Pancreatic exocrine insufficiency and pancreatic enzyme replacement therapy

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Declaration of interests: Honoria received for speaking from Viatris, Mylan, Sanofi, Vitaflo, Nutricia Clinical Care, Abbott Nutrition and Merck.

Introduction: setting the scene

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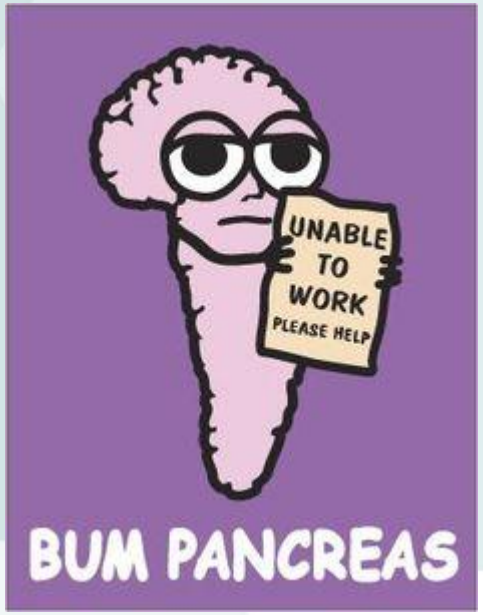


Introduction

Anatomy and function of the pancreas

Causes and incidence of pancreatic exocrine insufficiency

Impact of pancreatic exocrine insufficiency

Managing pancreatic enzyme replacement therapy

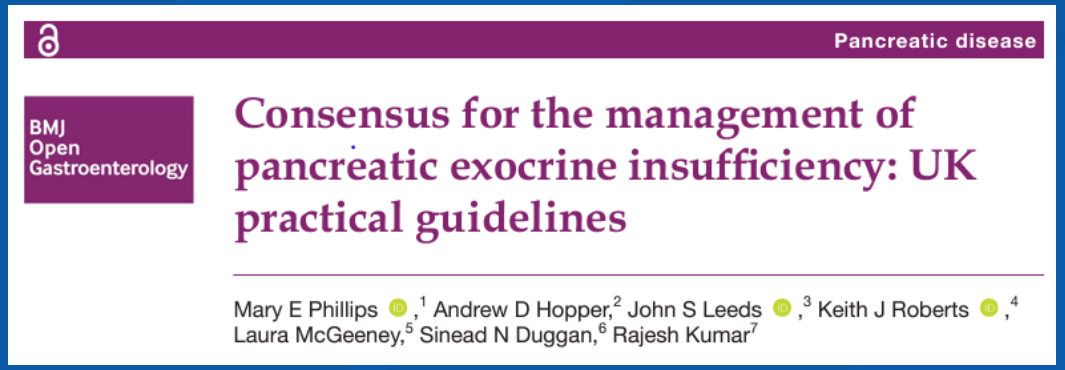
Recommendations for practice

Poll

What is PEI?

1) When the pancreas stops digesting fat
2) When the pancreas stops making insulin
3) When the pancreas is withered / atrophic
4) When the pancreas stops making enough enzymes

Definition



Definition and diagnosis of PEI

Statement 1.1: PEI is defined as a reduction of pancreatic exocrine activity in the intestine at a level that prevents normal digestion (grade 1C; 100% agreement)

