and cost'^{70,264}. As a result, particularly since it is not always obvious that a patient has dysphagia, the condition must be assessed and managed by a knowledgeable and skilled team.

8.11.2 Prevalence of dysphagia

The prevalence of oropharyngeal dysphagia is estimated to be 60% in nursing home residents and 12-13% of patients in hospital⁷⁰. The prevalence for the general population over 50 years is cited as $16\text{-}22\%^{203}$. Specific examples of conditions which may present with dysphagia include 27-100% of stroke patients 203 depending on the time assessed post stroke, adults with learning disabilities (36% of people with learning difficulties in hospital and 5.3% of those in the community present with dysphagia 161 and between 48-100% of patients with Motor Neurone Disease (MND) 203 . However, there is considerable variation in prevalences cited, probably due to variation in the timing and completeness of assessments (e.g. in stroke the incidence of presentation with aspiration risk is 51% on admission, 27% at day 7, 6.8% at 6 months, and 2.3% after 6 months) 337 .

Nutrition support in adults: full guideline DRAFT (August 2005) Page 155 of 262

8.11.3 Identifying patients with dysphagia

Patients with dysphagia may present with a range of symptoms which can be divided into obvious and less obvious indicators (Table 19)

Patients with any of the obvious or less obvious indicators for dysphagia should be referred for assessment by healthcare professionals with specialist training in diagnosis, assessment and management of swallowing disorders. A variety of skills is needed including those of speech and language therapists, gastroenterologists, radiologists and specialist nurses. Healthcare professionals should be aware that patients with acute cerebral conditions, degenerative disorders, trauma, disease, or who have undergone surgery or radiotherapy to the upper aero-digestive tract, are at high risk of developing dysphagia.

Table 19: Obvious and less obvious indicators for dysphagia

Obvious Indicators	Less Obvious Indicators
Patient reports difficulty and/ or painful chewing and/ or swallowing.	Change in respiration pattern
Regurgitation of undigested food stuffs	Unexplained temperature spikes
Difficulty controlling food and/ or liquid in the mouth	Wet voice quality
Drooling	Tongue fasciculation (may be indicative of motor neurone disease)
Hoarse voice	Xerostomia
Coughing and/ or choking before, during, or after swallowing	Heartburn
Globus sensation	Change in eating – for example, eating slowly or avoiding social occasions
Nasal regurgitation	Frequent throat clearing
Feeling of obstruction	Recurrent chest infections
Unexplained/ involuntary weight loss	Atypical chest pain

8.11.4 Nutritional intervention strategies

There are a number of possible treatment strategies that may help to maintain or improve the nutritional status of patients with oro-pharyngeal dysphagia. These include modification of the consistency, temperature and/or taste of liquids and food. Factors to be considered before any modification is

Nutrition support in adults: full guideline DRAFT (August 2005) Page 156 of 262

undertaken are listed in table 2 but more detailed guidance can be found in specialist documents (e.g. National descriptors for Texture Modification in Adults, 2002⁴⁴) In some situations, however, modification of texture and consistency may compromise hydration status, nutritional intake, and swallowing safety\efficiency for patients³⁷⁸ and so help from appropriately trained healthcare professionals should always be sought and all oral and nonoral options must be considered¹¹¹.

8.11.5 Methods

We searched for systematic reviews and RCTs investigating either the effectiveness of modified foods and fluids or the use of and enteral tube feeding in dysphagic patients. No studies or systematic reviews were found, probably because RCTS are not feasible in this patient group. The GDG therefore appointed a sub-group of experts to develop our recommendations which were ratified by the whole GDG through informal consensus.

8.11.6 Rationale for Recommendations

Due to the complex nature of dysphagia and the range of its presentations our recommendations offer a framework upon which to make decisions which is based on individual patients' symptoms rather than specific diagnoses. The recommendations must take into account the appropriateness of intervention in individual cases and all ethical/legal issues (section 3) and decisions should always involve the patient, family and clinical teams. Dysphagia specialists should advise the clinical teams.

8.12 Recommendations

8.12.1.1 Patients with any of the obvious or less obvious indicators for dysphagia (Table 20) should be referred to healthcare professionals with specialist training in the diagnosis, assessment and management of swallowing disorders for example speech and language therapists, gastroenterologists, radiologists, neurologists, specialist nurses. [D(GPP)]

Table 20: Obvious and less obvious indicators for dysphagia

Obvious indicators	Less obvious indicators
Patient reports difficulty and/ or painful chewing and/ or swallowing.	Change in respiration pattern

Nutrition support in adults: full guideline DRAFT (August 2005) Page 157 of 262

Regurgitation of undigested food stuffs	Unexplained temperature spikes
Difficulty controlling food and/ or liquid in the mouth	Wet voice quality
Drooling	Tongue fasciculation (may be indicative of motor neurone disease)
Hoarse voice	Xerostomia
Coughing and/ or choking before, during, or after swallowing	Heartburn
Globus sensation	Change in eating – for example, eating slowly or avoiding social occasions
Nasal regurgitation	Frequent throat clearing
Feeling of obstruction	Recurrent chest infections
Unexplained/ involuntary weight loss	Atypical chest pain

- 8.12.1.2 Healthcare professionals should recognise that patients with acute and chronic neurological conditions and those who have undergone surgery or radiotherapy to the upper aero-digestive tract are at high risk of developing dysphagia. [D(GPP)]
- 8.12.1.3 When managing patients with dysphagia, healthcare professionals with relevant competencies in swallowing assessment/ management should consider:
 - risk/ benefits of the feeding options for each individual (oral for example modified consistency and or enteral nutrition support)
 - factors listed in Table 21. [D(GPP)]

Table 21: Factors to be considered before any modification on nutrition and hydration methods

Recurrent chest infections	
Mobility	

Nutrition support in adults: full guideline DRAFT (August 2005) Page 158 of 262

Dependency on others for assistance to eat

Perceived palatability and appearance of food/drink for the patient

Level of alertness

Compromised physiology

poor oral hygiene

Compromised medical status

Metabolic and nutritional requirements

Vulnerability (for example immuno- compromised)

Co-morbidities

- 8.12.1.4 For patients with dysphagia, healthcare professionals with relevant experience in swallowing problems and drug administration should perform a drug review to ascertain if the current drug formulation, route and timing of administration remain the most appropriate and without contraindications for either the feeding regimen or drug therapy.[D(GPP)]
- 8.12.1.5 Healthcare professionals with the relevant competencies in swallow assessment/management should regularly monitor and reassess patients having modified diets until the patient is stabilised.[D (GPP)]

8.13 Research recommendations

8.13.1.1 What are the benefits of patients (in hospital or the community, including older people) identified as high risk of malnutrition by a screening tool such as 'MUST' being offered either oral sip feeds compared to a) dietary modification and or food fortification, or b) dietary modification and or food fortification and dietary counselling in terms of determining complications, survival, length of hospital stay, quality of life and cost effectiveness?

This is an essential recommendation for research since there is insufficient evidence on the benefits of intervention used for oral nutrition support in particular the benefits of often first line treatment e.g. food fortification and or dietary counselling. It is essential to know this so that the indications on who to treat can be further supported.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 159 of 262

8.13.1.2 What are the benefits to patients in hospital identified as at high risk of malnutrition by a screening tool such as 'MUST' being offered either a) complete oral sip feeds b) combined micro and macronutrient supplements or b) micronutrient supplementation alone compared to placebo in terms of survival, hospital admissions, quality of life and cost effectiveness?

This is an essential recommendation for research since there is insufficient evidence on the benefits of intervention using oral nutrition support and/or micronutrients but indications that such interventions might decrease complications, mortality and lengths of stay. Results will clarify indications on who to treat and the best means of doing so.

8.13.1.3 What are the benefits to patients in primary care identified as high risk of malnutrition by a screening tool such as 'MUST' being offered either oral sip feeds compared to being offered; a) combined micro and macronutrient supplement or b) micronutrient supplementation alone c) standard care (no specific dietary intervention) or d) placebo in terms of survival, hospital admissions, quality of life and cost effectiveness?

This is an essential recommendation for research since there is insufficient evidence on the benefits of intervention used for oral nutrition support. It is essential to know this so that the indications on who to treat can be further supported.

8.13.1.4 Further research is needed into whether thickened liquids or standard/ unthickend liquids improve low mood and reduce dehydration, mortality, the need for enteral feeding and the number of aspiration incidents in patients with oro-pharyngeal dysphagia (as assessed by a trained practitioner).

There is not enough/satisfactory research into whether thickened fluids used with patients with oro-pharyngeal dysphagia improves their swallow function/safety, and/or allows patients to receive adequate hydration. There are also cost implications this question.

8.13.1.5 Further research is needed into whether pureed food or standard/ soft food improves nutritional intake, the safety and efficiency of swallow, and the number of aspiration incidents in patients with oro-pharyngeal dysphagia (as assessed by a trained practitioner).

There is not enough/adequate research to make an informed decision about whether puree diets are either safe or offer adequate nutritional support for

Nutrition support in adults: full guideline DRAFT (August 2005) Page 160 of 262

patients with oro-pharyngeal dysphagia (these diets are often offered to patients with poor nutritional reserve initially, and a compromised swallow).	S

9 Enteral tube feeding

9.1 Introduction

For the purposes of these Guidelines, enteral tube feeding (ETF) refers to the delivery of a nutritionally complete feed (containing protein or amino acids, carbohydrate +/- fibre), fat, water, minerals and vitamins) directly into the gut via a tube. The tube is usually placed into the stomach, duodenum or jejunum via either the nose, mouth or the direct percutaneous route 1. ETF is not exclusive and can be used in combination with oral and/or parenteral nutrition. Patients receiving ETF should be reviewed regularly to enable re-instigation of oral nutrition when appropriate. Most enteral feeding tubes are introduced at the bedside but some are placed surgically, at endoscopy or using radiological techniques. Whenever possible the patient should be aware of why this form of nutritional support is necessary, how it will be given and for how long, and the potential risks involved.

Innumerable questions regarding best ETF practice could be asked but for these guidelines, reviews were restricted to studies providing potential guidance on the indications for ETF, studies on the benefits of ETF compared to oral or parenteral nutrition, and studies on some technical aspects of delivering enteral feeds. No studies on different types of enteral feed were reviewed.

¹ Enteral feeding tubes may also be used for the administration of drugs, frequently on an unlicensed basis. Information and choice on suitable drug preparations can be obtained from local pharmacy or Medicines Information Departments. Further information can also be obtained from 'Guidance in administering drugs via enteral feeding tubes' from www.bapen.org

9.2 General Indications for Enteral Tube Feeding

9.2.1 Introduction

Enteral tube feeding (ETF) is used to feed patients who cannot attain an adequate oral intake from food and/or oral nutritional supplements, or who cannot do so safely. The aim is to improve nutritional intake and so improve or maintain nutritional status. It is used most commonly in patients with dysphagia either because they cannot meet their nutritional needs despite supplements and/or modifications to food texture/consistency, or because they risk aspiration if they try to do so. The GI tract must be accessible and functioning sufficiently to absorb the feed administered. Common indications for ETF are listed in Table 22, although this is not necessarily an exhaustive list. If there are any contra-indications to ETF (e.g. inaccessible GI tract, severe malabsorption, excessive gastrointestinal losses), parenteral nutrition is likely to become the therapy of choice.

Table 22: Indications for enteral tube feeding

Indication for enteral tube feeding	Example
Unconscious patient	Head injury, ventilated patient
Neuromuscular swallowing disorder	Post-CVA, multiple sclerosis, motor neurone disease, Parkinson's disease
Physiological anorexia	Cancer, sepsis, liver disease, HIV
Upper GI obstruction	Oro-pharyngeal or oesophageal stricture or tumour
GI dysfunction or Malabsorption	Irritable bowel disease, reduced bowel length (although PN may be needed)
Increased nutritional requirements	Cystic fibrosis, renal disease
Psychological problems	Severe depression or anorexia nervosa
Specific treatment	Inflammatory bowel disease, for short term enteral access during surgery i.e. head and neck cancer,
Other situations	Learning disabilities

Nutrition support in adults: full guideline DRAFT (August 2005) Page 163 of 262

9.2.2 Relevant Studies

Most studies on indications for ETF (rather than timing, type of tube, type/amounts of nutrients etc) exclude all patients with the most common clinical indication for ETF (i.e. those with a functional GI tract but unsafe swallow, who would starve or require PN if ETF were not used). The findings from these studies do not therefore provide help with decision making for routine clinical practice. The recommendations were therefore derived using expert opinion.

9.3 Recommendations

9.3.1 Indications for enteral nutrition support

- 9.3.1.1 Healthcare professionals should consider enteral tube feeding in patients who have a functional, tube accessible gastrointestinal tract and who despite the use of oral interventions if appropriate, still have an inadequate or unsafe oral intake and are:
 - malnourished (BMI < 18.5 kg/m² and unintentional weight loss > 10% within the previous 3-6 months or BMI < 18.5 -20 kg/m² and unintentional weight loss > 5% within the previous 3-6 months), and /or
 - at risk of malnutrition (eaten very little for > 5 days and or unlikely to eat more than very little amounts for the next 5 days). [D (GPP)]

9.4 Enteral tube feeding versus standard care

9.4.1 Introduction

Some patients are put at potential risk of malnutrition (or worsening of preexisting malnutrition) through a limitation of oral intake or absorptive capabilities from effects of their disease or direct and indirect consequences of surgery (e.g. nausea or ileus and/or clinical practice of restricting post surgical oral intake). If this limitation is severe and long-lasting, nutrition support using ETF or PN will be needed but ETF could also be beneficial for patients who are likely to have limited intake for only a few days (as in most post-operative patients), especially if they already malnourished. However, the benefits from using ETF in this elective, supplementary role is uncertain and it is possible that the risks might outweigh any clinical benefits. Two reviews were therefore conducted to identify:

Nutrition support in adults: full guideline DRAFT (August 2005) Page 164 of 262

- RCTs comparing patients who received ETF (with or without oral intake) vs patients receiving standard care (e.g. normal hospital diet and/or oral nutrition supplements) and
- RCTs that included patients receiving elective early post-operative ETF vs. no early post-operative nutrition (i.e. nil by mouth post-surgical dietary care with simple IV fluids until clinical signs of returning GI function).

9.4.2 Studies of ETF vs standard care

The review conducted identified 10 RCTs^{20,53,147,188,238,323,326,347,348,368} (Table 45). Four of these compared the effect of patients receiving 12 to 24 hours of nasogastric tube feeding plus continued normal hospital diet with patients receiving a standard hospital diet only ^{147,238,347,348}. Two studies compared nasogastric/nasoduodenal feeding with standard hospital diet 53,188. One study compared nasogastric feeding with standard hospital diet plus ad lib snacks ²⁰, while another had two intervention arms in which patients received a nasogastric feed with amino acids alone or a nasogastric feed containing amino acids plus carbohydrates ²²⁸. The control group continued on a normal hospital diet. A further study compared oesophagostomy tube feeding with a clear liquid diet, advancing to a normal diet as tolerated 323 and one investigated the benefits of pre-operative ETF (nasogastric tube feeding) compared with routine hospital diet ³²⁶. The final study examined the effect of perioperative nutrition in malnourished head and neck cancer patients ³⁶⁸ using three intervention arms: one group received no preoperative and standard postoperative ETF; another group received standard preoperative and postoperative ETF; and the third group received arginine supplemented preoperative and postoperative tube feeding.

The patients included in the studies were orthopaedic hip fracture patients (four studies covering 337 patients)^{20,147,347,348}, people who were generally malnourished (one study covering 86 patients)²³⁸, malnourished surgical patients (one study covering 110 patients) ³²⁶, total laryngectomy patients (one study covering 67 patients)³²³, malnourished patients undergoing surgery because of a head and neck malignancy (one study covering 49 patients) ³⁶⁸ and patients with alcoholic liver disease (two studies covering 66 patients)^{53,188}.

9.4.3 Clinical evidence ETF vs standard care

The main outcomes reported were nutritional intake achieved, changes in nutritional status, mortality, length of stay and complications associated with tube feeding (e.g. tolerance of the feeding tube).

