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Quality and Safety in the Prescribing of Parenteral Nutrition

Sarah Zeraschi

Consultant Nutrition Pharmacist

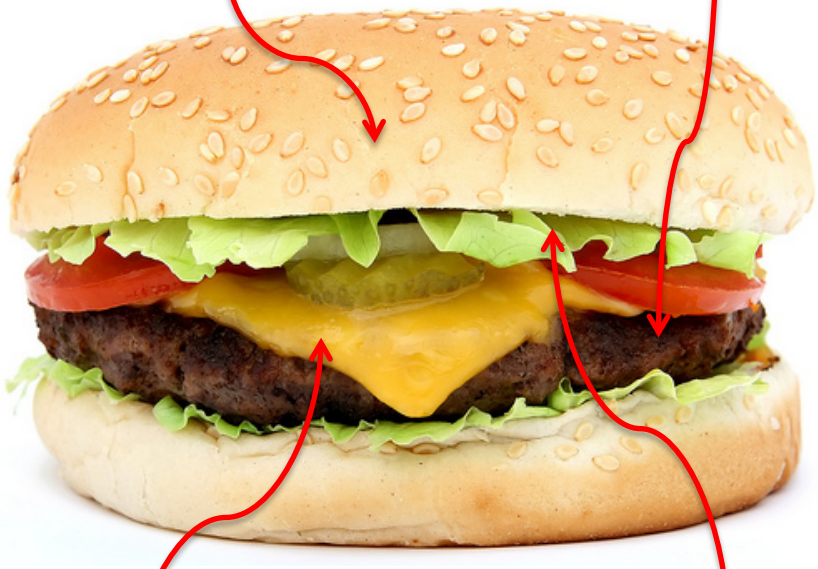
(Non-Medical Prescriber)

Pharmacy Services

Aims

- Assessment of patients requiring PN
- Impact on aseptic services
- Stability of PN solutions
- Strategies to improve quality and safety

What is Parenteral Nutrition?



What is Parenteral Nutrition?

- Well established technique for providing nutritional support to patients with an inaccessible or non-functioning gut
- Widely used and available to all clinicians, regardless of specialty or expertise in its use
- Whilst PN is a potential lifesaver it can also have potentially fatal complications

NCEPOD - A Mixed Bag

- To examine the process of care of patients receiving PN in hospital in order to identify remediable factors in the care received by these patients
  - Indication for PN
  - Type of PN
  - Prescribing PN
  - Catheter choice, insertion and care
  - Complications
  - Nutrition teams

Why are we concerned?

NCEPOD findings

Overall of assessment of PN care – Advisors' opinion

Overall Assessment	Number of patients	%
Good practice	171	19.5
Room for improvement - clinical	295	33.6
Room for improvement – organisational	81	9.2
Room for improvement – clinical and organisational	209	23.8
Less than satisfactory	83	9.5
Insufficient data	38	4.3
Total	877	

Initial Assessment
Who?

- “Patients who need parenteral nutrition should have their nutritional requirements determined by healthcare professionals with the relevant skills and training in the prescription of nutrition support” NICE 2006

Table 2.6 Nutrition team involvement in the decision to commence PN

Nutrition team involved	Number of patients	%
Yes	610	52.7
No	547	47.3
Subtotal	**1157**	
Unknown	128	
Not answered	47	
Total	**1332**	

Table 2.11 Nutrition team involvement in determining the patient's PN nutritional requirements

Nutrition team involved	Number of patients	%
Yes	931	79.8
No	235	20.2
Subtotal	1166	
Unknown	**128**	
Not answered	38	
Total	**1332**	

Initial Assessment
Why nutrition team?

Table 2.12 Advisors' opinion on the appropriateness of the first PN prescription

First PN appropriate for the patient	Number of patients	%
Yes	425	85.0
No	75	15.0
Subtotal	**500**	
Unknown/insufficient data	377	
Total	**877**	

Table 2.15 Advisors' opinion on whether the patient received an adequate biochemical and nutritional assessment prior to the commencement of PN

Adequate assessment given	Number of patients	%
Yes	339	45.9
No	399	54.1
Subtotal	**738**	
Unknown/insufficient data	139	
Total	**877**	

Members of the Nutrition Team

- Core
  - Dietitian
  - Doctor
  - Nurse specialist
  - Pharmacist

- Additional
  - Biochemist
  - Co-ordinator
  - Dietietic Assistant
  - HCA / CSW
  - IV therapy nurse
  - Microbiologist
  - Psychiatrist, Clinical Psychologist, Mental Health Nurse
  - Speech and language therapist
  - Surgeon

Initial Assessment

- Appropriate referral?
- Adequate trial of enteral nutrition?
- Requirements
- Venous Access
- Ancillary medications / fluids required

Table 2.17 Advisors' opinion on the adequacy of clinical and biochemical monitoring

Adequate monitoring	Number of patients	%
Yes	387	56.7
No	296	43.3
Subtotal	**683**	
Unknown/insufficient data	194	
Total	**877**	