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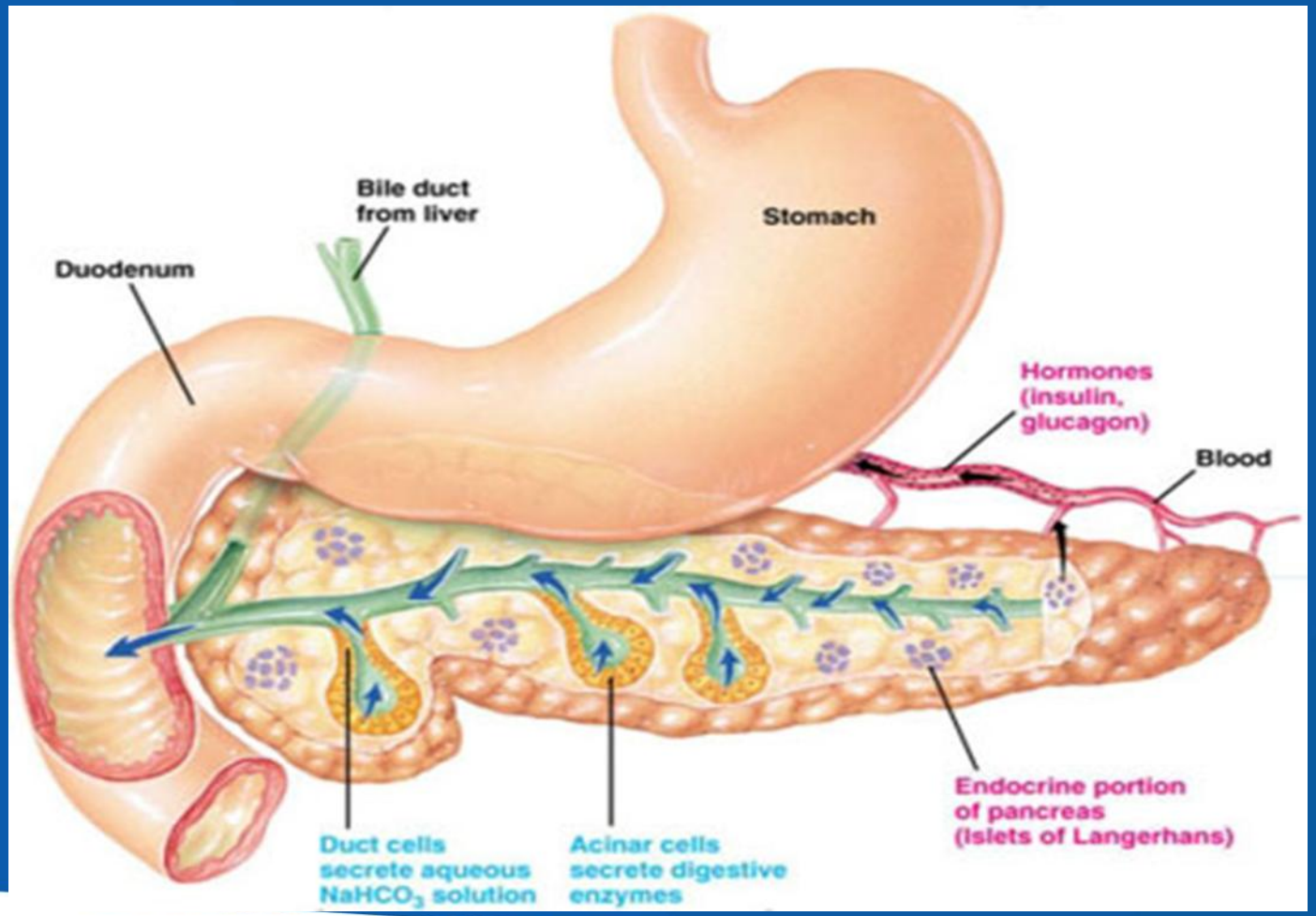
Anatomy and function



- Oblong gland 12.5 x 2.5cm
- Consists of endocrine cells: islets of langerhans) which produce glucagon, insulin etc (1% of all cells)
- 99% cells – exocrine function – producing pancreatic enzymes and fluid. (1200-1500mls/day)

Digestive enzymes

Site	Carbohydrate	Fat	Protein
Saliva	Amylase	Salivary lipase	
Gastric Secretion	Gastric Amylase	Gastric Lipase	Pepsin; Rennin; Gelatinase;
Pancreatic Secretion	Amylase	Lipase; Steapsin	Trypsin; Elastase; Chymotrypsin; Carboxypeptidase;
Jejunal / Ileal Secretion	Sucrase; Maltase; Lactase Isomaltase;	Intestinal Lipase	Brush Border Peptidases

Anatomy and function of the pancreas

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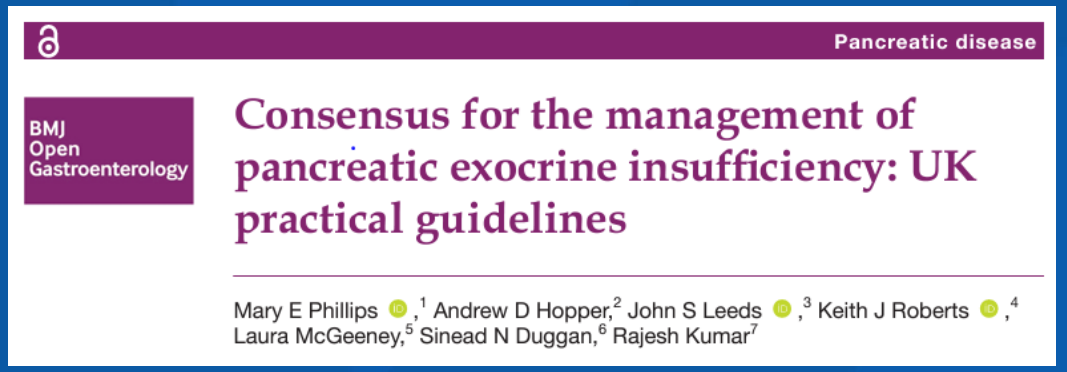
Definition