The difference in nutritional intake (usually reported as energy and/or protein intake) between the enterally tube fed patients and those receiving standard care was reported in six studies^{53,147,188,238,347,348}. In all six studies, the enterally fed group achieved a significantly greater nutritional intake (range p<0.0001 to 0.012).

Nutrition support in adults: full guideline DRAFT (August 2005) Page 165 of 262

Five studies reported changes in measures of nutritional status 20,188,238,326,368 with three showing improvement 20,238,326 (range p=0.001 to p=0.05) while two showed no differences 188,368 .

Mortality was reported in 8 studies 20,53,147,188,326,347,348,368 . Four showed no differences between groups 20,347,348,368 but one 53 did show significantly lower mortality in the ETF group (p=0.02) and two further studies reported lower mortalities but with no significance values given 188,326 . One study, 147 noted a higher mortality rate for the patients who were tube fed but again no p-value was reported.

There were no significant differences in post-operative complications reported in four studies ^{323,347,348,368}; nor in the incidence of pressure sores in one study ¹⁴⁷; diarrhoea in one study ¹⁸⁸, or infection rates in one study ⁵³. In one study ³²⁶ the incidence of wound infection, nausea and vomiting were lower in the ETF group although no p-value was reported.

Five studies reported that ETF had no influence on length of hospital stay ^{188,323,347,348,368}; although in one study ²⁰, median time to independent mobility was lower in the ETF group (p 0.02 -0.04).

Three studies^{20,238,326} provided information on patient's tolerance of ETF but no p-values were reported. In two studies 22%²⁰ and 30%²³⁸ of study participants experienced problems tolerating the nasogastric tube. In the third study ³²⁶ 7 out of 67 patients receiving ETF (10.5%) needed it to be discontinued due to uncontrollable diarrhoea, vomiting or severe aversion to the smell and taste of the feed.

9.4.4 Cost-effectiveness evidence ETF vs standard care

Four studies were found that reported a cost comparison^{105,220,244,265}: two RCTs, one retrospective cohort study and a study that constructed a simple model on the basis of two small trials (Table 60).

One RCT²²⁰ evaluated insertion of double-lumen gastrojejunostomy tube compared with routine care by the surgeon after pancreatico-duodenectomy. Half the patients in the routine care arm received PN; and the other group probably received NG feeding (but the route of feeding was unclear). The study found significant reductions in gastro-paresis and in costs. The second RCT¹⁰⁵ compared early nasogastric enteral feeding with early oral feeding after colorectal resection in cancer patients. They found that early oral intervention was safe but there were no cost savings or improvements in clinical outcomes.

The aim of the retrospective study 244 was to test whether there were cost savings in using tube-feeding rather than a carer manually feeding the patient (which requires expensive staff time and risks causing aspiration) for patients with advanced dementia. The results showed that the total costs were higher for the patients with feeding tubes compared with those without tubes (£5,600 vs. £3,100, p=0.04). The difference was due to tube feeding placement cost

Nutrition support in adults: full guideline DRAFT (August 2005) Page 166 of 262

and hospital costs arising from complications directly related to tube feeding. However, the sample size of this study was small (11 patients in each group) and potentially biased since it was a convenience sample. Costing was also made using Medicaid and Medicare reimbursement rates, which may not be applicable to the UK NHS setting.

The fourth cost-effectiveness study evaluated the cost of preoperative enteral nutrition ²⁶⁵. ETF (10-21 days) was compared with no ETF. The study was a sensitivity analysis based on the two small trials with the largest reduction in complication rate. Incremental cost per complication averted was between £9,000 and £94,500 with hospital preoperative ETF, depending on the assumptions made. However, they found that home preoperative ETF is more likely to be cost saving.

There were no economic studies evaluating pre and post-operative ETF.

9.4.5 Studies of early post-operative ETF vs. no early post-operative nutrition

We identified one systematic review²¹⁶ that looked at early post-operative feeding (oral or enteral) versus post-operative 'nil by mouth'. There were 11 studies included in this review: 6 on early post-operative enteral feeding versus no early post-operative nutrition ^{27,59,153,309,318,374} and 5 on early post-operative oral feeding versus post-operative 'nil by mouth' ^{32,148,267,299,342} (included in the oral chapter 8). In this section we have included the six studies from the systematic review that looked at the effect of early post-operative ETF. In addition to the studies from this systematic review, we identified 17 further studies that looked at the effect of early post-operative ETF versus no early post-operative nutrition. The RCTs were analysed according to the type of surgical patients included in the studies.

Five studies included patients undergoing upper GI surgery ^{46,153,272,349,374} (Table 55). Three studies included patients undergoing lower GI surgery ^{225,309,318} (Table 55). Six studies included both upper and lower surgery ^{27,59,165,306,329,336} (Table 57). Three studies included patients undergoing hepatobiliary surgery ^{118,149,169} (Table 58). Six studies included acute trauma patients ^{66,99,183,226,248,290} (Table 45).

We extracted data on seven outcomes: vomiting, anastomotic dehiscence, pneumonia, death, intra-abdominal abscess, wound infection and hospital length of stay (LOS) where available. Where appropriate we pooled the data for these outcomes. We were unable to pool the data for LOS as the studies reported the data in different units and information needed to convert these units was not available.

9.4.6 Clinical evidence: early post-operative ETF vs. no early post-operative nutrition

Analyses for each of the surgical subgroups showed no statistically significant differences in any of the outcomes extracted. The P value from tests for heterogeneity was greater than 0.1 for all outcomes in all the groups.

We also conducted a combined analysis which included all the surgical studies (Appendix Eight: Meta-Analyses Enteral versus Nil Post Operative Nutrition Support). This also identified no statistically significant differences in any of the outcomes extracted which included vomiting, anastomotic dehiscence, pneumonia, intra-abdominal abscess, wound infection and mortality (Error! Reference source not found.). The data on lengths of hospital stay reported in fourteen studies 59,99,118,149,153,226,248,272,290,309,329,336,349,374 were not adequate to permit a

combined analysis but statistically significant differences were only detected in two studies with one showing that early feeding led to fewer days in hospital (p< 0.05)³⁰⁹ whilst the other showed it extended length of stay (p< 0.01)³³⁶

Table 23: Outcomes reported in studies of early enteral tube feeding

	No. patients (early feeding/late feeding)	RR (fixed) 95% CI
Vomiting (reported in four studies ^{27,153,183,226}	298/280	1.27 [0.92, 1.75]
P value from test for heterogeneity	P= 0.21	
Anastomotic dehiscence (reported in 10 studies ^{27,153,225,272,309,318,329,336,349,374}	257/264	0.60 [0.33, 1.10]
P value from test for heterogeneity	P= 0.79	
Pneumonia (reported in 9 studies ^{27,99,153,226,248,272,318,329,336}	355/361	0.76 [0.53, 1.08]
P value from test for heterogeneity	P= 0.36	
Death (reported in 10 studies ^{27,99,153,226,272,290,309,318,329,336}	368/375	0.72 [0.45, 1.15]
P value from test for heterogeneity	P=0.37	
Intra-abdominal abscess (reported in eight studies 27,99,153,248,309,318,329,336	250/256	0.60 [0.32, 1.14]
P value from test for heterogeneity	P=0.69	
Wound infection (reported in 12 studies 27,99,118,153,168,226,272,290,309,329,336,349	402/408	0.92 [0.68, 1.23]
P value from test for heterogeneity	P= 0.26	

Nutrition support in adults: full guideline DRAFT (August 2005) Page 168 of 262

9.4.7 Cost effectiveness evidence: early post-operative ETF vs. no early post-operative nutrition

We identified three cost-effectiveness analyses for ETF compared to nil nutrition post-operatively^{27,149,151}, although all three were small and potentially biased due to methodological weaknesses. Results were inconsistent although all reported a lower number of infections in the ETF groups compared to the nil groups. Estimated effects on cost were as follows:

- A non-randomised prospective US study of patients undergoing bowel resection¹⁵¹ showed a cost saving (the magnitude and statistical significance is unclear due to poor reporting) with jejunal feeding tube placed during surgery and feeding initiated within 12 hours of surgery compared with usual care (which was not detailed). The cost savings were due to a reduction in infections.
- A small Danish RCT²⁷ reported a non-significant difference in (median) cost of about £1,500 for a 4 day naso-duodenal intervention compared with placebo after major abdominal surgery. Mean costs, which are more relevant than median costs, were not reported.
- A small US RCT comparing naso-jejunal tube feeding from 12 hours after surgery with maintenance iv fluid after liver transplantation ¹⁴⁹ found a non-significant incremental cost of £1,200, despite a 50% reduction in infections. Control patients that were moved to tube feeding were excluded.

9.4.8 Conclusions

ETF in patients where there is some doubt about the adequacy of oral intake is effective in increasing nutritional intake over and above the intake observed with standard care and/or oral supplements and this usually leads to an improvement in nutritional status. However, this does not seem to produce consistent benefit in terms of length of stay or mortality rates and tube tolerance is sometimes a problem in these patients. The evidence of benefit related to complications, quality of life, costs and cost-effectiveness is very limited and ETF use in older people with dementia could be more expensive than oral feeding. The cost-effectiveness of preoperative enteral nutrition is unclear but might be improved if administered in the patients' home. However, oral nutrition support is likely to be more cost-effective, when this can be tolerated by the patient.

The studies on early post-operative ETF compared to standard practice of nil by mouth until return of GI function, do not support the use of early ETF although most did not focus on very malnourished patients who might benefit from this approach. There may be cost benefits associated with the use of post-operative jejunostomy feeding in some circumstances but more research is needed.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 169 of 262

The studies that examined elective ETF in malnourished patients prior to surgery suggest that they benefit in terms of nutritional status. However, much larger trials are needed to determine whether there are any benefits in lengths of hospital stay or mortality.

9.4.9 Rationale for recommendation(s)

Although ETF does increase nutritional intakes in patients the evidence that this benefits outcomes such as length of hospital stay or mortality is not clear.

9.5 Recommendations

- 9.5.1.1 Elective enteral tube feeding should not be given to patients unless it is either in the context of a clinical trial or they present with the indications for enteral feeding:
 - a functional, tube accessible gastrointestinal tract and an inadequate or unsafe oral intake and
 - malnourished (BMI < 18.5 kg/m² and unintentional weight loss > 10% within the previous 3-6 months or BMI < 18.5 -20 kg/m² and unintentional weight loss > 5% within the previous 3-6 months), and /or
 - at risk of malnutrition (eaten very little for > 5 days and or unlikely to eat more than very little amounts for the next 5 days). [A]
- 9.5.2 Enteral nutrition support for surgical patients
- 9.5.2.1 Malnourished surgical patients (BMI < 18.5 kg/m² and unintentional weight loss > 10% within the previous 3-6 months) who are due to undergo major abdominal procedures should be considered for pre-operative enteral tube feeding. [B]
- 9.5.2.2 General surgical patients who are expected to resume normal oral intake within 5 days should not have enteral tube feeding within 48 hours post-surgery outside the context of a clinical trial unless they have a functional, tube accessible gastrointestinal tract and an inadequate or unsafe oral intake and:

Nutrition support in adults: full guideline DRAFT (August 2005) Page 170 of 262

- malnourished (BMI < 18.5 kg/m² and unintentional weight loss >10% within the previous 3-6 months or BMI < 18.5 -20 kg/m² and unintentional weight loss > 5% within the previous 3-6 months), and /or
- at risk of malnutrition (eaten very little for > 5
 days and or unlikely to eat more than very little
 amounts for the next 5 days). [A]
- 9.5.2.3 Healthcare professionals should consider enteral tube feeding in post surgical patients who have a functional, tube accessible gastrointestinal tract and an inadequate or unsafe oral intake and:
 - malnourished (BMI < 18.5 kg/m² and unintentional weight loss > 10% within the previous 3-6 months or BMI < 18.5-20 kg/m² and unintentional weight loss > 5% within the previous 3-6 months), and/or
 - at risk of malnutrition (eaten very little for > 5 days and or unlikely to eat more than very little amounts for the next 5 days). [D(GPP)]

9.6 Enteral tube feeding routes of access

9.6.1 Introduction

Many types of enteral feeding tubes can be used to deliver nutrition into the stomach or upper small intestine. Choices depend on the proposed/expected period of feeding, clinical condition, and anatomy. Nasogastric (NG) tubes are used most frequently but others include nasoduodenal or nasojejunal tubes and gastrostomies or jejunostomies placed by endoscopic, radiological or surgical means.

9.6.1.1 Nasogastric tubes

NG tubes are used mainly for short-term support in patients who do not have problems such as vomiting, gastro-oesophageal reflux, poor gastric emptying, ileus or intestinal obstruction, although they can also be used for longer term support where other enteral access is not possible or carries a risk. NG tubes are potentially dangerous in patients with an unsafe swallow and those who need to be nursed prone or flat and a risk assessment should be carried out before placement. Fine bore $(5-8\ FrG)$ NG tubes should be used for ETF unless there is a need for repeated gastric aspiration. NG tubes should be placed by appropriately trained staff in hospital or the community.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 171 of 262

There is a small risk that NG tubes can be misplaced on insertion or move out of position at a later stage. Position of NG tubes should be verified on initial placement and before each use. Guidance from the National Patient Safety Agency ²⁵⁵ advocates aspiration of gastric contents and the use of pH graded indicator paper. It is recommended that a pH <5.5 is consistent with gastric placement. If aspirate cannot be obtained or the pH is >5.5 feeding should not commence. The NG tube should be left in place, the patient's position changed and the aspirate re-tested in one hour. The feed itself can increase the pH in the stomach, so aspiration should take place at least 1 hour after the feed has been stopped. Radiography (a chest x-ray) is not recommended routinely, but it is suggested that local policies be developed for high risk groups (e.g. intensive care or neonatal units) or for where an aspirate is not obtained. Radiography in these circumstances would depend on the clinical situation and failure of aspiration checks. N.B. Gastric antisecretory drugs can cause the gastric acid pH to be altered. Clinical judgement needs to be exercised in this situation together with local guidance.

9.6.1.2 Nasoduodenal and nasojejunal tubes

Nasoduodenal (ND) and nasojejunal (NJ) tubes are those placed into the gastrointestinal tract with the distal tip lying beyond the stomach in the duodenum or jejunum respectively. These tubes can be placed at the bedside or with endoscopic/radiological assistance but the position needs to be confirmed by abdominal X-ray after placement (unless placed under fluoroscopic guidance).

9.6.1.3 Gastrostomy and jejunostomy

Gastrostomy tubes pass through the abdominal wall directly into the stomach. They are usually used for patients who require medium to long-term feeding or where NG access is difficult. Gastrostomy tubes are usually placed endoscopically (Percutaneous Endoscopic Gastrostomy - PEG) but they can also be placed radiologically or surgically

Jejunostomy tubes pass through the abdominal wall into the jejunum and are usually placed surgically. However, many percutaneous jejunostomy tubes are placed endoscopically or radiologically via gastric puncture with an extension through the pylorus into the duodenum or jejunum (Percutaneous Endoscopic GastroJejunostomy PEGJ)

Gastrostomy feeding does not negate the risks associated with reflux and aspiration, although risks may be lower than with NG feeding. In patients at high risk of aspiration, jejunostomy tubes or PEGJ tubes should be considered since they probably do reduce aspiration risks.

9.6.2 Nasogastric (NG) versus nasoduodenal (ND) or nasojejunal (NJ) tubes

9.6.2.1 Introduction

Patients receiving ETF via the naso/oro gastric route can have problems tolerating their enteral feeding regimen due to gastro-oesophageal reflux or delayed gastric emptying. As a result, patients may experience reflux or vomiting which may cause aspiration pneumonia and also result in a reduced nutrient intake. When these problems occur despite drug intervention, nasoduodenal or nasojejunal feeding should be considered.