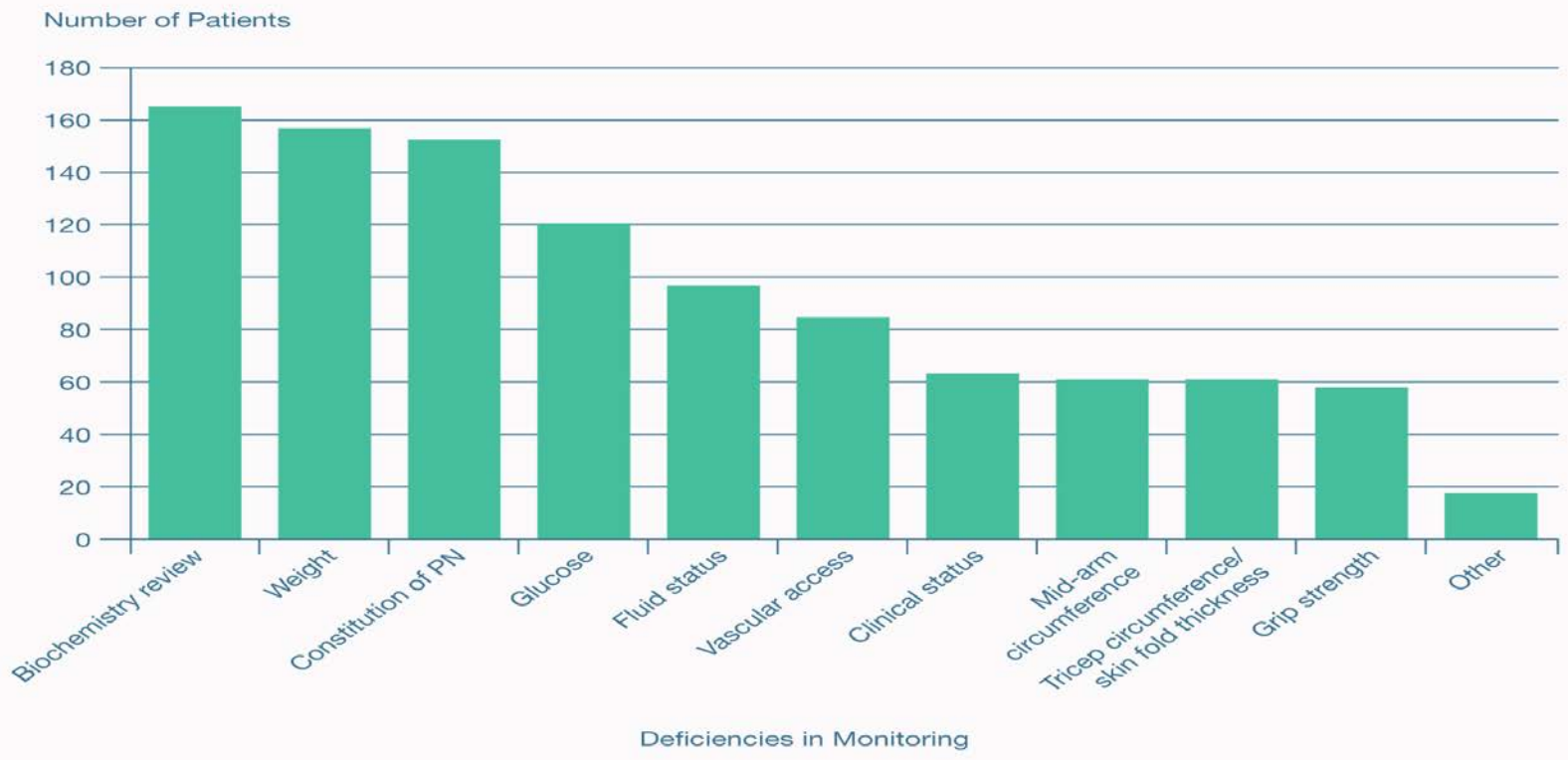


Figure 2.7 Deficiencies in monitoring (answers may be multiple)