Pancreatic disease

BMJ Open Gastroenterology

Consensus for the management of pancreatic exocrine insufficiency: UK practical guidelines

Mary E Phillips [1], Andrew D Hopper [2], John S Leeds [3], Keith J Roberts [4], Laura McGeeney [5], Sinead N Duggan [6], Rajesh Kumar [7]

Definition and diagnosis of PEI

Statement 1.1: PEI is defined as a reduction of pancreatic exocrine activity in the intestine at a level that prevents normal digestion (grade 1C; 100% agreement)

Primary PEI: Lack of pancreatic secretion (cancer, pancreatitis, resection)

Secondary PEI: Lack of pancreatic stimulation (gastric resection /duodenal bypass)

Others – small bowel disease, enterokinase deficiency, endocrine failure

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Poll

Which of these is NOT correct?

1. Up to 98% of patients will have PEI after a Whipples
2. More than 50% of people with pancreatic cancer will have PEI on diagnosis
3. People with PEI will always have diarrhoea
4. PEI usually gets worse with time

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How common is PEI in pancreatic cancer?

- Present in the vast majority of people with pancreatic cancer
- Progressive
- 66-94% of patients have PEI at first presentation (all comers)
- Function deteriorates at approximately 10% per month
- Function tests can take 2-6 weeks to give results
- Incidence after surgery depends on the type of operation
  - 20-80% tail of pancreas (distal pancreatectomy)
  - Up to 98% head of pancreas (pancreatico-duodenectomy / Whipple)

Sikkens et al, 2014, Tseng et al, 2016, Phillips et al, 2021, Phillips M, 2015, Okano, 2016