9.6.2.2 Studies on Nasogastric (NG) versus nasoduodenal (ND) or nasojejunal (NJ) tubes

We identified 14 RCTs (707 patients) that compared nasogastric feeding with nasoduodenal or nasojejunal feeding (Table 46) 34,77,78,97,137,154,158,187,200,209,245,246,256,346 Twelve studies included intensive care

^{34,77,78,97,137,154,158,187,200,209,245,246,256,346}. Twelve studies included intensive care patients ^{34,77,78,97,137,154,158,187,200,245,246,256}, one study malnourished neurological patients ³⁴⁶ and one study was in healthy people ²⁰⁹. In five of these studies the intervention and comparison arms used the naso/oro gastric route but did not specify the number of patients for each.

The main outcomes reported included aspiration 97,158,187,256, pneumonia 77,78,187,200,245,246,346, vomiting 78,245,246,256, diarrhoea 77,78,187,245,246 and percentage of target energy received 34,78,97,137,245. Other outcomes reported included: length of stay in ICU and in hospital, mortality and change in nutritional status.

9.6.2.3 Clinical evidence: Nasogastric (NG) versus nasoduodenal (ND) or nasojejunal (NJ) tubes

No significant differences were found for mortality, length of stay in intensive care or hospital, incidence of pneumonia, vomiting or diarrhoea. Two studies reported the mean weight change, one showed no significant difference ¹⁸⁷ while the other reported a significant weight gain for the nasogastric group ²⁶⁰. However, the weight change for the latter study was only recorded for 21 of the 38 patients entered into the study. Four out of the five studies reported no significant difference in the percent of prescribed calorie intake^{34,78,97,137} but one showed the nasojejunal patients achieving a significantly higher percent of their daily goal caloric intake than the nasogastric patients²⁴⁵.

9.6.2.4 Cost-effectiveness evidence Nasogastric (NG) versus nasoduodenal (ND) or nasojejunal (NJ) tubes

No study reporting cost or cost-effectiveness was found.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 173 of 262

9.6.2.5 Conclusions Nasogastric (NG) versus nasoduodenal (ND) or nasojejunal (NJ) tubes

Feeding patients with a nasogastric tube is usually as effective as a post-pyloric tube (nasoduodenal/nasojejunal) for delivering nutrients to patients (especially to patients on intensive care). The expected problems of gastric feeding in patients with gastro oesophageal reflux and delayed gastric emptying are not apparent in these studies.

It must be noted, however, that for ethical reasons randomised studies have not been performed in the patient groups usually considered for post pyloric feeding, although some information about the effectiveness and safety of post pyloric feeding in these patients may be gained from trials that compare post-pyloric feeding to parenteral nutrition.

9.6.2.6 Rationale for recommendation(s)

The gastric route is usually technically simpler and in most circumstances achieves similar nutrient delivery with similar risks. Clinical studies have failed to show any clear advantage in feeding post-pylorically.

9.7 Recommendations

- 9.7.1.1 General medical, surgical and intensive care patients should be fed via a tube into the stomach unless there is upper gut dysfunction. [A]
- 9.7.1.2 Patients with upper gut dysfunction (or an inaccessible upper GI tract) should be considered for post-pyloric (duodenal /jejunal) feeding.[D(GPP)]
- 9.7.2 Percutaneous Endoscopic Gastrostomy (PEG) versus Nasogastric (NG) Feeding

9.7.2.1 Introduction

For some patients with acute or chronic conditions requiring enteral feeding there is the option of feeding through a nasogastric tube or a gastrostomy (usually a PEG). Nasogastric tube feeding is usually successful but problems include dislodgement of the tube with the need for replacement which can be invasive and uncomfortable. For some patients the location and securing by tape of the nasogastric tube can also be irritating and may raise ethical issues

Nutrition support in adults: full guideline DRAFT (August 2005) Page 174 of 262

surrounding patient restraint. For some patients the tube itself may also cause discomfort in the back of the throat and occasionally swallowing problems

In contrast, a gastrostomy tube cannot be dislodged as easily and is more comfortable. However, there are potential difficulties and risks in placement; feed aspiration can still occur and there can be greater difficulties surrounding any decision to withdraw gastrostomy feeding compared to NG/NJ feeding (although from the ethical stand-point there is no difference between short and long-term tubes, nor between withdrawing feeding compared to not instigating it in the first place (section 4.3). Since gastrostomy feeding is increasingly considered for patients likely to require long-term ETF we undertook a review of studies comparing the two access techniques.

9.7.2.2 Studies considered for this review

Our review compared percutaneous endoscopic gastrostomy with nasogastric feeding (Table 47). Three small published RCTs ^{15,260,276} and a large multicentre randomised controlled trial ³⁵¹ met the inclusion criteria. One study looked at neurological, surgical and ear, nose and throat (ENT) patients ¹⁵, while the multi-centre study and the other two studies focused on stroke patients with accompanying dysphagia ^{260,276,351}.

The main outcomes reported in the studies were absolute risk of death and risk of death or poor outcome (using the Modified Rankin Scale - MRS), treatment failure, amount of feed received, weight change, mortality GI - haemorrhage and pressure sores. Other outcomes reported were: the time needed for tube insertion, length of hospital stay, convenience of care, quality of life, fixation of tube to patient and the incidence of aspiration or pneumonia.

9.7.2.3 Clinical evidence

There were some methodological problems with two of the smaller studies. One¹⁵ had more sick patients in the PEG group than did the NG group suggesting a possible allocation bias between groups, while in another ²⁷⁶ most of the patients in the NG arm crossed over to the PEG arm less than halfway through so that by day 28 of the study period, 18 out of the 19 patients had switched to PEG feeding.

Two studies^{260,276} reported significantly greater intake of prescribed feed and consequently significantly greater weight gain in PEG patients. In three studies^{15,260,276} there was a non-significant increase in treatment failure in the nasogastric group.

Mortality was reported for all of the trials. One of them ²⁷⁶ showed no difference between study groups, one showed significantly higher mortality in the nasogastric arm than the PEG arm ²⁶⁰ and two ^{15,351} reported higher mortality in the PEG group especially if inserted within the first two weeks following a stroke. In addition to the small increase in risk of death demonstrated by the large multi-centre randomised trial ³⁵¹, this study also

Nutrition support in adults: full guideline DRAFT (August 2005) Page 175 of 262

showed an increased risk of poor outcomes, although for secondary outcomes such as GI haemorrhaging, PEG patients fared better.

9.7.2.4 Cost-effectiveness evidence

We did not find any study reporting cost or cost-effectiveness.

9.7.2.5 Conclusions

The results of the largest multi-centre trial showed that significant benefit of a PEG over an NG tube is very unlikely and there is a significant mortality/ morbidity from PEG insertion. However, patients generally prefer a PEG to a NG tube for long term treatment as it less likely to displace, can remain unseen and is more comfortable. A PEG should therefore be considered after a patient has been shown to tolerate gastric feeding via a nasogastric tube for 2-4 weeks or in patients unable to tolerate a nasogastric tube despite the tube being well secured. After an acute neurological event such as a stroke, insertion of a PEG should be delayed until; the prognosis/QOL of the patient can be better predicted.

If the patient cannot decide for themselves, the patient's carer and an appropriate multidisciplinary health team should aim to act in the patient's best interest, deciding on the type and duration of treatment needed (see Section 4.3). A similar group should decide whether feeding should be stopped. In clinical practice it is more difficult to stop feeding through a PEG than though an NG tube although the same ethical/ moral considerations apply.

9.8 Recommendations

- 9.8.1.1 In the acute setting for example following stroke, patients unable to swallow safely or take sufficient energy and nutrients orally, should have an initial 2-4 week trial of nasogastric tube feeding. Healthcare professionals with the relevant competencies in nutrition support and swallow assessment/management should assess the prognosis and the appropriateness of future options for feeding. [A]
- 9.8.1.2 Gastrostomy feeding should be considered in patients likely to need long-term (4 weeks) enteral tube feeding. [D(GPP)]

Nutrition support in adults: full guideline DRAFT (August 2005) Page 176 of 262

9.9 Commencing enteral tube feeding after insertion of a percutaneous endoscopic gastrostomy

9.9.1 Introduction

Percutaneous endoscopic gastrostomy (PEG) is a relatively common procedure but it has a significant mortality/morbidity (NCEPOD report). The length of time one should wait before commencing feeding after insertion of the tube has been subject to controversy. Many clinicians believe that feeding should be delayed for at least 24 hours post-insertion but others use PEGs much earlier. Delays in starting PEG feeding may result in unnecessary prolongation of hospital stay and costs. A review was therefore performed to assess the safety of early PEG feeding (within four hours of installation) compared with delayed feeding (more than 24 hours after installation).

9.9.1.1 Studies considered for this review

Four published RCTs (including 290 patients) met the inclusion criteria^{47,64,233,341} (Table 50). The more recent studies were of higher methodological quality. The mean age of patients in all studies was more than 60 years.

9.9.2 Clinical evidence

No significant differences were reported for mortality (three studies) or complication rates (4 studies), although two studies reported more gastric distension which had resolved by day three after insertion.

9.9.2.1 Conclusion

Since none of the studies detected a significant difference or trend between the early or late groups it can be assumed that in an uncomplicated patient there is no reason to delay the start of feeding for more than 4 hours after insertion of a new PEG tube.

9.10 Recommendation

9.10.1.1 PEG tubes which have been placed without apparent complications can be used four hours after insertion. [A]

9.11 Types of enteral feeds

Most enteral feeds come as ready to use liquid microbial free preparations that contain energy, protein, vitamins, minerals, trace elements and fluid +/-

Nutrition support in adults: full guideline DRAFT (August 2005) Page 177 of 262

fibre. They are usually nutritionally complete within a specific volume. A ready to use standard feed will usually contain 1 kcal and 0.04g protein per ml but many other types of enteral feed preparations are available with differing energy: protein ratios and types of fat or protein.

The GDG did not undertake a formal review of the literature related to different types of enteral feed, however a summary is provided in Table XXX**

Table 24: Types of enteral feed

Type of feed	Usage
Standard 1kcal/ml – with or without fibre	Suitable for the majority of patients.
	Combination of soluble and insoluble
	fibre added for use in patients on long
	term feeding.
High energy 1.2-2.0 kcal/ml – with or	Used for patients on fluid restriction, or
without fibre	with increased nutritional requirements.
	Combination of soluble and insoluble
	fibre added for use in patients on long
	term feeding.
Low energy formulas	Contain 0.5 – 1 kcal/ml are complete for
	vitamins and minerals in a lower volume.
	Usually used for long term HETF
	patients with low energy requirements.
Elemental / Peptide feeds	Provide nitrogen in the form of free
	amino acids or peptides and may be
	used in the presence of severe
	maldigestion or malabsorption
Milk free feed	Standard 1kcal/ml feed with a soya
	based protein source
Low Sodium feeds	Standard feeds with the sodium content
	reduced to around 10-15 mmol/litre
Renal feeds	Contain reduced amounts of sodium,
	potassium and phosphate. The protein
	content is variable, providing similar or
	lower protein: calorie ratios compared to
	standard feeds. Energy dense versions
	for fluid restriction are available, with

Nutrition support in adults: full guideline DRAFT (August 2005) Page 178 of 262

	subtle modification of other nutrients e.g.
	higher water soluble vitamin content to
	allow for intradialytic losses
Respiratory feeds	Contain a higher percentage energy
	content from fat, which may reduce the
	amount of carbon dioxide produced from
	feed metabolism, and may be useful in
	patients with respiratory failure
Immune feeds	Contain variable amounts of specific
	amino acids or fats, together with altered
	levels of specific micronutrients which
	have an immune benefit attributed to
	them
Jejunostomy/Ileostomy feeds	These need to have an osomolality of
	300 mOsm/L and a sodium content of
	100 mmol/L.

9.12 Mode of delivering Enteral Tube Feeding

9.12.1 Bolus v continuous

Administering an enteral feed into the stomach rather than small intestine permits the use of hypertonic feeds, higher feeding rates and bolus feeding. Enteral feeding pumps are available to alter rates and in patients with doubtful GI motility, the stomach may be aspirated every 4 hours. If aspirates are high (e.g. exceed 200 – 300 mls depending upon local policy), the pump rate may be reduced and/or prokinetic drugs considered. This is usually recommended in the critical care setting though an aspirate of under 400 ml correlates poorly with the risk of aspiration or pneumonia²³⁵. Enteral feeding delivery is usually increased gradually over the first 24 hours (or slower in the very malnourished, see section 6.6).

When using NG feeding, enteral feeds can be delivered continuously over a variable number of hours or intermittently as boluses. There are potential advantages and disadvantages to both methods. We therefore identified studies that compared different modes of delivering enteral feeds. The RCTs found were categorised into continuous v bolus and continuous (24hr) v continuous (16-18hr). The rationale for non-continuous feeding is that it is more physiological and allows the stomach to completely empty and hence may reduce bacterial colonisation of the stomach which may be safer should an episode of aspiration occur.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 179 of 262

9.12.2 Studies on bolus vs continuous

Nine studies compared continuous v bolus regimens in neurological dysphagic patients, patients with injuries to the head, post-operative cancer patients, critically ill patients³²², older patients and healthy adults^{24,35,67,159,197,210,285,340} (Table 48). Most regimens described in the studies compared 24 hourly continuous feeding with 3-6 hour bolus feeds (250 - 500ml). The main outcomes reported were: abdominal discomfort, aspiration pneumonia, change in nutritional status, clogged tubes, nurse preference and biochemical changes.

9.12.3 Clinical evidence on bolus vs. continuous

For abdominal discomfort, aspiration pneumonia and nurse preference there was no evidence of benefit between the continuous and bolus fed group^{55,67,210,340.} However, in one study²⁸⁵ the continuous group were found to have a significant improvement in nutritional status (body weight and arm circumference) compared to the bolus fed group (p<0.01), while in another ⁶⁷ there was less clogging of nasogastric tubes with bolus feeding (p=0.01).

9.12.4 Continuous vs cycled continuous

Five studies compared continuous ETF (24hours) v cycled continuous ETF (16-18hours) with daily breaks (2 – 4 hours) or even intermittent ETF (e.g. 4-6 hours feeding then 2 hours rest). Studies were undertaken in critically ill, ventilated patients and post surgical patients 35,56,137,331,367. The main outcomes reported were; length of hospital stay, duration of enteral feeding, mortality, ventilator associated pneumonia, gastric pH and rate of gastric colonisation.

9.12.5 Clinical evidence: continuous vs cycled continuous

There were no significant differences between the 24 hour continuous feeding groups and the 16-18 hour feeding groups in either mortality or ventilator associated pneumonia; 35,137,367 , and rates of gastric colonisation and levels of gastric pH were also similar 35,331 In one study however 367 there was a significant reduction in hospital stay for a 16 hour fed group compared to a 24 hour continuous group (p=0.04).

9.12.6 Cost-effectiveness

No study reporting cost or cost-effectiveness was found.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 180 of 262

9.12.7 Conclusions

Bolus feeding is as effective as continuous (16-24 hours) feeding. Overall, however, the mode of feed delivery can be dictated by practical issues. For example, in patients who pull or dislodge nasogastric tubes regularly, bolus feeding can be used as a practical safe alternative to continuous feeding, while in intensive care the severity of illness and issues of gastric emptying, metabolic stability and control of glucose levels favour continuous feed administration.

9.13 Recommendations

- 9.13.1.1 For patients being fed into the stomach, either bolus or continuous methods should be considered, taking into account patient preference, convenience and drug administration. [B]
- 9.13.1.2 For patients in intensive care, nasogastric tube feeding should usually be delivered continuously over 16-24 hours daily. Where insulin administration is required it is safe and more practical to administer feeding continuously over 24 hours. [D(GPP)]

9.14 Motility Agents

9.14.1 The use of enteral motility agents

If patients with impaired gastrointestinal motility are fed enterally they may develop symptoms of abdominal distension vomiting, gastro oesophageal reflux, pulmonary aspiration, pneumonia or sepsis. They may also have large gastric aspirates and impaired fluid and nutritional intakes. The administration of prokinetic agents is used widely to help with these problems by promoting gastric emptying and improving intestinal motility. We conducted a review to identify studies comparing patients receiving enteral feeds with and without motility agents to see whether this approach is of benefit.