Ongoing Assessment

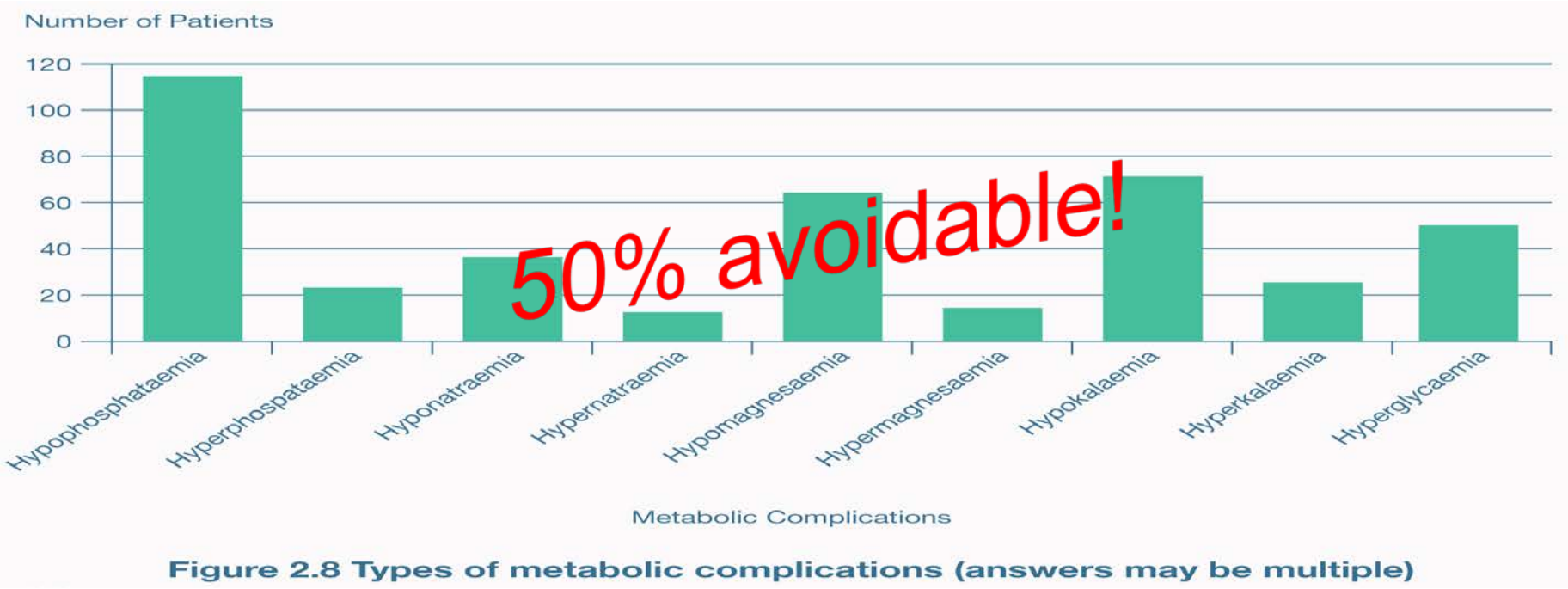


Figure 2.8 Types of metabolic complications (answers may be multiple)

Documentation What?

Table 2.16 Documentation of patients' nutritional requirements

Requirements documented	Number of patients	%
Yes	408	47.7
No	448	52.3
Subtotal	**856**	
Insufficient data	21	
Total	**877**	

Re-feeding Syndrome

Table 2.24 Advisors' opinion on whether the patient was at risk of RFS

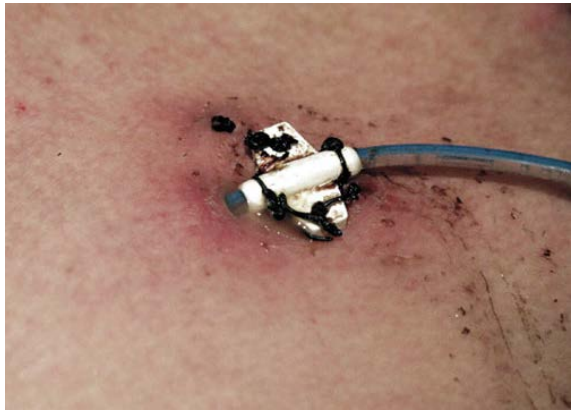
At risk	Number of patients	%
Yes	455	60.3
No	300	39.7
Subtotal	**755**	
Unknown/insufficient data	122	
Total	**877**	

Table 2.25 Risk of RFS documented in notes

Risk documented	Number of patients	%
Yes	224	49.8
No	226	50.2
Subtotal	**450**	
Insufficient data	5	
Total	**455**	

Catheter documentation

- Inadequate documentation of insertion in a third of adults and a quarter of neonates
- Tip position not documented in >50% of adults and 38% of neonates
- Catheter complications in a quarter of adults and a quarter of neonates



Situation

Dietitian **Nurse** **Pharmacist** **Doctor**

Other

Referral from _____

Patient consent to review Y / N

Background / Presenting complaint:

Estimated duration: <7days, 7 – 14 days, 15 – 28 days, > 28days

Past Medical History:

Refeeding risk?

IV Access: (check INR)

Blood results		Date			
Na		TPro		C Ca.	
K		Alb.		Mg	
Ur		T Bil		Phos	
Creat		ALP		Hb	
eGFR		ALT		WCC	
INR		CRP		Plat	

Anthropometry		BMI	
Recent weight (/ /)	kgs	Est Dry Weight	
Height		Wt increase/decrease	

Assessment			
NEWS		Temperature	
BGL		Insulin (Y/N)	
		Bowel function	

Critical care only			
Propofol	ml/hr	Ventilation	
Inotrope		CVVH	

Fluid Balance: last full 24hours - Date:			
Input		Output	
Oral		Urine	
Enteral		NG asp / drainage	
IV fluid		Vomit	
IV Medication		Stoma	
IV Nutrition		Drainage	
St Marks		Other	
Other		Other	
Total in		Total out	
	+ / - balance		