9.14.2 Studies on enteral motility agents in ETF

Ten studies were identified and were categorised into 5 groups according to the type of prokinetic agent administered; erythromycin, metaclopromide and or cisapride (Table 51 and Table 52). However, since cisapride has now been withdrawn, the studies using that drug are not reported here. Most of the studies included patients on intensive care in whom gastrointestinal feed intolerance is associated with a worse outcome and the development of aspiration pneumonia. However, this association is not considered to be

Nutrition support in adults: full guideline DRAFT (August 2005) Page 181 of 262

causal and the inclusion of these high risk patients in the studies makes interpretation difficult.

9.14.2.1 Erythromycin v placebo

5 studies were included in which erythromycin was administered intravenously either as a single dose ^{62,222} or every six hours for a minimum of five days^{30,297,387} (Table 50). Four studies included intensive care patients and one pancreatico-duodenectomy patients. In 2 studies patients were only recruited if they demonstrated intolerance to enteral feeding^{62,222}. The outcomes assessed included mortality, pneumonia, length of stay, complications, gastric emptying, residual gastric volume and feed tolerance.

One study³⁰ detected no significant differences in mortality, pneumonia or length of stay between the intervention and control group and two studies 30,387 reported similar complication rates. Gastric residual volumes were lower with erythromycin in one study²⁹⁷ but there were no differences reported in another 387 . Improved tolerance to enteral feeds in the intervention group, was observed in one study³⁰, p=0.001 during the first 48 hours of feeding but there were no significant differences by the end of the study period. In another study⁶² enteral feeding was more successful in the intervention group after 1hour, p=0.05 and 12 hours, p=0.01 of a single initiating dose of erythromycin but there were no significant differences 24 hours after the dose.

9.14.2.2 Metoclopramide v placebo

Three studies were included ^{184,222,386} one of which also had an additional arm for erythromycin²²² (Table 51). All the studies included intensive care patients who were tube fed, with one study ²²² only recruiting patients who were not tolerating enteral feeds. The metoclopramide was administered intravenously in one study¹⁸⁴ and via a naso/orogastric tube in the other two^{222,386}. No differences were found in intensive care mortality or nosocomial pneumonia, however, this could be due to the inadequate power of the studies. Gastric emptying rates were higher with metaclopramide (p=0.04) in one study ¹⁸⁴ but similar in another ²²².

9.14.2.3 Cost-effectiveness

Motility agents could be cost-effective, if they get the gut working without having to resort to parenteral nutrition in a substantial proportion of patients. No study reporting cost or cost-effectiveness was found.

9.14.2.4 Additional considerations

Prior to administration of motility agents healthcare professionals should review the patient's need for drugs with known effects in delayed gastric

Nutrition support in adults: full guideline DRAFT (August 2005) Page 182 of 262

emptying, such as opiates. A reduction in the dose of these drugs may itself improve intolerance to enteral feeds. Within intensive care elevating the head of the patient above 30 degrees is recommended at all times for ETF also turning on the right side may improve gastric emptying.

Patients with moderate to mild gastric motility problems should be offered oral/enteral/IV erythromycin unless there is a high probability of intolerance. Patients with severe gastric problems and those who do not respond to oral agents after 48 hours, should be offered IV motility agents and alternative methods of nutrition support such as post-pyloric ETF or PN may be needed.

9.14.2.5 Conclusions

Metaclopromide and erythromycin appear to be effective in improving gastric motility and may improve tolerance to enteral feeds for a limited period. However, the studies do not provide evidence of benefit for important long term clinical end points. In the intensive care population care should be taken to consider the risk of drug interactions and side-effects (e.g. dystonic reactions in older people with metoclopramide).

9.15 Recommendations

- 9.15.1.1 For patients in intensive care with delayed gastric emptying who are not tolerating enteral feeding a motility agent should be considered unless there is suspicion of gastrointestinal obstruction or a pharmacological cause. [A]
- 9.15.1.2 Patients in other acute care settings who have delayed gastric emptying and are not tolerating enteral feeding should also be offered a motility agent unless there is suspicion of gastrointestinal obstruction or a pharmacological cause. [D(GPP)]
- 9.15.1.3 If patients have delayed gastric emptying which severely limits feeding into the stomach, despite the use of motility agents, post-pyloric ETF and/or PN will need to be considered. [D(GPP)]

9.16 Complications of enteral tube feeding

9.16.1 Introduction

Although the GDG did not conduct a formal review of the literature, it is important to recognize that Enteral Tube feeding is associated with a number of complications. These are summarised in Table 25.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 183 of 262

Туре	Complication					
Insertion	Nasal damage, intra-cranial insertion,					
	pharyngeal/oesophageal pouch perforation, bronchial placement, variceal bleeding.					
	PEG/PEJ insertions – bleeding, intestinal/colonic perforation.					
Post insertion trauma	Discomfort, erosions, fistulae and strictures.					
Displacement	Tube falls out', bronchial administration of feed					
Reflux	Oesophagitis, aspiration					
GI intolerance	Nausea, bloating, pain, diarrhoea					
Metabolic	Refeeding syndrome, hyper-glycaemia, fluid overload, electrolyte disturbance.					

In view of the above, placement of all enteral tubes should only be undertaken by suitably trained individuals. The position of all NG tubes should be confirmed after placement and before each time of using aspiration and pH paper (with X-ray if necessary) as per the advice from the National Patient Safety Agency ²⁵⁵. This advice should be incorporated in local protocols which should also address the clinical criteria (e.g. unchanged length of tube, absence of any apparent ETF related problems) which will allow ETF to proceed when the ability to repeat checks of position are limited (aspiration and pH checking may be impossible or unhelpful due to gastric acid suppression and repeated X-rays before every feed are not practical). The initial placement of post-pyloric tubes requires X-ray with clinical checks before repeated use. All patients receiving ETF should be closely monitored. particularly early after instigation. Monitoring allows quantification of losses to enable daily estimation of replacement requirements, maintenance of metabolic balance, detection of toxicity/deficiency states, and early detection of complications (see Chapter 6).

9.17 Recommendations

- 9.17.1.1 Patients requiring enteral tube feeding should have the enteral feeding tube inserted by healthcare professionals with the relevant competencies in passing and managing enteral tubes (or by trainees under their direct supervision). [D(GPP)]
- 9.17.1.2 The position of all NG tubes should be confirmed after placement and before each time of use by aspiration and pH paper (with X-ray if necessary) as per the advice from the National Patient Safety Agency (NPSA 2005). Local protocols should address the clinical criteria (for example

Nutrition support in adults: full guideline DRAFT (August 2005) Page 184 of 262

unchanged length of tube, absence of any apparent ETF related complications) which permit ETF to proceed when the ability to make repeat checks of the tube position are limited by inability to aspirate the tube or the checking of pH is invalid because of gastric acid suppression. [D(GPP)]

9.17.1.3 The initial placement of post-pyloric tubes requires an abdominal X-ray with protocol agreed clinical checks before repeated use. [D(GPP)]

9.18 Research recommendations

9.18.1.1 What are the benefits to Intensive care patients likely to stay for >5 days, who are offered ETF only compared to ETF and PN if they fail to tolerate >60% of their target nutritional needs 2 days after starting ETF in terms of survival, complications and hospital costs?

This is an area of common practice but where the benefits of these interventions are unclear and poorly reported.

9.18.1.2 What are the benefits to malnourished surgical patients who have indications for ETF being offered ETF only compared to ETF and PN if they fail to tolerate >60% of their target nutritional needs two days after starting ETF in terms of survival, complications and hospital costs?

Currently patients who present with the indications for enteral feeding are being given PN early when it seems that they are not tolerating enough enteral feed to meet requirements, however the benefits of fairly early intervention with PN are unclear.

9.18.1.3 What are the benefits to Intensive care patients likely to stay for > 5 days who have contraindications to ETF being offered standard PN compared to either PN with additional glutamine, PN with additional selenium, or PN with additional glutamine and selenium in terms of survival, complications including catheter related infections and hospital costs? Although the use of novel substrates such as glutamine were not included in the scope of this guideline the GDG believed that over the last 10 years, two important nutritional observations from clinical trials are the improved survival rates of ICU patients administered these novel substrates via parenteral nutrition. However further RCT's are required to confirm this and

furthermore the benefits of novel substrates should perhaps be addressed when this guideline is updated.

Nutrition support in adults: full guideline DRAFT (August 2005) 186 of 262

10 Parenteral nutrition

10.1 Introduction

Parenteral nutrition (PN) refers to the administration of nutrients by the intravenous route. It is usually administered via a dedicated central or peripheral placed line and is generally used where there is:

a. failure of gut function (e.g. with obstruction, ileus, dysmotility, fistulae, surgical resection or severe malabsorption) to a degree that definitely prevents adequate gastrointestinal absorption of nutrients

and

 the consequent intestinal failure has either persisted for several days (e.g. >5) or is likely to persist for many days (e.g. 5 days) before significant improvement.

It may also be needed in patients with reasonable gut function who cannot eat when ETF is impossible or impractical for reasons of tube access.

PN is an invasive and relatively expensive form of nutrition support (equivalent to most 'new generation' IV antibiotics daily) and in inexperienced hands, can be associated with risks from line placement, line infections, thrombosis and metabolic disturbance. Careful consideration is therefore needed when deciding to who, when and how this form of nutrition support should be given. Whenever possible, patients should be aware of why this form of nutrition support is needed and its potential risks and benefits.

In view of the complex issues surrounding PN administration, we conducted a number of reviews in an attempt to provide evidence based guidance on the indications and benefits/risks of PN versus enteral, oral and no nutritional intervention. The reviews also aimed to provide guidance on some technical issues of delivering parenteral feeds. The GDG, however, were acutely aware of the limited relevance to normal clinical practice of studies examining indications for using PN for two important reasons:

- RCTs of PN vs alternative or no nutrition support have excluded on ethical grounds patients with a 'definite' indication for such feeding i.e. those with indications for nutrition support but who have intestinal failure to a degree prohibiting feeding by oral or enteral tube methods. Results may therefore be inapplicable to patients in whom PN is usually administered.
- most studies comparing PN to ETF have been undertaken in surgical and intensive care settings in patients who can only tolerate small amounts of enteral feed. The studies therefore not only compare different routes of nutrient provision but usually different amounts, with these severely ill patients getting levels of PN support that raise concerns amongst GDG members.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 187 of 262

The general recommendations for PN use are therefore based upon the principles elucidated in Chapter 2 of these guidelines, taking into account the results of the studies reviewed where possible.

10.2 PN versus no PN

10.2.1 Introduction

PN is generally started in order to prevent or minimize the adverse effects of malnutrition in patients who would otherwise have no significant nutritional intake. However, the length of time that a patient can tolerate complete or near complete starvation without harm is unknown and probably variable. In the well nourished it is likely to be many days before the outset of problems but even then, early 'elective' PN support may be beneficial. Indeed, preemptive PN support (e.g. PN for malnourished patients before surgery likely to cause temporary intestinal failure) might also be of value. We therefore conducted reviews of studies that randomized patients to the elective use of PN versus standard care of simple IV fluids with oral intake as tolerated or as dictated by routine clinical practice (e.g. restricted for a few days after surgery).

10.2.2 Studies considered for this review

One general review identified a systematic analysis ¹⁹⁹ that looked at the efficacy of PN compared with no nutritional support on clinically important parameters such as mortality, morbidity and length of hospitalisation (Table 62). This systematic review included randomised studies in patients with a variety of conditions such as pulmonary disease, liver disease, oncological, peri-operative, acute pancreatitis, Inflammatory Bowel Disease (IBD) and Acquired Immunodeficiency Syndrome (AIDS). In addition to the systematic review, four RCTs^{186,304,312,384} (Table 62) were identified: one ³⁰⁴ including 55 well-nourished, females with stage II-IV breast cancer undergoing high-dose chemotherapy and haematopoietic cell transplantation (HCT); one ³⁸⁴ including 122 patients following major thoracic-abdominal procedures; one ³¹² including 300 patients undergoing major general surgical procedures; and one ¹⁸⁶ including patients with gastric cancer undergoing total gastrectomy.

Independently from the above, a second review examined the elective use of PN around the time of surgery. These surgical patients could be subdivided into two further groups:

- a. Pre-operative supplementary PN versus no pre-operative supplementary nutrition: Two RCTs ^{29,335} (Table 80)studied the effect of pre-operative PN vs. no pre-operative nutrition support in malnourished GI surgical patients defined by weight loss (>10%) or a Prognostic Nutritional Index (PNI score >30%).
- b. *Pre and post-operative PN versus no supplementary peri-operative nutrition.* Seven RCT's^{42,100,101,250,354,356,373} (Table 80) examined various periods of pre- and post-operative PN versus no peri-operative nutrition

Nutrition support in adults: full guideline DRAFT (August 2005) Page 188 of 262

support in groups of surgical patients who were also malnourished at the time of surgery, most with gastro-intestinal malignancy.

10.2.3 Clinical evidence

10.2.3.1 Elective PN in all patients

The combined data from all patient groups in the Koretz systematic review showed no benefit for giving early PN compared to no early nutrition support, and in the group of oncology patients (including 19 trials of 1050 patients) PN use resulted in an increase in infectious complications, although there was no change in mortality. However, all results from this review have a major limitation in that the RCTs examined had all excluded severely malnourished patients from the studies. Furthermore, several of the studies came from a period when very high levels of PN support were given to patients, often resulting in significant hyperglycaemia which is known to increase risks. The findings are therefore inapplicable to usual UK PN practice.

In addition to the overall findings of the Koretz review, the studies within it and the other studies we identified showed little or no benefit from early elective use of PN in various sub groups. PN usage did improve nutritional status and/or nitrogen balance in some cases but clinical outcomes were no better in most instances and in some they were worse. For example, in two trials of patients with acute pancreatitis (subgroup analysis within the Koretz review) and one trial in gastric cancer resection patients ¹⁸⁶, PN resulted in significantly more complications and longer hospitalisation compared to standard therapy of IV fluids only.

10.3 Elective PN in surgical patients

The studies in surgical patients receiving only pre-operative PN ^{29,335} showed no significant differences in mortality or length of hospital stay between PN fed and control groups, although Bellatone reported increased septic complications in controls (p<0.05). However, studies in patients receiving both pre-and post-operative PN support did suggest benefits from this approach. Four studies ^{42,101,250,354} showed lower mortality in patients given PN compared to controls although only in one²⁵⁰ did this reach significance (p<0.05). The same four studies ^{42,101,250,354} also showed reduced complications in severely malnourished patients given peri-operative PN, although in only 2 studies ^{42,250} this was not significant. Two RCTs^{101,356} showed greater weight gain for patients receiving peri-operative nutrition with one ³⁵⁶ reaching significance (p<0.01). One study ³⁷³ also reported lower intra-abdominal abscess rates in malnourished PN supported patients versus malnourished controls (p<0.05) and another ³⁵⁴ found that whilst borderline or mildly malnourished patients given PN had increased rates of infections, severely malnourished patients had reduced non-infectious complications and no increase in infectious problems when given PN.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 189 of 262

The beneficial effects of peri-operative PN in malnourished individuals identified in the last mentioned study above ³⁵⁴ were only seen in patients who received > 7 days PN. This has led to a widespread belief that PN in normal clinical use (i.e. in those who really need it) is of no value unless given for >7 days. The GDG believe that this is not true. Patients with definite indications for PN support are not the same as those in the trial and within the first few days of PN administration to a malnourished patient with reversible gastro-intestinal failure, it is not uncommon to see rapid resolution of that failure as nutrient deficiencies and adverse changes in metabolism and physiology are corrected. The patient is then able to resume feeding by the oral or enteral route.

10.3.1 Cost-effectiveness evidence

Six cost studies and one cost-utility study were found (Table 80). Three were evaluating the preoperative use of parenteral nutrition and four its postoperative use.

A US cost analysis ⁸⁹ based on a relatively large well-conducted RCT³⁵⁴ compared pre and post-op PN (16 days) vs. no pre-op and post-op PN at clinician's discretion. The patients were malnourished (mainly men) and were undergoing laparotomy or thoracotomy. They found overall no difference in complications. For the intervention group, who were admitted early for pre-operative PN, there was a longer length of stay and an incremental cost of £1,900 per patient (significance not stated). However, for high-risk patients (identified using Subjective Global Assessment) there was a significant reduction in non-infectious complications with an associated cost-effectiveness of £4,300 per complication averted.

A smaller US RCT³⁵⁰ compared PN over 28 days with individualised oral, enteral parenteral nutrition support for patients in early recovery stage after bone marrow transplantation. PN patients had a longer length of stay, increased infections and increased complications, but the patients receiving PN were probably sicker than those in other groups. There was an incremental cost of £850 per patient. A Spanish study⁵⁴ based on a single cohort also estimated the incremental cost of PN in this patient group but compared it with a programme of intensive monitoring – it too found an incremental cost associated with the use of PN.

A Spanish RCT ⁵⁸ compared early PN over five days with IV fluids alone in patients undergoing total gastrectomy for gastric cancer. This reported substantial cost savings through the use of PN, although a Japanese RCT¹⁸⁶ in very similar patients, found that early oral intake was less costly than early PN.

A decision analysis³⁶⁵, again in a US context compared 10 days preoperative PN with no PN for patients undergoing surgery for gastrointestinal cancer. They assumed reductions in length of stay and complication rates and hence estimated an incremental cost saving of about £1000 per patient. In contrast, a Canadian decision analysis¹³² comparing PN (10 days) with both selective

Nutrition support in adults: full guideline DRAFT (August 2005) Page 190 of 262

PN and no PN in patients undergoing major upper GI surgery with and without cancer, suggested that both cancer and non-cancer groups would have increased life expectancy but at increased cost. The use of PN was relatively cost-effective (which they defined as <£30,000 per QALY gained) in the following groups:

- Non cancer high and moderate risk
- Localised stomach cancer high risk and moderate risk
- Regionalised stomach cancer high risk
- Localised oesophageal cancer high risk

Benefits of PN were small for patients with low life expectancy i.e. those with more advanced cancer. The fact that the US model assumed a greater reduction in major complications and a greater cost per complication was the reason why the US model suggested cost savings whilst the Canadian model did not (Error! Reference source not found.).

Table 26: Comparison of model assumptions

	US study	Goel ¹³²	Goel ¹³²
		Not cancer	Cancer
Patients with a major complication averted			
(a)	19%	2%	11%
Cost per major complication (b)	£26,000	£6,500	£6,500
			·
Cost savings per patient (a x b)	£5,000	£130	£740

10.3.2 Conclusions

Evidence from these reviews of elective PN use is difficult to interpret since, the use of PN in the majority of patients included in trials was out of line with routine UK clinical practice. The negative findings in the reviews therefore have little relevance to PN use in patients who have been or are likely to be unable to feed by other means. PN should be considered in all such patients, taking into account whether likely benefits outweigh potential risks. There is no evidence to support the idea that PN is unnecessary if, in such patients, it proves to be required for <7 days.

The evidence from the review does suggest that in certain groups elective, supplementary PN can reduce complications and mortality. For well nourished patients there is no evidence that pre or post-operative PN support is of

Nutrition support in adults: full guideline DRAFT (August 2005) Page 191 of 262

benefit but for severely malnourished GI and thoracic surgical patients preoperative/perioperative and postoperative PN there is evidence of benefit. Similarly, although there is no evidence that peri-operative PN is cost-effective in general (indeed if given to all general surgery patients there would probably be increased health service costs with no health gain), elective supplementary peri-operative PN is probably cost-effective in severely malnourished surgical patients.

10.4 Recommendations

- 10.4.1.1 Healthcare professionals should consider parenteral nutrition in patients who have a non-functional and/or inaccessible gastrointestinal tract such that they cannot be adequately fed by other means and are:
 - malnourished (BMI< 18.5 kg/m² and unintentional weight loss > 10% within the previous 3-6 months), or
 - at risk of malnutrition (eaten very little for > 5 days and/ or unlikely to eat more than very little amounts for the next 5 days). [D(GPP)]
- 10.4.1.2 The introduction of PN should be progressive, usually starting at a maximum of 50% of estimated needs with close monitoring. Parenteral nutrition can be withdrawn once patients are tolerating adequate nutrition orally or enterally and whose nutritional status is stable.

 Withdrawal should be planned and stepwise with a daily review of the patient's progress. [D(GPP)]
- 10.4.1.3 PN should be stopped when the patient is established on adequate oral and/ or enteral support. There is no minimum appropriate length of time for duration of PN and even stopping after only 1 or 2 days, should not infer that it was started unnecessarily. [D(GPP)]
- 10.4.1.4 For surgical patients who have limited gut function and who are already severely malnourished (i.e. BMI < 18.5 kg/m² and have unintentional weight loss > 10% within the previous 3 –6 months) elective supplementary pre- and/ or post-operative PN should be considered. [B]
- 10.4.1.5 Peri-operative supplementary parenteral nutrition should not be given to surgical patients who are neither severely

malnourished (BMI > 18.5, no history of weight loss > 10%) nor at particular risk of malnourishment (have had some food intake during last 5 days and are likely to have some food intake within 5 days). [B]

10.5 Parenteral versus enteral tube feeding

10.5.1 Introduction

As mentioned above, PN is usually reserved for those who need support but who have either a non-functioning or non-accessible GI tract. The choice of PN versus ETF is therefore not an issue and furthermore, there can be no means of conducting meaningful RCTs to examine this primary indication for PN. Nevertheless, many patients who are severely ill or who have undergone major surgery are unable for many days to meet much if any of their nutritional needs by mouth. They may therefore benefit from elective nutrition support given by enteral and/or parenteral routes. In general, ETF is preferred since it is perceived to be both cheaper and safer than PN. However, in some patients there is debate about whether gut function is adequate to permit ETF and in these cases, RCTs of PN versus ETF are possible. Nevertheless, a literature search identified only one RCT ³⁸³ addressing this point directly (also included in 2 systematic reviews ^{157,328}) and all other studies identified, examined the use of PN in patients whose GI tract was both accessible and functional to a degree that at least made ETF feasible. The use of PN in some patients in these other studies was therefore 'elective' since such patients would NOT usually receive PN as either a supplementary or sole source of nutrition until ETF had been shown to fail.

10.5.2 Studies considered for this review

In addition to the single study of ETF vs. PN in patients of uncertain GI function 383 , we identified many RCTs examining elective PN use (Table 63,Table 64,Table 65,Table 66,Table 67,Table 68,Table 69,Table 70,Table 71,Table 72,Table 73). These included 16 RCTs 16,38,41,43,134,139,167,170,249,270,300,311,321,325,389,390 and 3 systematic reviews 157,229,328 . The 3 systematic reviews and 14 of the RCTs 16,38,41,43,134,139,155,157,167,170,229,300,311,321,325,390 compared patients who received PN alone with patients on ETF alone(Table 63,Table 64,Table 65,Table 66,Table 67,Table 68,Table 69), while 3 RCTs compared the effects of PN alone vs. a combination of PN and ETF 249,270,389 (Table 71,Table 72,Table 73). One systematic review 157 (Table 70) compared ETF alone vs. a combination of ETF and PN.

Studies were grouped into disease populations and looked at patients with liver disease, Crohns disease, ulcerative colitis, acute pancreatitis, abdominal trauma, bone marrow transplant, cancer, the critically ill and surgical patients.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 193 of 262

10.14.1 Clinical evidence

In the single study that selected patients for ETF or PN on the grounds of likely gastrointestinal function ³⁸³, 237 patients were considered to have GI function adequate to try enteral tube feeding, 267 patients were felt to have intestinal failure to a degree that required parenteral nutrition, and 64 were considered to have marginal intestinal failure at a level which made the decision of whether to use ETF or PN genuinely equivocal. This last group was therefore randomised to either ETF or PN support. The study showed that in the elective, non randomised ETF and PN groups there was no difference in septic morbidity but a higher non-septic complication rate in the ETF group associated with a significant increase in mortality. A similar higher mortality was also seen in the group randomised to ETF within those with questionable GI function. ETF patient groups, both randomized and selected also had significantly lower nutritional intakes than those who were randomized or selected for PN.

The RCTs on elective PN use showed the following results in different patient groups.

10.14.1.3 Critically ill patients

Two systematic reviews ^{157,328} compared the effects of ETF v PN in the critically ill (Table 69). Heyland et al. ¹⁵⁷ showed a significant reduction in infectious complications for the enteral group. There was no significant difference in mortality between groups. However, the other systematic review ³²⁸ which had a few studies in common with Heyland et al. ¹⁵⁷ concluded that there was a greater risk of mortality in the patients receiving ETF although this was only evident in studies where initiation of ETF had been delayed.

10.14.1.4 Cancer patients

Many RCTs studied the use of supplementary PN vs. ETF in cancer patients, mostly in the peri-operative period. The six RCTs^{16,41,43,170,300,311} that we identified were classified into three groups according to the nutritional status of the patients included (Table 65).

Two studies 41,43 included GI cancer patients undergoing elective surgery with a weight loss \geq 10% of the usual body weight in the past 6 months. In one of these studies 41 , 158 patients received PN whilst 159 received ETF via a jejunostomy catheter or nasojejunal tube. Results showed that overall post-operative complications were significantly fewer for patients in the ETF group (p<0.005) 41 . However, in a sub-group of malnourished patients analyzed separately within the second study 43 (48 PN fed patients versus 43 ETF patients fed by jejunostomy or nasojejunal tube), no significant differences were observed. Adverse effects of specialised nutrition (abdominal distension, cramps, diarrhoea and vomiting) were reported in one study 41 with the ETF group showing a significantly higher incidence (p<0.0001). Both

Nutrition support in adults: full guideline DRAFT (August 2005) Page 194 of 262

studies reported no significant difference in hospital length of stay and mortality.

Three studies included malnourished and non-malnourished GI cancer patients undergoing surgery 16,43,300 , although only one 43 provided a definition of malnutrition - involuntary weight loss > 10% with respect to their usual body weight in the preceding 6 months). Patients were randomised to receive PN or ETF by jejunostomy catheter.

One study reported the number of patients achieving their nutritional goal within four days post-operatively⁴³. There was a significantly greater number of patients achieving this in the PN group than the ETF group (p<0.001). The same study⁴³ reported time to first flatus and bowel movement. The first flatus and bowel movement occurred earlier in the ETF group than the PN group (p=0.001). One study reported catheter-related complications and non-catheter related complications¹⁶. For catheter-related complications, there was no significant difference between the groups. However, the PN group had a significantly greater number of non-catheter related complications (p<0.05). These included life-threatening and non-life threatening complications. Length of hospital stay was reported in one study⁴³ and there was no significant difference between the groups. Mortality was reported in the three studies and there were no significant differences between the groups.

Two studies were included PN vs. ETF in cancer patients with exclusion of those who were severely malnourished ^{170,311}. One study¹⁷⁰ included patients undergoing total laryngectomy (n=48). Patients were randomised to receive PN (n=24) or ETF (n=24) by percutaneous endoscopic gastrostomy.

The ETF group had a significantly shorter hospital length of stay than the PN group (p< 0.05). There were no significant differences between the groups in wound infections and surgical complications. The other study³¹¹ included patients undergoing curative total gastrectomy (n= 29). Patients were randomised to receive PN (n=16) or ETF by nasojejunal tube (n=13). The study did not report the patients' nutritional status.

10.14.1.5 Pancreatitis

A systematic review of studies in patients with acute pancreatitis²²⁹ (Table 63) showed significant reductions in length of hospital stay, infections and the need for surgical interventions in the ETF group, although in individual studies on this topic it is unclear whether the advantage is due to the route of enteral tube feeding (nasojejunal) or due to the PN fed patients receiving high levels of support which made many of the PN fed patients hyperglycaemic.

10.14.1.6 Inflammatory bowel disease

Two studies on patients with Crohn's disease or ulcerative colitis ^{134,139} (Table 68)showed a significant reduction in post-operative infections and

Nutrition support in adults: full guideline DRAFT (August 2005) Page 195 of 262

complications from nutrition support in the ulcerative colitis population only. There were no other significant differences in these studies.

A few studies have reported changes in nitrogen balance with equivocal findings. A study of patients undergoing major GI surgery ³⁸ demonstrated significantly higher nitrogen balance for the ETF group, whereas a study in patients with abdominal trauma ³²¹ showed significantly higher nitrogen balance in the PN group. The study reported no significant differences in postoperative complications and hospital length of stay.

10.14.2 Clinical evidence PN versus (PN+ETF)

Three studies compared the effects of PN versus the combination of PN and ETF in different patient groups. One studying patients with pancreatitis ³⁸⁹ (Table 71)showed that those receiving combined PN and ETF had greater weight gains compared to those on PN alone. A similar study design, in patients having bone marrow transplantation²⁴⁹ (Table 72) showed that combination feeding reduced the days of diarrhoea but no other significant differences were seen. A study in patients who had abdominal surgery ²⁷⁰ (Table 73) demonstrated no differences between PN fed and combination PN and ETF fed patients.

10.14.3 Clinical evidence ETF versus (PN+ETF)

The one systematic review¹⁵⁷ comparing ETF to PN feeding with simultaneous commencement of ETF in critically ill patients contained data from 5 RCTs. No significant differences for any outcomes were demonstrated but all of the RCTS were small, low quality studies.

10.14.4 Cost-effectiveness evidence

Fifteen cost analyses were found – ten from the USA and one each from Canada, China, Finland, France and Italy (Table 83 and Table 83). One study compared ETF and PN with ETF and placebo and the rest compared total PN with ETF. The studies varied in terms of both setting and patient group: post-operative (10), acute pancreatitis (2), home (1), ICU (2). There were also varied study designs: RCT (10), retrospective cohort (4), meta-analysis (1). A major problem was that ten studies only included the cost of nutrition therapy and support, with only five studies including the costs of treating complications or extended hospitalisation. It is doubtful if even these included all the costs. Direct comparison of the cost savings was also complicated by the studies reporting in different currencies, in different years, in different health care systems and varied techniques were used to provide ETF. Nevertheless, it is very likely that ETF is cheaper than PN and Table 27 indicates the relative size of the hospital cost savings.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 196 of 262

Table 27: Cost savings attributable to enteral tube feeding compared with parenteral nutrition (RCT evidence)

				Reduction in	
Study	Year	Country	Patient group	cost	p-value
McClave	1997	USA	Pancreatitis	76.9%	0.001
Sand	1997	Finland	GI surgery (cancer)	76.5%	N/R
Bower	1986	USA	GI surgery	73.6%	0.001
Braga	2001	Italy	GI surgery (cancer)	72.5%	N/R
Adams	1986	USA	Laparotomy (trauma)	63.9%	N/R
Trice	1997	USA	Surgery (trauma)	62.9%	N/R
Hamaoui	1990	USA	Abdominal surgery	56.9%	0.001
Bauer	2000	France	ICU (not surgery)	48.0%	0.0001
Barzotti	1994	USA	Head injury	46.4%	N/R
Abou-Assi	2002	USA	Pancreatitis	23.4%	0.0004
Zhu	2003	China	GI surgery (cancer)	11.8%	< 0.05

N/R=not reported

10.14.5 Conclusions

Once again evidence from the enteral versus parenteral review is difficult to interpret since the use of PN in the majority of patients included in the trials was out of line with routine UK clinical practice. In the one study that is relevant ³⁸³, PN in expert hands was found to be as safe and probably safer than ETF, especially in patients with gastrointestinal function that is so marginal that the likelihood of tolerating ETF is uncertain (PN fed patients in this group had lower mortality and achieved higher feeding rates with lower non-septic complication rates than ETF patients).

The other studies, examining the 'elective' use of PN in circumstances when it was not absolutely necessary, are much less relevant but the findings do support current UK thinking. PN provides no significant advantages when ETF can be used and ETF patients tend to do better for outcomes such as weight gain, length of stay and infections. There are no definite advantages of combinations of feeding although studies are too small and underpowered to make firm conclusions. However, working from first principles, the GDG felt that the use of combination feeding makes sense. The arrival of nutrients in the GI tract is likely to stimulate GI function and immunity and will probably provide useful metabolic signalling to help with liver processing of nutrients. The GI tract should therefore be used to supply as much of the patient's nutrient needs tolerance and function allows, with PN used if necessary to provide the remainder.