Nutritional Requirements	Date calculated:	Calculated by:	
BMR		Nitrogen (g)	
Stress factor		Fluid	
Activity factor			
Total Kcal		Non protein kcal	

Recommendations

1. IV Access □ to be arranged □ arranged □ in place
2. Refeeding Risk? If yes …… IV Pabrinex 1+2 daily / twice daily for _____days
3. Fluid balance chart
4. QDS blood glucose monitoring
5. Blood monitoring

	First week until stable	Once stable
Na, K, Urea, Creatinine, Bone profile	Daily	Twice weekly
Glucose	4 times daily capillary blood glucose	Daily urinalysis
Liver Function Tests	Twice weekly	Twice weekly or weekly
Haematinics	Not advisable in the acute phase	
Magnesium and phosphate	Daily until risk of disturbance ceased	Twice weekly

6. IVN regimen: ___gN _____Na ____K _____volume
7. Additional IV fluid required

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Documentation

ADULT NUTRITION SUPPORT TEAM FOLLOW UP REVIEW
for Parenteral Nutrition

Reviewing team member(s):

Nutritional assessment:
Type of nutrition support provided:

_____
Current PN regimen:
_____over:_____hours
Building up ☐ at goal ☐ weaning down ☐
Assessment of route of feeding:
Type of access: _____ CLESS: __
(For Acute CVC; days insitu____)
Type of enteral feeding tube (where applicable):_____
Comments:

_____
Medication review:
Short bowel medications:

_____
_____
_____
Other relevant medications (e.g. insulin, octreotide, dioralyte):

_____

Observations:
Temperature: _____ºC
(Paired cultures taken?□)
Blood glucose: _____mmol/L

Fluid Balance:

Input	Volume	Output	Volume
Parenteral nutrition		Urine	
Intravenous fluids (include type)		Bowels/ stoma/ fistula	
Oral fluid intake		Wound/ Drains	
Enteral feed (include type)		Vomit/NG	
Total:		Total:	

Fluid balance total: _____

Bloods/biochemistry:
Date of last bloods: _____ Comments:

_____
Day next bloods due:
MON/TUES/WED/THURS/FRI/SAT/SUN
Urine sodium result (where applicable):_____

NCEPOD – Prescribing

- The PN prescription was most commonly signed by a doctor 789/1076 (73%)
- Only 40% of prescribers were part of a nutrition team
- 256 cases where the identity of the prescriber was not known

Non-medical Prescribers

- Ensures professionals with appropriate experience prescribing for patients
  - 3 Pharmacists in adult service, 10 in paediatric and neonatal service
- Carter report
  - Variation in hospital prescribing pharmacists 2.5 to 71% (average 14%)
- Limitations
  - Doctor acceptance
  - Prescriber not on ward round
  - CPD

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PARENTERAL NUTRITION PRESCRIPTION (ADULTS)

ALLERGY STATUS

First Name:	Surname:	
Hospital No:	NHS No:	DOB:
Consultant:	Ward	Hospital:

Date							
Day of PN							
Route: central/peripheral							
No. of days line in place							
Regimen							
Total Sodium^{+} (mmoL)							
Total Potassium^{+} (mmoL)							
Total Calcium^{2+} (mmoL)							
Total Magnesium^{2+} (mmoL)							
Total Phosphate^{3-} (mmoL)							
Total Zinc^{2+} (µmoL)							
Total Selenium^{2-} (nmoL)							
Cernevit 5mls							
Addatrace 10mls							
Other instructions							
Volume to infuse (mL)							
Duration infusion (hour)							
Prescriber's signature							
Prescriber's name (PRINT)							
Checker's signature							

PHARMACY USE:

Pharmacist's signature							
Release signature							
Batch number							
Total volume (mL)							
Infusion rate (mL/hour)							

NURSING USE:

Nurse's signature							
Second signature							
Date/Time infusion started							
Date/Time infusion stopped							

PLEASE DO NOT ALTER RATE OF INFUSION WITHOUT PRIOR DISCUSSION WITH A MEMBER OF THE NUTRITION TEAM.