The cost-effectiveness evidence varied with methods and reporting but also support the widely recognized notion that ETF is a cheaper option.

Page

10.15 Recommendations

10.16.1.1 In the presence of inadequate intestinal tolerance ETF should be supported with or replaced by PN which is equally safe if undertaken by experts. [B]

10.17 Venous access for PN

10.17.1 Introduction

All PN admixtures should be administered via dedicated intravenous catheters, through electronic volumetric pumps/controllers with occlusion and air in line alarms. Some authorities strongly endorse and recommend 1.2 micron filtration of PN admixtures containing a fat emulsion, and 0.2 micron filtration of other PN admixtures for long term patients and those with complex PN formulations. This issue was reviewed by the GDG but no papers where found which met the necessary criteria for review. Venous catheters for PN can be either peripherally or centrally inserted and GDG did investigate whether there are advantages of one route over the other. The decision to commence PN is never an emergency. Catheter insertion should be planned and performed using optimum aseptic precautions. When considering the need for intravenous access, the most appropriate site should be obtained by assessing the risk of infection against the risk of mechanical complications⁸¹.

10.17.1.1 Peripheral access

Full intravenous feeding using low osmolality fat emulsion based feeds can be given via a peripherally placed small catheter (22 – 23 Fr) with 48 hourly change of catheter site. However, fine bore, mid length catheters inserted peripherally but running up into larger veins, or peripherally inserted central catheters are more commonly used. All are alternatives to subclavian and jugular venous catheter placement⁸¹. Catheters can be put in on the ward but only when using a strict aseptic technique with adequate skin preparation e.g. 0.5% chlorhexidine in 70% methylated spirits), sterile field, and sterile gloves.

10.17.1.2 Indications for insertion of central venous (CV) lines

Central venous access

The insertion of CV lines for PN is associated with greater risks than peripheral feeding lines and should therefore be undertaken by experienced personnel, where other access is not available or feasible, or where multiple lumen CV lines are needed as part of the patient's clinical management. Where multiple lumen CV lines are used a lumen should be dedicated for the use of PN only. CV lines need to be considered in patients with no peripheral

Nutrition support in adults: full guideline DRAFT (August 2005) Page 198 of 262

access and in those requiring some specialised feeds. Indications for CV lines include:

- Patients identified as likely to require PN for a period of more than 2 weeks
- Patients already having suitable central venous access with a lumen which can be used solely for feeding (e.g. post-op from theatre)
- · Patients with no suitable veins for peripheral feeding
- Patients requiring specialised PN feeds that cannot be given into smaller peripheral veins (e.g. hypertonic feeds (>1300-1500 mosmol/l such as fat free or restricted volume solutions).

All central venous access devices should be inserted in optimum sterile conditions, using full aseptic conditions including sterile drapes, gown and gloves⁸¹.

10.17.2 Methodology

We conducted three reviews that looked at the effect of delivering PN via different venous lines:

- peripherally-inserted central catheters versus standard central venous catheters
- central versus peripheral venous catheters
- tunnelled versus non-tunnelled venous catheters

10.17.3 Peripherally- inserted central catheters (PICC) versus standard central venous catheters (CVC)

10.17.3.1 Introduction

PN solutions can be very hypertonic and some specialised formulations can only be infused into veins with high blood flow such as the superior vena cava. Central venous catheters (CVC) inserted into subclavian veins are commonly used for PN delivery but traumatic insertion problems are common and, as with all central lines, there are risks of sepsis and thrombosis ¹³⁸. Peripherally inserted central venous catheters (PICCs) can be used as an alternative to central venous catheterisation. PICCs are inserted into the basilic or cephalic veins and the tip is advanced into the superior vena cava. It has been suggested that the potential benefits of PICCs might include the reduction of complications (it has been suggested that PICCs are associated with a lower rate of infection compared with other non-tunnelled CVCs⁸¹) and perhaps cost savings, as PICCs can be inserted by non-physicians.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 199 of 262

A review was therefore conducted to identify studies which compared the efficacy of PN delivered through PICCs compared to CVCs. We identified only one RCT⁷² (Table 74).

10.17.3.2 Study considered for this review

The RCT included 102 hospitalised adult patients who required PN. The patients were all GI suffering from pancreatitis, post-operative ileus and primary abdominal malignancy among other diseases. Fifty-one patients were randomised to receive PN through a PICC (catheters were inserted into the basilic vein in most cases, other vessels used were the cephalic and median antecubital veins), while fifty-one had PN via a CVC (subclavian vein).

10.17.3.3 Clinical evidence

The use of both access techniques was often successful. The main outcome reported was the completion of therapy without complication. The CVC group had significantly higher percentage of patients that completed the therapy without complication than the PICC group (p<0.05). PICC lines were associated with greater number of difficult insertion attempts (required more than two but less than five needle sticks) (p<0.05), clinically-evident thrombophlebitis (p<0.01) and mal-position on insertion (p<0.05). There were significantly higher incidence of falsely suspected line infection in the CVC group (p<0.05). No significant difference was noted between the two groups in aborted insertion attempts, insertion time, pneumothorax, line occlusion, catheter infection, dislodgement or mortality.

10.17.3.4 Cost-effectiveness evidence

A US study⁷² compared the cost of CVC with the cost of PICC. It included hospital costs for inserting catheters and costs of diagnosing and treating complications arising from catheter insertion. It was expected that PICCs would have lower hospital costs, because nurses can insert them. However, the results of the analysis showed that PICCs were more costly by £39 per patient because PICC insertion and maintenance was more difficult and associated with higher rates of thrombophlebitis.

10.17.3.5 Conclusion

Findings from this study suggest that PICCs are associated with higher incidence of placement and mechanical complications than CVCs but nevertheless, their use is often successful. The relative costs of PICCs versus CVCs depends upon insertion success rates and rates of line complications. Studies were limited because changes in health status or quality of life were not measured or reported and results may not be transferable to specific patient subgroups.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 200 of 262

10.18 Recommendation

10.18.1.1 Patients having PN in hospital can have a peripherally inserted central catheter (PICC) as an alternative to a centrally placed central venous catheter. A free dedicated lumen in a multi-lumen centrally placed catheter can also be used in hospital PN. [B]

10.19 Peripheral PN versus central PN

10.19.1.1 Introduction

Many PN admixtures are very hypertonic and can only be administered into veins with high blood flow (central veins) since peripheral vein infusion is likely to result in thrombophlebitis, characterised by redness, a severe burning sensation and rapid thrombosis ¹³⁸. However, there are also complications associated with central venous PN particularly catheter insertion trauma, sepsis and thrombosis. An alternative to central PN is the infusion of peripheral parenteral nutrition using a fine-bore silicone catheter delivery system. Fat emulsion containing admixtures are often used in peripheral parenteral nutrition as these generally are not as hypertonic as admixtures using glucose alone as an energy source. Similarly fat emulsion based admixtures may have a pH better tolerated by small vessels. Additions of concentrated electrolytes can increase the tonicity and affect the pH of PN admixtures, careful attention to formulation is required for successful peripheral parenteral nutrition. Peripheral delivery systems may avoid some of the complications associated with central venous catheterisation and the fact that they are easier to place may provide overall cost savings¹⁹⁸.

A review was conducted to assess the potential benefits of peripheral PN compared with central PN. The review identified three RCTs^{71,198,231} (Table 75).

10.19.1.2 Studies considered for this review

One study¹⁹⁸ included adult surgical inpatients requiring PN. These were GI patients who underwent pancreatic, oesophageal and gastric surgery among other procedures. Patients who received PN in the intensive care unit and those who required multiple-lumen venous access were excluded. This exclusion affects a considerable number of potential PN patients.

Patients were randomised to receive peripheral PN (n=23) or central PN (n=23). Patients allocated to receive peripheral PN were given a fat emulsion containing PN admixture through a paediatric fine-bore silicone catheter inserted into the deep median basilic vein. The catheters were not tunnelled subcutaneously or sutured to the skin for fixation. Patients allocated to

Nutrition support in adults: full guideline DRAFT (August 2005) Page 201 of 262

receive central PN were given a glucose-based PN admixture through a single-lumen silicone catheter inserted into the subclavian vein.

The other two studies^{71,231} included gastroenterological patients requiring PN. The total number of patients included in these studies was 91: 42 received peripheral PN and 49 received central PN infused into the superior vena cava.

10.19.1.3 Clinical evidence

In one study¹⁹⁸, the patients allocated to receive peripheral PN had higher total patient treatment days (426 d compared to 322), spontaneous catheter retraction (3 cases vs. no cases in the central group) and cases of non-infective thrombophlebitis (4 vs. no cases). Patients allocated to receive central PN had higher insertion-site infection (2 vs. 1), problems with venous access (1 vs. 0) and catheter-related bacteraemia (3 vs. 0); however only one of the three cases of bacteraemia was thought to be due to a primary catheter infection. The main outcome reported was probability of a complication-free system function with time. There was no significant difference in the risk of overall complication. The incidence density of complication ratio was 0.66 (95% confidence interval 0.24-1.82).

Another study⁷¹ reported no significant differences between the groups regarding median duration of feeding. However, morbidity occurred more frequently in the group of patients allocated to receive PN (one catheter related sepsis and two pneumothoraces) than in the group allocated to receive peripheral PN (severe phlebitis was not encountered).

In the other study²³¹ 21 out of the 26 patients (80%) allocated to receive central PN completed their course of PN compared with 13 out of the 23 of the patients (56%) who received peripheral PN. Four patients who received peripheral PN were immediate failures because inadequate forearm veins and six were converted to central feeding as peripheral access became difficult. There were six line fevers (23%) and two pneumothoraces (7%) in the group of patients allocated to receive central PN (n=26) compared with 3 line fevers (13%) in the group of patients who received peripheral PN (n=23).

10.19.1.4 Cost effectiveness evidence

A UK study²³¹ compared the cost of central PN with the cost of peripheral PN. Their analysis was based on a prospective trial. The study group was all hospitalised patients who required PN. PN delivered peripherally was found to be cost-saving by £125 per patient compared with using the central route. This was because peripheral PN had a lower cost associated with insertion and fewer complications.

10.19.1.5 Conclusion

The studies reviewed were limited by their small sample size and because changes in health status or quality of life were not measured or reported. The overall results from this analysis suggest that there is little significant difference in the risk of complication between peripheral and central PN and only marginal savings in cost, with the analysis dependent on assumptions regarding successful insertion and rates of line complications. The formulation of the PN, in particular its volume, the use of fat emulsions and hypertonic concentrated electrolytes, will make a major difference to the complication rates and length of feeding achieved via the peripheral route, but it has not been possible to ascertain these factors from these studies. Similarly the use of drug therapy might ameliorate the thrombophlebitic complications and thombosis, but their inclusion may detrimentally affect the stability of the PN admixtures used and would add to cost. The results may not be generalisable to specific patient subgroups.

10.20 Recommendation

10.20.1.1 Administration of PN via a peripheral venous catheter can be considered for patients who are likely to require short term PN (< 14 days) who have no need for central access for other reasons. Attention to pH, tonicity and long term compatibility of the PN admixture should be considered to avoid stability or administration problems. [B]

10.20.2 PN via a tunnelled catheter versus PN via a non-tunnelled catheter

10.20.2.1 Introduction

A practice used widely in the 1980s to potentially reduce the risk of central catheter related infection was the use of tunnelled catheters. These catheters are inserted through the skin and advanced subcutaneously before the tip is inserted into the vein. It has been suggested that this technique reduces the risk of infection by increasing the distance between the potentially contaminated skin entry site and the venous entry site²⁹³. A tunnelled catheter also grants practical advantage to ambulant patients in that they allow easier dressing of the catheter entry site and provide more stability, reducing the risk of dislodgement¹²¹.

10.20.2.2 Studies considered for this review

A review was conducted to assess the benefits of PN through tunnelled catheters compared to non-tunnelled catheters (Table 76). One systematic review was identified that looked at the efficacy of tunnelling short-term central venous catheters to prevent catheter-related infections. While the inclusion criteria for this review were RCTs on adult or paediatric patients with catheters in place for an average of <30 days, only studies investigating adults were found. Catheters were placed using a subcutaneous tunnel. The review identified seven RCTs on adult patients ^{75,79,121,141,191,240,359} but two ^{75,359} were excluded from our analysis since the catheters were not placed for PN. Five studies were therefore included in tour assessment. The population of these studies were: surgical (n=150²⁴⁰ and n=38¹²¹), medical and surgical (n=83¹⁹¹) and cancer patients (n=74¹⁴¹ and n=109⁷⁹). In all the studies catheters were inserted into the subclavian vein.

The systematic review extracted data from each study for three outcomes: catheter colonisation, clinical sepsis and catheter-related bacteraemia. These data were used in the review (excluding data from the two studies mentioned above) to conduct a meta-analysis for these three outcomes.

10.20.2.3 Clinical evidence

10.20.2.3.1 Catheter colonisation

Four studies reported catheter colonisation^{79,141,191,240}. The pooled effect showed that tunnelling decreases the risk of infection (relative risk 0.46; 95% confidence interval 0.26- 0.80).

10.20.2.3.2 Catheter-related septicaemia:

Four studies reported catheter related sepsis^{79,121,141,240}. The overall result showed no significant difference between the groups (relative risk 0.63; 95% confidence interval 0.29-1.38).

10.20.2.3.3 Clinical sepsis

Two studies reported clinical sepsis^{121,240}. The overall result showed no significant difference between the groups (relative risk 1.25; 95% confidence interval 0.63-2.48).

10.20.2.4 Conclusion

Results from this analysis indicate that tunnelled catheters reduce the risk of catheter colonisation compared with non-tunnelled catheters. However, there are no significant differences in the risk of catheter related septicaemia and catheter sepsis. In long-term catheter use the tunnelling of a short segment of

Nutrition support in adults: full guideline DRAFT (August 2005) Page 204 of 262

line with a cuff that allows fibrosis to occur avoids external fixation and improves comfort.

10.21 Recommendation

- 10.21.1.1 Tunnelling subcutaneous catheters is recommended for long-term use (> 14 days). [D(GPP)]
- 10.21.1.2 Tunnelling catheters is not recommended for shortterm use (< 14 days). [B]

10.22 Tailored PN preparations versus standard PN preparations

10.22.1 Introduction

Patients requiring PN can either receive a standardised fixed feeding regimen, or a PN regimen compounded to meet individual nutritional, electrolyte and fluid requirements. Both methods should always have the addition of vitamins and trace elements and standardised PN may also need the addition of electrolytes and other nutrients to ensure it is complete and appropriate. Additions must be made under controlled pharmaceutical conditions and not at ward level. The stability of either means of providing PN needs to be known to avoid serious complications resulting from unstable PN formulations. One of the disadvantages of fixed regimens is that in order to achieve an adequate amino acid intake, patients may receive calories in excess of their requirements or metabolic capacity (excess energy intake may worsen respiratory difficulties and may lead to hyperglycaemia). Furthermore, standardised PN may not be appropriate for patients with special prescription needs such as the critically ill, those with organ failure, or those who have high electrolyte losses.

10.22.2 Studies included in this review

A review was performed to assess the efficacy of tailored (individualised) PN preparations compared with standard preparations (Table 77). Only one real RCT was identified³⁰¹. The study included twenty hospital inpatients requiring PN after abdominal surgery. The mean age of patients was 46 (3 patients where under 18: two 17 and one 15 years old). Patients were randomised to receive either a constant regimen containing 2600 calories per day and 15.55g Nitrogen per day (n=10) or a varied regimen with fixed calorie: Nitrogen ratio of 167:1 but with the calorie intake adjusted according to the previous days metabolic expenditure (n=10).