PN Regimen details	Nutriflex Lipid Peri-1250mLs	Nutriflex Lipid Plus (EF)-1250mLs	Nutriflex Lipid Plus (EF)-1875mLs	Nutriflex Lipid Special (EF)-1250mLs	Nutriflex Lipid Special (EF)-1875mLs	SmofKabiven 12 (EF)-1477mLs	SmofKabiven 16 (EF)-1970mLs
Route (central/peripheral)	P/C	P/C	P/C	C	C	C	C
Osmolality (no additions)	920	1350	1350	1840	1840	1600	1600
Nitrogen (g)	5.7	6.8	10.2	10	15	12	16
Glucose (Kcal)	320	600	900	720	1080	748	1000
Lipid (Kcal)	475	475	715	475	715	552	800
Total energy (Kcal)	955	1265	1900	1475	2215	1600	2200
Non-protein energy (Kcal)	795	1075	1615	1195	1795	1300	1800
Total Sodium^{+} (mmoL)	50 (≤120)	0 (≤120)	0 (≤180)	0 (≤120)	0 (≤180)	0 (≤225)	0 (≤300)
Total Potassium^{+} (mmoL)	30 (≤120)	0 (≤120)	0 (≤180)	0 (≤120)	0 (≤180)	0 (≤225)	0 (≤300)
Total Calcium^{2+} (mmoL)	3 (≤10)	0 (≤10)	0 (≤15)	0 (≤10)	0 (≤15)	0 (≤7.5)	0 (≤10)
Total Magnesium^{2+} (mmoL	3 (≤10)	0 (≤10)	0 (≤15)	0 (≤10)	0 (≤15)	0 (≤7.5)	0 (≤10)
Total Phosphate^{3-} (mmoL)	7.5(≤23.6)	3.6(≤ 23.6)	5.4(≤35.4)	3.6(≤23.6)	5.4(≤35.4)	4.2 (≤22.5)	5.6 (≤30)
Total Zinc^{2+} (µmoL)	30(≤150)	0(≤150)	0(≤175)	0(≤150)	0(≤175)	0 (≤250)	0 (≤300)
Total Selenium^{2-} (nmoL)	0(≤8000)	0(≤8000)	0(≤9000)	0(≤8000)	0(≤9000)	0 (≤850)	0 (≤1000)
Volume (mL)	1250	1250	1875	1250	1875	1477	1970

The combined total of sodium and potassium must not exceed the maximum monovalent cation allowance. Magnesium can be increased in favour of calcium but not vice versa.

Components available for custom feeds		
Amino Acids	**Glucose**	**Lipids**
Aminoven 25 (12.88g N/500mL)	Glucose 50% (1000kcal/500mL)	Intralipid 30% (1000kcal/333mL)
Vamin 18EF (9gN/500mL)	Glucose 40% (800kcal/500mL)	Lipidem 20% (955kcal /500ml)
Vamin 14EF (7gN/500mL)	Glucose 20% (400kcal/500mL)	Lipofundin 10% (511kcal/500mL)
	Glucose 10% (200kcal/500mL)	SMOF Lipid(1000kcal/500mL)
	Glucose 5% (100kcal/500mL)	Intralipid 10% (550kcals/500mls)

Restricted use of an amino acid additive - Dipeptiven (3.86g N/100mL) Contains 13.46g glutamine/100mL

Contacting nutrition team:

Nutrition Nurse:	80 - 6198	or	80 - 1175
Nutrition Fellow:	80 - 4436	or	80 - 1333
PN Dietitian:	80 - 6122	or	80 - 3337
PN Pharmacist:	80 - 4191	or	80 - 2731
Aseptics:	SJUH ext 68933 or 68773		LGI ext 26556

Monitoring:

- Blood glucose 6-hourly for 72 hours, then daily.
- Strict daily fluid balance.
- Daily weight recorded in nursing notes
- Daily U & Es.
- Daily Ca^{2+}/Mg^{2+}/PO_4^{2-}/LFTs.
- Trace elements weekly.

Referrals to TPN team:

- Complete referral form, and fax form to number on form.
- Bleep a member of the relevant team.
- Monday - Friday: refer patient to team by 11am for TPN to start that day.
- PN cannot be started at weekends

Other information:

- PN will have trace elements added every day unless specified. Additional zinc and selenium will be added as appropriate and documented in the total zinc and selenium columns.

Failure to ensure adequate monitoring may lead to PN being withheld for safety reasons.

Developed by:	Registered by D &T Risk Management Sub-Committee	Review Date	Ref No.	PU ref no.
Helen Lynch, Lead Pharmacist, Parenteral Nutritional (Adults) Bleep 80-2731	April 2008 Re-registered Feb 2011	Feb 2013	08/004v1.1	WPG626

What Happens Next?

"Additions [to PN solutions] should be made under appropriate pharmaceutically controlled environmental conditions before administration" NICE 2006

Why do we need an Aseptics Service?

It exists to turn the vials, ampoules, bottles and bags of a limited range of medicines into their final, ready-to-administer forms.
The medicines processed may require specialist handling (e.g.: chemotherapy), or complex compounding (e.g.: neonatal IV nutrition), or we may be able to save nursing time (or money) by vial sharing or 'campaign' dispensing.

Some figures and facts...

2 modern unlicensed Aseptic dispensing units
22 cabinets (a mix of isolators and LFC's)
100+ clinical trials needing Aseptics support
SJUH pioneer site for dose rationalisation
BSL-2 suite in use for biological agents
7-day service in operation

IV nutrition → 13,609 bags dispensed in 2015/16

Chemotherapy → 48,119 items dispensed in 2015/16

IV additives → 75,909 items dispensed in 2015/16

Or an alternative view of the year...

Enough IV nutrition dispensed to fill 12 and a half average sized hot tubs...

Enough needles used to stretch (end to end) from the LGI to St James... And back again. Twice!

Plans for 2016...

New, networked PN system to facilitate cross-site access to patient information
Update our worksheet and labelling system to automate critical calculations
Introduction of tracking technology

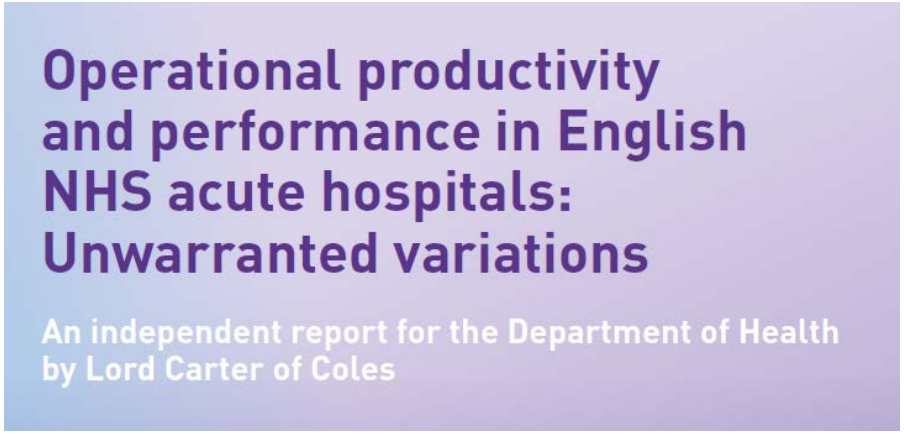
- “Before using most parenteral nutrition products, micronutrients and trace elements should be added and additional electrolytes and other nutrients may also be needed.” NICE 2006

Table 2.10 First type of PN given

Type of PN	Number of patients	%
Off the shelf	399	42.7
Off the shelf and micronutrients	124	13.3
Off the shelf and micronutrients and tailored additions	208	22.2
Bespoke	204	21.8
Subtotal	**935**	
Unknown	328	
Not answered	69	
Total	**1332**	

Standard PN

Carter Report Feb 2016



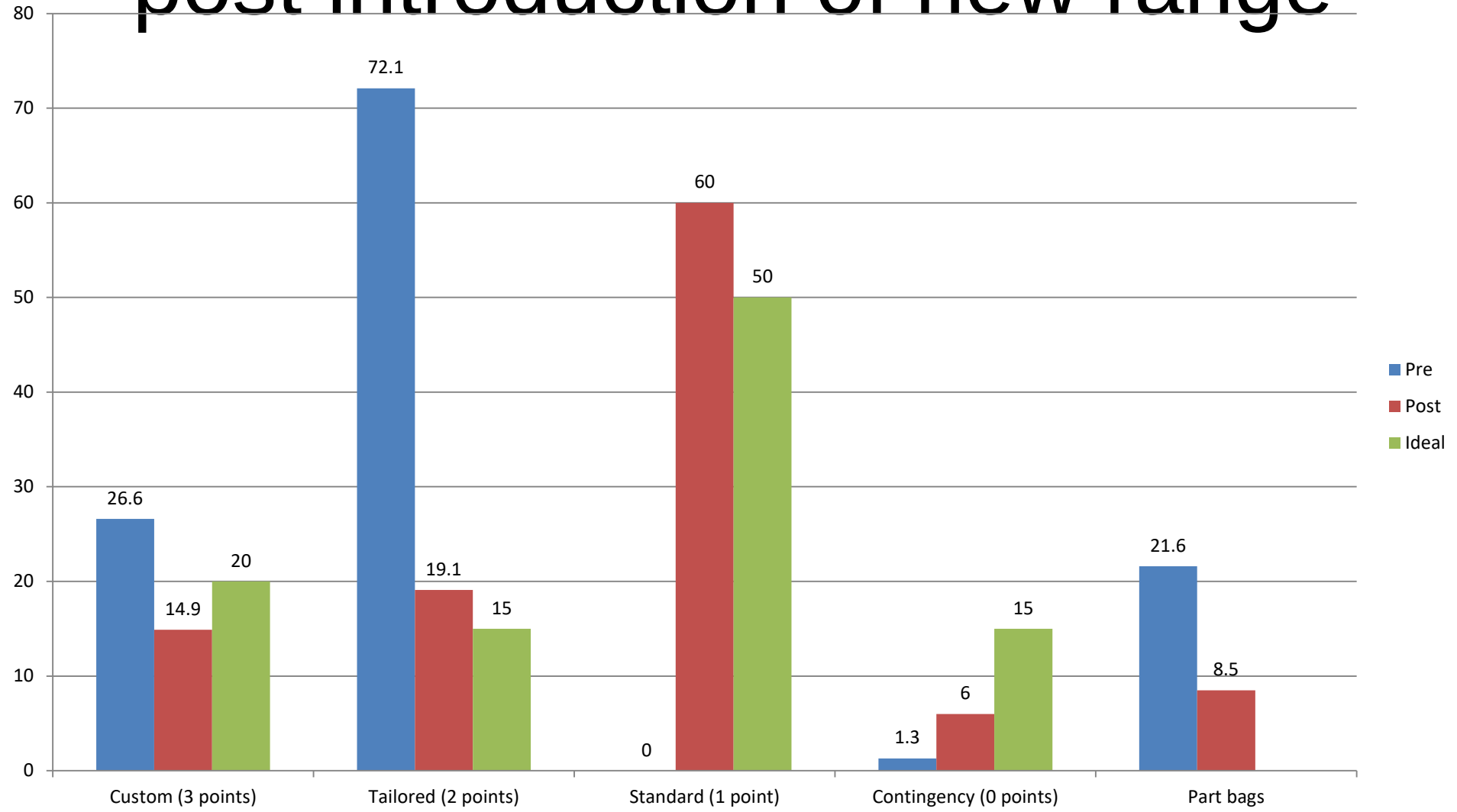
"Better performing trusts such as Leeds, who having introduced standardised doses for chemotherapy, reduced aseptic service demand by 24% for chemotherapy, whilst also reducing waste and drug expenditure"