Nutrition support in adults: full guideline DRAFT (August 2005) Page 205 of 262

10.22.3 Clinical evidence

The study reported calorie and nitrogen intake, respiratory quotient, production of CO₂, body fat and body mass change. There were no significant differences in any of the outcomes.

10.22.4 Cost-effectiveness evidence

No studies were found that estimated the incremental cost or costeffectiveness of standard vs. tailored PN.

10.22.5 Conclusion

Findings from the included study suggest that there are no differences in outcome from either form of PN. However, the study is nowhere near large enough to identify possible clinical advantages of one or other approach, or to assist in identifying which patient groups are suitable for standardised as opposed to individualised PN regimens.

10.23 Recommendation

10.23.1.1 Patients prescribed standardised PN should have their nutritional requirements determined by healthcare professionals with the relevant competencies in the prescription of nutrition support before selection of a particular parenteral nutrition product. The addition of vitamins and trace elements is always required and occasionally additional electrolytes and other nutrient supplements. Additions must be made under appropriate pharmaceutically controlled environmental conditions before administration. [D (GPP)]

10.24 Delivery of PN cyclically versus continuously

10.24.1 Introduction

PN can be administered as continuous infusion (24 h) or cyclically (intermittently over shorter periods e.g.10-18 hours). For patients on long term PN cyclical administration allows patients periods of free movement, periods when the line is available for other therapeutic purposes, and potential metabolic benefits (a period of 'rest' for processing and assimilating nutrients). However, controversy persists as to the optimal method of PN administration and a review was therefore conducted to compare PN given cyclically with PN given continuously.

10.24.2 Studies considered for this review

The review conducted identified six RCTs 7,116,193,230,273,313 (Table 78).

Nutrition support in adults: full guideline DRAFT (August 2005) Page 206 of 262

10.24.3 Clinical evidence

In three studies patients received peripheral PN only^{193,230,273}. The main outcome reported was incidence of infusion phlebitis. The population included in these studies were patients requiring PN excluding those in whom central venous catheterisation was necessary. Continuous PN was delivered as a constant 24 h infusion and cyclic PN as a 12 h infusion with a 12 h break (Table 78).

In one study¹⁹³, patients on cyclical PN had significantly lower Daily Madox Score (Criteria used for assessing phlebitis. There are 6 score levels from 0 mild phlebitis to 5 severe phlebitis) (p< 0.001-0.05) and incidence of severe phlebitis (p<0.05) compared to patients on continuous PN with or without elective cannula change. In another study²³⁰, patients on cyclical PN with elective cannula change had significant lower phlebitis score compared to patients on cyclical PN with cannulas left in situ (p<0.05) and patients on continuous PN with fine-bore catheter left in situ (p<0.01). The same study showed significantly lower phlebitis score with 18 G Teflon cannulas (4-5 cm) comparing with 18-G Silastic (15 cm) cannulas in patients on cyclical PN when cannulas were left in situ (p<0.05). Another RCT²⁷³ reported significantly lower incidence of PN failures in patients on cyclical PN group with elective change of 18G Teflon cannulas compared with patients on continuous PN group with 23G Teflon cannulas (15 cm) left in situ (p<0.05). The same study recorded patients' signs of anxiety and depression. There were no significant differences between the groups for these two outcomes.

The other three studies included patients receiving central venous PN (one study did not report the infusion site) in post bone marrow transplant patients⁷, traumatised or infected patients on mechanical ventilation¹¹⁶ and post major surgery patients³¹³. Continuous PN was administered as a constant 24 hour infusion in all three studies but there were variations in the cyclic PN regimens. In one study⁷ the patients received 12 hour cyclical infusions, in another¹¹⁶ patients were infused PN for 12 hours and low energy glucose for the following 12 hours, and in the third study ³¹³ patients received bolus PN infusions for 1 hour followed by 2 hours without infusion for 12 hours.

The outcomes reported were also varied and included both clinical and metabolic parameters. The study in bone marrow transplant patients⁷ showed no significant differences in duration of PN, energy provided, plasma level of glucose and proteins, neutropenia time, change of weight, hepatic parameters, use of haematopoietic growth factors, incidence of hepatic veno-occlusive disease, incidence of catheter infection, or post-transplantation length of stay. The study on trauma or infected patients on mechanical ventilation¹¹⁶ showed no differences in clinical parameters including length of artificial ventilation, length of stay in ICU and in hospital mortality, but patients in the cyclic group had statistically significant higher: energy expenditure (p< 0.05), O₂ uptake (p< 0.05), CO₂ elimination (p< 0.05), and nutrient induced thermogenesis (p< 0.05). They also had lower positive energy balance (p<

Nutrition support in adults: full guideline DRAFT (August 2005) Page 207 of 262

0.05) and hence the authors concluded that continuous PN resulted in a more efficient utilisation of nutrients.

The study on major surgery patients 313 also showed slight metabolic advantages from continuous PN administration in terms of less negative "minimum" nitrogen balance (p< 0.01) and higher "maximum" nitrogen balance (p< 0.05).

10.24.4 Conclusions

The three studies comparing patients receiving peripheral PN continuously with those receiving peripheral PN cyclically showed that patients in the cyclical PN group with elective cannula change had lower rates of phlebitis compared with the continuous PN group but this may well reflect catheter management rather than PN administration times. The three studies of continuous versus cyclical centrally administered PN show that continuous PN leads to better nutrient balance than cyclical administration. None of the studies apply to longer term PN when cyclical administration becomes very important to help maintain patients' free movement and quality of life. There may also be metabolic advantages for longer term patients to have nutrient free 'breaks'.

10.25 Recommendations

- 10.25.1.1 Continuous administration of parenteral nutrition should be offered as the preferred method for infusion in most severely ill patients who require this method of nutrition support. [B]
- 10.25.1.2 Cyclical delivery of PN should be considered when using peripheral venous cannulae with planned routine catheter change. [B]
- 10.25.1.3 A gradual change from continuous to cyclical PN administration should be considered in patients requiring PN support for periods of more than 2 weeks. [D(GPP)]

10.26 Complications from PN

10.26.1 Introduction

The use of PN in inexperienced hands is associated with a number of potential risks. No formal literature reviews on these problems were undertaken but nevertheless, the GDG felt that brief recommendations based on expert opinion and previous published recommendations e.g. NICE Guidelines on Infection²⁵³ and The Department of Health⁸¹ could be made.

10.26.2 Complications related to intravenous access

Establishing and maintaining the intravenous catheters needed for PN support can lead to:

- Trauma on central line placement e.g. carotid puncture, pneomothorax
- Thrombophlebitis (particularly with peripheral venous access)
- Catheter occlusion and thromboembolism (including serious pulmonary embolism)
- Air embolism
- Catheter related sepsis

All the above can be reduced if lines for PN usage are inserted by suitably trained and experienced personnel using full aseptic technique. All catheters used for PN should then be monitored (see Chapter 6) and cared for by suitably trained and experienced individuals (see Chapter 10). All PN admixtures should be administered via dedicated intravenous catheters, through electronic volumetric pumps/controllers with occlusion and air in line alarms. Risks from catheter related sepsis can be reduced if all catheter and changes of PN bags are made using strict aseptic techniques (see NICE Guidelines on Infection control²⁵³). Hospitals should audit their rates of PN catheter related complications, especially catheter related sepsis.

10.26.3 Metabolic and fluid related complications

PN overrides many homeostatic mechanisms and presents a large osmolar load to the circulation. Rapid and serious derangement of biochemistry can therefore occur including the re-feeding syndrome (see Section 4.3). Hyperglycaemia, especially if a patient is diabetic or has stress induced insulin resistance is common and should generally be treated with insulin using a sliding scale. PN can also cause liver dysfunction although this is relatively uncommon and abnormalities seen in PN fed patients are more frequently due to other factors such as the presence of sepsis or side effects from other drugs. In view of the above, all PN fed patients should be monitored closely (see Chapter 6)

PN usage inevitably contributes a significant fluid load and it is essential that fluid balance is monitored careful in all patients receiving PN (see Chapter 6)

Nutrition support in adults: full guideline DRAFT (August 2005) Page 209 of 262

with careful allowance for fluid from all other sources e.g. oral, ETF, and other intravenous fluids and/or intravenous drugs.

10.27 Recommendations

10.27.1.1 Health care professionals competent in catheter placement should be responsible for placement of catheters and should be aware of the importance of monitoring and managing these safely. [D(GPP)]

10.28 Research recommendations

10.28.1.1 What are the benefits to patients who need short-term PN support being offered standard PN compared to either PN and minimal ETF (<25ml/hr) or PN with Glutamine and minimal ETF (<25ml/hr) in terms of survival, complications and hospital costs?

This is an area of untested yet advocated practice and requires a number or a large randomised control trial.

10.28.1.2 What are the benefits to patients who present with the indications for PN being fed only 50% of estimated protein and energy needs but with full micronutrient and electrolyte provision for first 5 days, followed by feeding at full needs compared to being fed 100% of estimated needs from the first day of feeding in terms of; metabolic complications, infection rates, length of PN feeding, mortality, length of hospital stay, and time to 'medically fit for discharge.

In the absence of evidence on the management of feeding very sick people with marked metabolic disturbance research in this area is essential to support/refute concerns about early feeding in sick people.

10.28.2 What are the benefits to patients who have indications for PN due to acute but reversible intestinal failure (e.g. prolonged ileus) being commenced on PN within 6 days of developing that failure compared to not commencing until 12 days after the development of that failure if the feeding problem has not resolved in terms of; metabolic complications, infection rates, duration of PN feeding, mortality, duration of hospital stay, time to 'medically fit for discharge.

A randomised control trial is required to further support the rationale for the timings proposed in the PN nutrition support recommendations.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 210 of 262

11 Nutrition Support at Home

11.1 Home enteral tube feeding

11.1.1 Introduction and prevalence

Long term home enteral tube feeding (HETF) is usually required in patients who are unlikely to be able to eat and drink adequately for an indefinite period. The commonest reasons for prolonged failure of oral intake are dysphagia caused by neurological problems (e.g. CVA, MND, MS) or partial intestinal failure that either prevents enough from being eaten or limits its absorption. Anorexia which can also cause prolonged failure of oral intake is a very uncommon indication for HETF.

In 2003 there were 16,890 adult HETF patients registered via the British Artificial Nutrition Survey with point prevalence of 359/million adult population in England and 386/million in Wales¹⁸⁰. This may be an underestimate since significant numbers of patients may not be registered. The indication for HETF was swallowing disorder in 70% of cases, more than two-thirds of which related to neurological problems especially CVA.

11.1.2 Organization of HETF

Patients requiring HETF will normally have enteral access and their ETF regimen established in hospital from where they will be discharged home. In most cases, gastrostomy or jejunostomy tube feeding is use for convenience although some prefer to self-intubate with an NG tube each time they need to feed or have long term NG tubes. The organisation required to successfully discharge and establish a patient on HETF needs a multidisciplinary team approach usually involving a doctor, ward nurse, nutrition nurse specialist, community nurse, speech and language therapist, GP and dietitian. Home care company nurses are also involved in many cases according to local policy and patient choice.

All patients should receive pre-discharge education on the management of their feeding regimen which would include self monitoring of their enteral feeding tube and how to deal with problems that might occur. Any community staff who involved in the care of the patient after discharge should also receive appropriate training. Patients will also require the organisation of supplies of feeds and ancillaries and regular support and monitoring.

11.1.3 Methods

No specific reviews were undertaken for HETF although we did identify information on patient's perspectives about this aspect of care (section 11.5). Nevertheless, the GDG recognised that several important recommendations could be made relating to patients needing long term nutrition support and

Nutrition support in adults: full guideline DRAFT (August 2005) Page 212 of 262

that some recommendations made elsewhere in the report had particular relevance in this context.

11.2 Recommendations

- 11.2.1.1 All patients on enteral tube feeding in the community should be supported by coordinated multidisciplinary care, which includes input from dietitians and district, care home or homecare company nurses and other allied healthcare professionals (for example speech and language therapists) as appropriate. Close liaison with patients, carers and GPs regarding diagnoses, arrangements and potential problems is essential. [D(GPP)]
- 11.2.1.2 Patients being discharged into the community on enteral tube feeding and/or their carers should receive an individualised care plan which includes a monitoring plan. Patients should also receive training and information from healthcare professionals with the relevant competencies in nutrition support (specialist nutrition nurses and dietitians) on:
 - the management of their enteral feeding delivery systems and their enteral feeding regime, outlining all procedures related to setting up feeds, using feed pumps, the likely risks and methods for troubleshooting common problems and be provided with an instruction manual (and visual aids where appropriate)
 - both routine and emergency telephone numbers to contact a healthcare professional who understands the needs and potential problems of patients on HETF
 - the arrangements for the delivery of equipment, ancillaries and feed with appropriate contact details for any homecare company involved. [D(GPP)]

11.3 Home parenteral nutrition

11.3.1 Introduction and prevalence

Prolonged PN is needed for patients with chronic intestinal failure; where oral or enteral feeding is either ineffective or unsafe. If the intestinal failure is considered to be irreversible within the foreseeable future the feasibility of home parenteral nutrition (HPN) should be considered.

In 2003 there were 517 adult HPN patients registered via the British Artificial Nutrition Survey with point prevalence of 9.5/million adult population for England and 4.5/million for Wales¹⁸⁰. However point prevalence varied between 0 and 21/million in different Strategic Health Authorities suggesting the application of widely varying selection criteria or standards of care.

Short bowel syndrome is the most common indication (54%) for HPN, followed by malabsorption 17%, fistula 8% and GI obstruction 6%. Crohns disease is the commonest underlying diagnosis in new registrations.

11.3.2 Organization of HPN

Patients requiring HPN will have their intravenous access (usually tunnelled catheter (see recommendation 9.6.3.5.1) and PN regimen established in hospital from where they will be discharged home. The organisation required to successfully discharge and establish a patient on HPN requires a multidisciplinary team approach with a minimum of; a gastroenterologist/GI surgeon, pharmacist, nutrition nurse specialist, dietitian, GP and community nurses. All patients should receive pre-discharge training in the management of their HPN and this education should extend to any community based staff who are to be involved in the care of the patient once discharged. It is essential that close support and monitoring by a hospital based team, experienced in looking after these complex patients, is continued after discharge for as long as the patient requires HPN.

Patients also need the organisation of all equipment, feed supplies and ancillaries on a regular basis. In many cases, home care companies (pharmaceutical) are contracted to provide for these needs and for some patients they also provide on-going specialist nursing care in the home or community setting.

11.3.3 Methods

No specific reviews were performed for HPN although we did identify information on the patient's perspectives about this aspect of care. Nevertheless, the GDG felt that important recommendations could be made for patients receiving this form of long term nutrition support.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 214 of 262

11.4 Recommendations

- 11.4.1.1 All patients having parenteral nutrition in the community should be supported by co-ordinated multidisciplinary care, which includes input from specialist nutrition nurses, dietitians and district and/or homecare company nurses. Close liaison with patients, carers and GPs regarding diagnoses, arrangements and potential problems is essential.[D(GPP)]
- 11.4.1.2 Patients being discharged into the community on parenteral nutrition and/or their carers should receive an individualised care plan which includes a monitoring plan. Patients should also receive training and information from healthcare professionals with the relevant competencies in nutrition support (specialist nutrition nurses, pharmacists and dietitians)on:
 - the management of their parenteral nutrition delivery systems and their feeding regime, outlining all procedures related to setting up feeds, using feed pumps, the likely risks and methods for troubleshooting common problems and be provided with an instruction manual (and visual aids where appropriate)
 - routine and emergency telephone numbers to contact a healthcare professional with the relevant competencies (nutrition nurse, pharmacist)
 - the arrangements for the delivery of equipment, ancillaries and feed with appropriate contact details for any homecare company involved [D(GPP)]

11.5 Working in partnership with patients, families and carers

Patients may use nutrition support in the long or short term and be based in hospital or the community (at home or in residential care homes). This section addresses general issues to facilitate working in partnership with patients (and their carers) who are using short and long term nutrition support.