A similar standardisation approach should be developed for parental nutrition for both adults and children

Review of Adult PN bags April 2016

- 597 PN bags compounded
- 108 different combinations of requirements
  - 158 (26.5%) Custom regimens
  - 121 (20.3%) needed strict electrolytes
  - 122 (20.4%) Lipid free bags
  - 176 (29.5%) Fish Oil
  - 129 (21.6%) Part bags

Projected PN usage pre and post introduction of new range



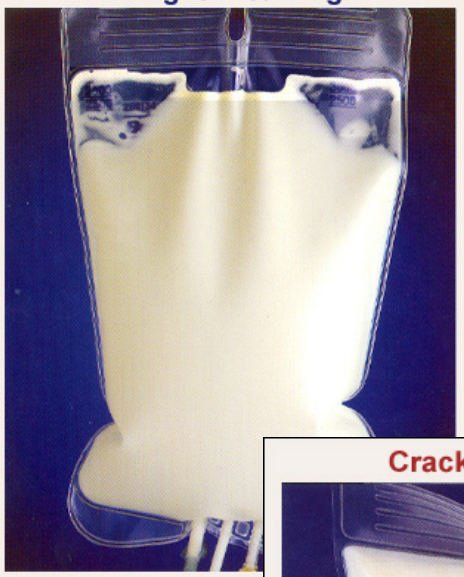
Benefits of standard bags

- Fit majority of patient requirements
- Ease for Nutrition Support Team
- Reduced wastage
- Pharmacy Aseptic Unit capacity
  - Batch Sheets
  - Stability statements

Emulsion definition

- A dispersion of one immiscible liquid in another as small droplets
  - Thermodynamically unstable, will separate into original states over time
  - Emulsifying agents can be used to overcome this by producing a mechanical or electrostatic barrier
- PN = Oil in water emulsion
  - E.g. milk, ice cream, salad cream, mayonnaise

Light Creaming



Heavy Creaming

Marbled

Cracked, Example 1

Pictures courtesy of Baxter and Fresenius Kabi

Further stability considerations

- Glucose
  - degradation products
  - variations in pH
- Amino Acids
  - Balance of acidic and basic, pH and charge
- Lipid
- Vitamin
- Electrolytes
  - Inorganic v organic, Valency and charge effects, calcium and phosphate

In view of complex chemical composition of TPN bags and difficulties with stability, often influenced by pH and charges:

Do NOT add any drugs to PN bags

Weekday PN Commenced

Table 2.4 Day of the week on which PN was commenced

Day PN was commenced	Number of patients	%
Monday	124	14.7
Tuesday	112	13.2
Wednesday	132	15.6
Thursday	141	16.7
Friday	198	23.4
Saturday	86	10.2
Sunday	53	6.3
Subtotal	**846**	
Unknown	31	
Total	**877**	

“PN should be started at the earliest opportunity but is rarely, if ever, indicated out of normal working hours” NCEPOD

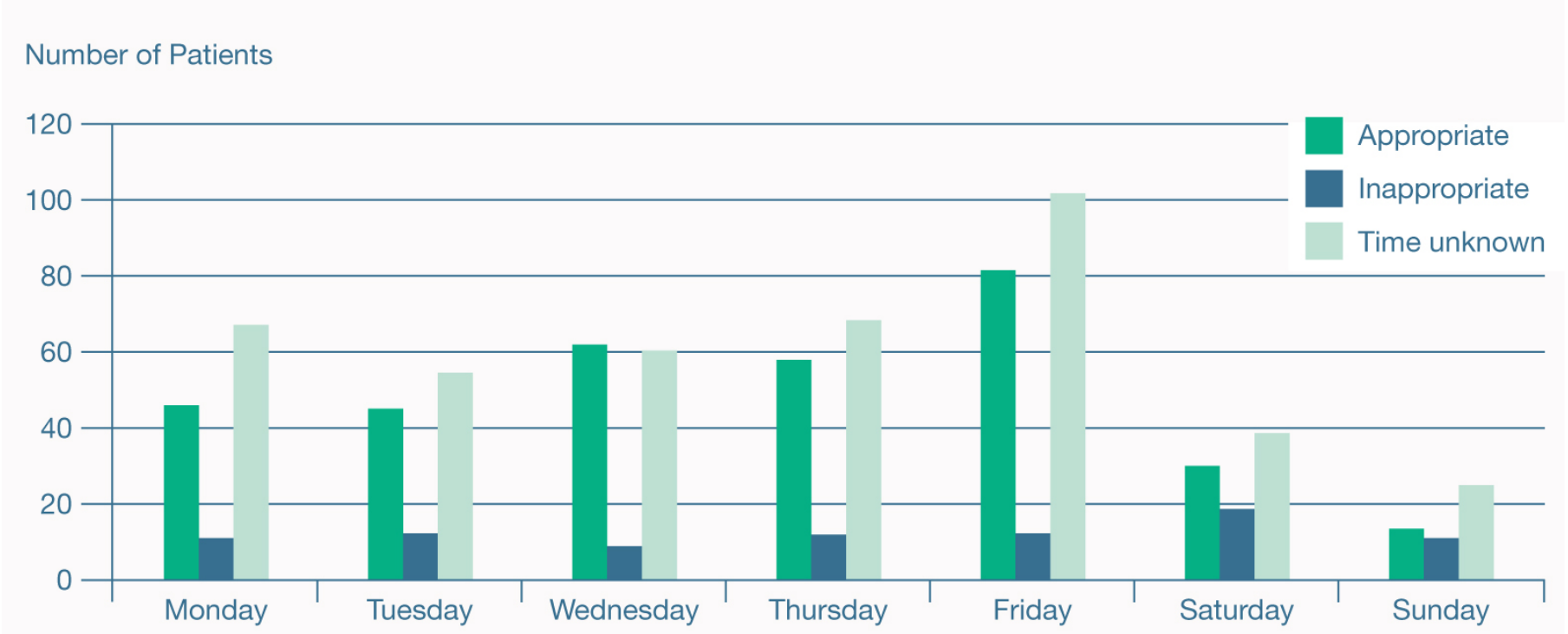


Figure 2.4 Day of the week on which PN was administered and the Advisors’ opinion on the appropriateness of the time of day it was commenced

PN is NEVER an emergency

Out of hours:

- Necessity for PN?
- High risk
  - Safer to wait for specialist assessment
  - Responsibility for prescribing?
- Roll standard bag?
  - No vitamins or trace elements
  - No electrolyte additions
  - Goes against NICE guidance
- ULM?

However……

"Unreasonable delay in starting PN in 9% once need identified" NCEPOD

LTHT Weekend and Bank Holiday Procedure

Risk of Catheter Related Blood Stream Infection? → **NOT FOR PN** → Prescribe appropriate peripheral intravenous fluids

Ensure patient has dedicated lumen for central venous access for safe administration of parenteral nutrition

Check recent (within 48 hours) U&E's, Ca, Mg and PO4

Ensure electrolytes in the starter PN bag are suitable for patient

Refer to Pharmacy Aseptics ext. 22460

0900-1800hrs (Referrals before 1500 will be processed same day)

Complete Referral to Nutrition Team and fax to number on form and Pharmacy Aseptics

Obtain pre-populated PN prescription from.....

Affix patient addressograph, and complete sections for consultant, ward, hospital, date, number of days CVC in situ, and sign prescription as the prescriber

Send prescription to Gledhow Inpatient Pharmacy (from SJUH) or LGI Pharmacy Aseptics (from LGI)

Prescribe Pabrinex 1 pair once daily for 4 days (unless comorbidities require higher doses), to start prior to PN

Prescribe additional IV fluids and electrolytes as required

NB Glucose infusion must be changed to an alternative due to refeeding risk

Document indication for PN in medical notes, including appropriateness of continuing until Nutrition Team review

Communicate decision with nurse in charge

Validating pharmacist to ensure Prescriber has carried out all points in Referring Team process

Prescription clinically screened and signed by validating pharmacist

Book out PN starter bag on JAC and attach label to PN bag

Affix additional label to bag stating Ward, flow rate and duration of infusion

PN bag checked against prescription by Pharmacist authorised to release PN

Lead Technician to document on handover

Weekday Lead Technician to liaise with Nutrition team Ext 68649 by 0900hrs

Recommendations

- PN should only be given where EN has been excluded as inappropriate or impractical
- The possibility of the requirement for PN should be recognised early
- PN should be started at the earliest opportunity but is rarely, if ever, indicated out of hours

Recommendations

- Patient assessment should be robust and goal and purpose of PN documented
- Mandatory monitoring of patient and prescription
- Mandatory monitoring of biochemistry
- Careful assessment before prescribing additional fluids

Recommendations

- Active under/postgraduate education around PN
- National standard proforma
    - Indication
    - Goal
    - Risk of RFS
    - Prescription
    - Weight
    - Biochemical Monitoring

Summary

- You are not alone TEAMWORK
- Standardise whenever possible
- Seek advice from specialist centres when needed
- NCEPOD toolkit