11.5.1 Patients on short and long-term nutrition support

Suffering from malnutrition can be a distressing experience for both the patient and their family or carers. It is important that appropriate information and support for the patient and carer(s) is provided so that informed choices

Nutrition support in adults: full guideline DRAFT (August 2005) Page 215 of 262

can be made. Information should include diagnosis, treatment options according to clinical condition, side effects and sources of physical, psychological and social (such as disability benefits) support where appropriate. The format and language of the information provided should be tailored to the individual's situation.

When delivering information, consideration should be given as to whether short or long-term nutrition support is required, and the method to be used (enteral and/or parenteral), as this has very different implications for both patients and carers. Consideration should also be given to the patient's cognitive abilities, gender, physical needs, culture and stage of life of the individual. The patient should be given the recognition for their ability to self-care or in their ability as a carer when receiving nutritional support at home. Many patients who have received nutrition support for a long time and their carers will have invested a lot of time into the management of their nutrition support and will consequently have become very knowledgeable in the administration of nutrition support in addition to being able to recognise and respond to any changes in order to remain healthy and free from complications.

Checklists can be used to remind both healthcare professionals and patients about information that should be discussed during consultations.

Patients and/or carers should be involved in the decision-making process regarding the method(s) of feeding and any cultural and/or ethnic needs and/or preferences should be taken into account. Whenever possible patients and carers should be aware of why nutrition support is necessary, how it will be delivered and the effect it will have on the patient.

Once the patient has been diagnosed and is using nutrition support, it is likely that care from a range of different health care professionals will be needed depending on the different setting: hospital (emergency/inpatient) or the community i.e. patients own home or care home setting. It is very important that everyone providing care or treatment for patients using nutrition support is familiar with the management of the different forms of such support and is able to provide essential information. Patients should understand that ongoing monitoring may establish a need for changes in their nutritional support and clinical developments may lengthen or shorten the need for artificial nutrition.

11.5.1.1 Methods

We conducted a literature search to identify patients' and carers' views on nutrition support. The majority of the studies in the review focussed on patients using long-term ETF or HPN. These were qualitative studies (surveys, questionnaires and personal accounts). Below is a summary of the review.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 216 of 262

11.5.1.2 Findings from studies of patients using long-term nutrition support

A predominant feature in the literature was the need for counselling:

- Living with the reality of what it means not to eat was reported in five studies^{37,98,221,327,391}. Not being able to eat was a major adjustment for the patients. A survey conducted in the United States on patients receiving HPN ³²⁷ reported that patients felt hungry while receiving PN and those in whom eating was contra-indicated found it difficult to cope with the temptation not to do so. Patients also explained how this affected their social lives as they were reluctant to join social events^{37,221,302,327,391}. In one survey ²¹⁷ some carers of patients on HETF reported they found it uncomfortable to eat in the presence of the patient.
- <u>Feelings of guilt and low self-esteem:</u> this was reported in three studies^{37,221,327}. Patients found it difficult to accept the physical limitations of their body and body image^{37,302}. Patients also experienced guilt and personal responsibility in relation to their illness.
- How to cope with the reaction of friends or the community at large

"Probably the most difficult aspect of enteral feeding is the emotional side. Once again there was never any discussion with either medics or family as to how one coped with the reaction of friends or the community at large and this for patients is equally as important as the practical aspect." 221

"[....]When patients come home they will meet with differing reactions from others. They may be surprised to find that some former friends or acquaintances do not come to visit them, some will come with almost overwhelming sympathy, some will perform a very hurried visit, and there are the most wonderfully sensitive people who put a hand on one's arm and ask if there is anything they can do to help. Patients need to be aware of these varying reactions as soon as possible so they can be mentally prepared to deal with them." ²²¹

[....] "there was no discussion at all about the varying emotions that may be experienced and how to cope with perhaps anger and a feeling of isolation or being ostracized by society" 221

A need to talk to someone who is on ETF or PN: In two studies^{221,327} patients expressed the importance of sharing their experiences with someone who is also receiving nutrition support.

Nutrition support in adults: full guideline DRAFT (August 2005) Page 217 of 262

"My friends have been very helpful [..] but they really don't get what it is like to live TPN-dependent. I need to talk to other adults who have been through what I am going through." 327

- <u>Fear of death/fear of liver damage from prolonged PN</u>: this was reported in one survey conducted in the United States³²⁷. Patients expressed their fear of death from their underlying disease or the use of PN.
- <u>Disturbed sleeping patterns were reported in two studies</u>^{302,327}.

From the above accounts, it is clearly very important that healthcare professionals are fully familiar with all these issues when dealing with patients on long-term nutrition support. This is summarised in the following conclusion from a study on patients on HPN:

"Health professionals involved in the home care of this group of patients (or indeed considering the use of this therapy even on a short-term in-patient basis) need to recognise the impact that this therapy can have on the individual. An understanding of the life of the chronically ill patient in the community can assist healthcare practitioners to "...gauge the intended as well as unintended effects of clinical measures (GERHARDT1990)" 237

It is also important to involve patients in the decision-making process about methods of feeding. A study conducted in a single NHS trust area offering a community-based support advice service to patients choosing HETF ²¹⁷, looked at decision-making around this process. Patients and carers reported that decisions were varied depending on whether or not it had taken place at a time of medical emergency. For example, in a sudden deterioration in swallowing, patients and carers stated that the advice of professionals was taken without hesitation but, in general, patients appreciated having time to consider options and being able to decide for themselves.

"Patients and carers generally perceived professional advice as a recommendation rather than an option for them to consider. One person reported that his consent had been influenced by discussion with the dietitian who had left the decision more open.

- [...] Another patient reported that it would have helped to have some opportunity to see the tube before surgery.
- [...] A number of patients revealed their reluctance to commence tube feeding, and that the opinion and influence of their family were important factors in their weighing up of the decision, as well as professional advice."²¹⁷

Nutrition support in adults: full guideline DRAFT (August 2005) Page 218 of 262

A US study ³¹⁹ evaluated patient preference for ETF compared to PN. A written questionnaire was distributed to 101 hospitalised oncology patients and 98 outpatients without gastrointestinal illness who acted as controls. Responses were obtained from 197 patients. Results from the study revealed that most patients preferred PN to ETF. This preference was related to patient's perception of the comfort of these interventions.

Another important area is the information needs for patient and carers particularly at discharge. Two surveys in the UK including patients on HETF and HPN ^{60,286} revealed some areas of concern:

"21% of patients were not provided with an instruction manual to undertake procedures (e.g. connecting up) when first discharged. 14% were not issued with emergency telephone numbers. In the event of an emergency, patients were advised to contact their hospital (75%), the local hospital (16%), or the general practitioner (14%). Four patients were advised to contact a combination of these.

"[..] Overall impression of home nutrition services was assessed [..]. Just over half the respondents had no comment to make (51%). 22% had positive comments to make (e.g. 'fine', 'always satisfied', 'homecare company excellent', 'service very good', 'excellent local hospital service'. 18% had negative comments: 'total lack of support', 'a pain to get dry goods', 'communication poor at times', 'tied by delivery service', 'would prefer additives already mixed', 'homecare service omits items'."⁶⁰

An audit of adult patients on HETF in a region of Northern Ireland ⁹⁸ looked at whether patients and carers were satisfied with the training received to prepare for HETF.

"Patients and carers felt that more emphasis should have been placed on the causes of pump alarming, preventing leaks, how to run feed properly through the giving set, preventing and treating tube blockages, and on stoma care. Further training was received by five of the patients and carers at home (26%); 12 (35%) of those who had not received further training felt it would have been useful". 98

In three qualitative studies in the UK^{98,217,286} patients expressed their concerns about the lack of experience of health professionals with home nutrition support:

"Whilst 12 (63%) of the patients and carers at home expressed satisfaction with the level of support received since coming home, seven (36%) were not satisfied. The issues of concern included: not being weighed regularly, lack of district nurse experience with home enteral tube feeding, stoma care and lack of emotional support for not being able to eat" 98

"This rapid building of expertise enabled patients and carers to recognise the inexperience of some of the health professionals whom they encountered. [..] One patient commented that the community nurse was 'very nice but didn't seem to know as much as me'. Conversely, recognition of inexpert practice by a health professional was a matter of concern. Some distress was reported when health professionals did not meet carers' or patients' standards."²¹⁷

"We had a vast array of comments in relation to emergency visits with the common factor being that parenteral nutrition was not commonly known about and the methods for dealing with such patients and related issues was commonly only known by the patient themselves or their carers."²⁸⁶

One of the surveys mentioned above²⁸⁶, also looked at patients' and carers' opinion about accessibility to nutrition support services. The majority of respondents preferred to have access closer to home in preference to a remote centre.

11.6 Recommendations

- 11.6.1.1 Healthcare professionals should ensure that patients and/or carers of patients having enteral tube feeding or parenteral nutrition in the community:
 - are kept fully informed and have access to appropriate sources of information in formats, languages and ways that are suited to an individual's requirements. Consideration should be given to cognition, gender, physical needs, culture and stage of life of the individual.
 - have opportunity to discuss diagnosis, treatment options and relevant physical, psychological and social issues
 - are given contact details for relevant support groups, charities and voluntary organizations. [D(GPP)]

11.7 Research Recommendations

11.7.1.1 Do patients managed by specialised centres have a better outcome (mortality, morbidity, complications, QOL) than those managed by a local hospital?

- 11.7.1.2 What factors contribute to the different numbers and indications for HEN and HPN in different regions in the UK (and in different countries)?
- 11.7.1.3 What are the health economic implications (cost effectiveness) of HEN and HPN?
- 11.7.1.4 How are specific complications best treated (and avoided) in the community (e.g. tube / catheter blockage)?

12 Audit criteria

Criterion

There should be documentation that healthcare professionals in hospital and community settings have received training in nutrition support on:

- 1)the importance of nutrition (for patients)
- 2)the indications for nutrition support and its delivery (routes, mode of access, prescription)
- 3) when and where to seek expert advice on nutrition support

Exception

Healthcare professionals who are recognised experts in the field of nutrition support as recognised within the local clinical governance structure.

Definition of terms

This should take place at the start of their employment and thereafter biannually.

To determine risk of malnutrition:

hospital inpatients are screened on admission and this is repeated weekly

hospital outpatients are screened at their first clinic appointment and at subsequent appointments as clinically indicated.

A clear process for documenting the outcomes of screening (that is 'nutritional risk score') and the subsequent actions (that is 'nutritional care plan') taken if the patient is recognised as malnourished or at risk of malnutrition should be planned.

Hospital departments considered to have patients at low risk of undernutrition. They will have specifically opted out of screening having followed an explicit process to do so via the local clinical governance structure and involving experts in nutrition support.

Patients having palliative care.

A simple screening tool should be used that includes BMI (or other estimate for example mid arm circumference when weight cannot be measured), percentage weight loss, and considers the time over which nutrient intake has been reduced. (for example MUST).

To determine risk of malnutrition:

Residents or patients in care homes should be screened for the presence or risk of malnutrition on admission and whenever Subsequent screening of residents or patients in care homes where there is no clinical A simple screening tool should be used that includes BMI (or other estimate e.g. mid arm circumference when weight cannot be measured), percentage weight loss, and

Page

Nutrition support in adults: full guideline DRAFT (August 2005) 222 of 262

Criterion

there is clinical concern (for example patients with fragile skin, poor wound healing, apathy, wasted muscles, poor appetite, altered taste sensation, impaired swallowing, altered bowel habit, loose fitting clothes, or prolonged intercurrent illness).

A clear process for documenting the outcomes of screening (i.e. 'nutritional risk score') and the subsequent actions (i.e. 'nutritional care plan') taken if the patient is recognised as malnourished or at risk of malnutrition should be planned.

Exception

concern about risk of under nutrition.

Residents or patients having palliative care.

Definition of terms

considers the time over which nutrient intake has been reduced. (for example MUST).

Documentation in patient records that options of oral interventions to improve intake have been considered in patients who can eat safely but who are either:

1) malnourished (BMI <18.5-20 kg/m² and unintentional weight loss > 5% within the previous 3-6 months)

or; 2) at risk of malnutrition (eaten very little for >5 days and or unlikely to eat more than very little amounts for the next 5 days).

(See recommendation in Oral chapter, section 8.5)

Patients who are eating well and are not at nutritional risk for example BMI >20 kg/m².

Patients who have a BMI of <18.5 kg/m², are eating well and have no history of weight loss

Patients who are unable to swallow safely.

Patients who present with indications for enteral and parenteral nutrition The documentation should include information about which types of oral intervention(s) were used and a record of any relevant complications.

Documentation in patient records that enteral tube feeding has been considered for a patient who has a functional, tube accessible gastrointestinal tract and who despite the use of oral interventions if appropriate, still has an

Patients who are eating well and are not at nutritional risk for example BMI >20 The documentation should include information about which type of enteral and if appropriate oral intervention(s) were used and a record of

Page

Criterion

inadequate or unsafe oral intake and:

is malnourished (BMI <18.5 kg/m 2 and unintentional weight loss > 10% within the previous 3-6 months or BMI < 18.5-20 kg/m 2 and unintentional weight loss > 5% within the previous 3-6 months)

And or 2) is at risk of malnutrition (eaten very little for > 5 days and or unlikely to eat more than very little amounts for the next 5 days).

(see recommendation in Enteral chapter, section 9.3.1)

Documentation in patient records that parenteral nutrition has been considered for patients who have a non-functional and /or inaccessible gastrointestinal tract such that they cannot be adequately fed by other means and are:

malnourished (BMI<18.5 kg/m² and unintentional weight loss>10% within the previous 3-6 months)

or

at risk of malnutrition (eaten very little for > 5 days and or unlikely to eat more than very little amounts for the next 5 days).

(see recommendation in Parenteral chapter, section 10.4)

Documentation in patient records that patients who present with any of the obvious or less obvious indicators for dysphagia (Table 19) are referred to healthcare professionals with specialist training in the diagnosis, assessment and management of swallowing disorders for example speech and language therapists, gastroenterologists,

Exception

kg/m².

Patients who have a BMI of <18.5 kg/m², are eating well and have no history of weight loss

Patients who are receiving and responding to the benefits of oral nutrition support.

Patients who have a BMI of <18.5, are eating well and have no history of weight loss

Patients who are receiving and responding to the benefits of oral and or enteral nutrition support.

Definition of terms

relevant complications.

Important outcomes should include documentation about which type of parenteral, enteral and if appropriate oral intervention(s) were used and a record of complications e.g. catheter related sepsis.

Patients who do not present with any of the obvious or less obvious indicators for dysphagia. Important outcomes should include documentation what type (if any) of nutrition support did the patient receive.

Page

Nutrition support in adults: full guideline DRAFT (August 2005) 224 of 262

Criterion	Exception	Definition of terms
radiologists, neurologists, specialist nurses.		
Prescription of nutrition support – documentation should include: 1) type of professional who develop prescribed the nutrition support	Patients not prescribed nutrition support	Consider the PENG ³⁵³ pocket guide for information on requirements.
2) estimated requirements of that patient		
3) special considerations for example risk of refeeding		
4) outcome - complications that may arise following initiation of nutrition support e.g. on set of refeeding problems, metabolic complications, incurring nutritional deficiencies, catheter related sepsis.		
There should be clear documentation that when patients are started on nutrition support consideration has been given to determine if they would be at risk of refeeding syndrome by having considered the criteria in Table 13.		Review the criteria for determining patients at high risk of refeeding syndrome are listed in Table 13.
There should be clear documentation that healthcare professionals involved in the provision of nutrition support (hospital and community) have:	receiving nutrition support. include documen which type of par enteral and if apprintervention(s) we record of complicit.	Important outcomes should include documentation about which type of parenteral, enteral and if appropriate oral
1) ensured that until patients are stabilised on nutrition support there is a review of the indications for, route of and goals of nutrition support daily or twice weekly		intervention(s) were used and a record of complications e.g. catheter related sepsis.
2) for patients established on nutrition support that a review of the indications for, route of and goals of nutrition support is done every three to six months until nutrition support is no longer required.		

Page

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Nutrition support in adults: full guideline DRAFT (August 2005) Page 226 of 262

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Appendices 1–9 are in a separate file