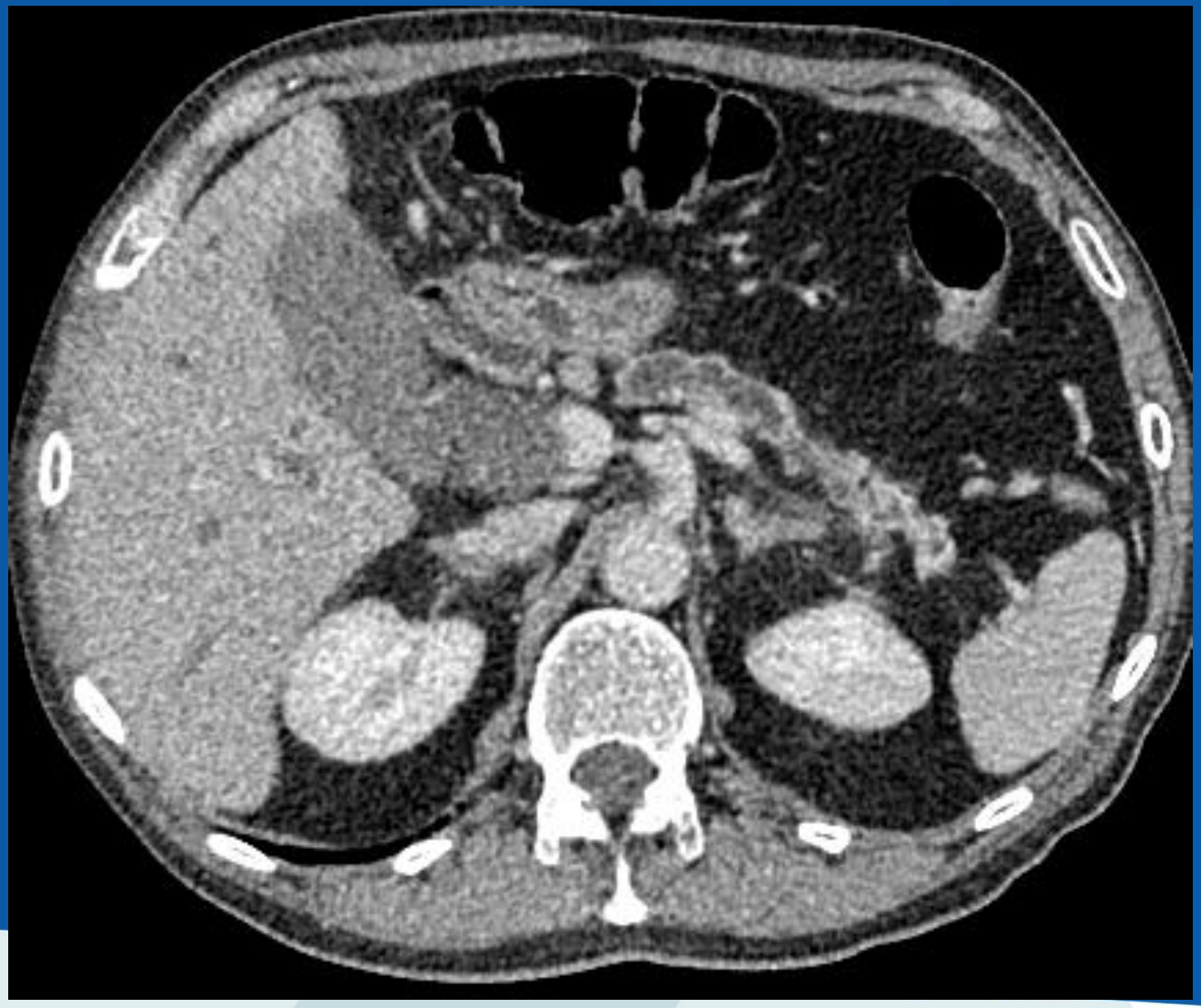
Pancreatic Function Tests

Faecal Elastase

- <200ug/g moderate PEI
- <100ug/g severe PEI
- 200 – 500ug/g (low sensitivity/specificity)
- >500ug/g normal: Consider age; Dilutional samples (watery / large volume stool); Sample collection technique
- Not validated after PPPD/ Whipples

Breath tests

Calibre of pancreatic tissue on imaging: Pancreatic ductal dilatation



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Poll

Which of these is NOT a symptom of PEI?

1) Bloating

2) Blood sugars that are lower than usual

3) Vitamin and mineral deficiencies

4) Failure to gain weight despite eating really well

5) New diagnosis of diabetes

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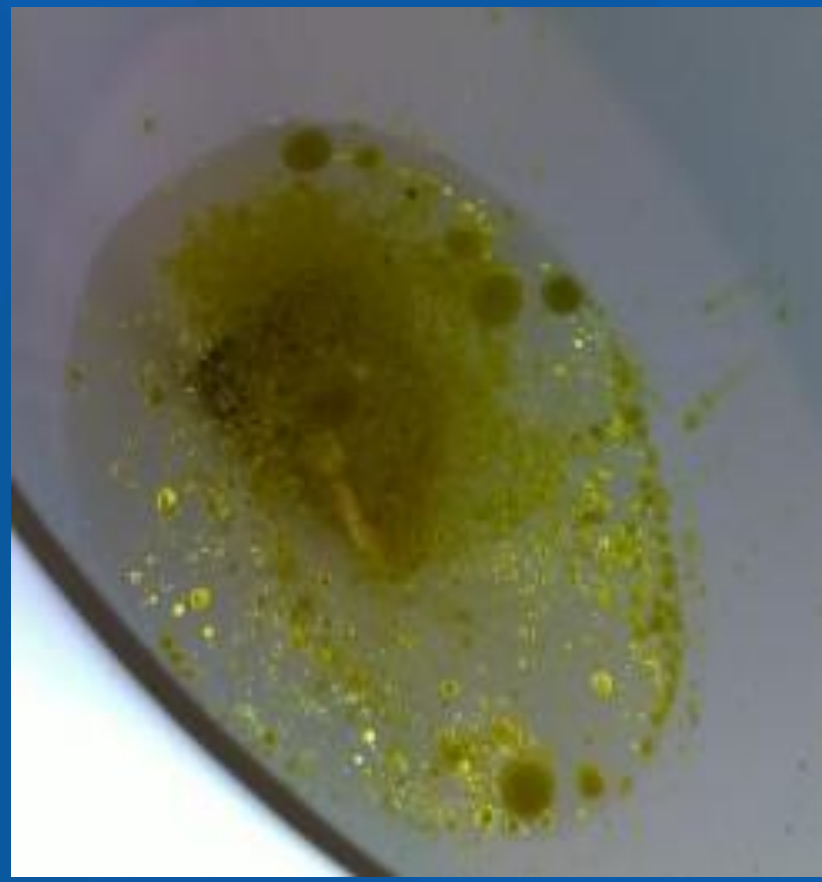
Clinical symptoms (1)

Steatorrhoea

- Loose watery yellow/orange stool / difficult to flush
- Floats / Oily / visible food particles

LIMITATIONS

- Only visible with >40g/day fat losses
- NOT PRESENT in low fat diet
- MASKED by constipating drugs
- VERY LATE symptom – only present in 14% cases



Midha et al, 2008

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Clinical symptoms (2)

- Large volume stool
- Undigested food in the stool
- Post-prandial abdominal pain
- Nausea / colicky abdominal pain
- Gastro-oesophageal reflux symptoms
- Bloating / flatulence
- *Weight loss despite good oral intake*
- Vitamin deficiencies (especially A,D,E,K,)
- *Hypoglycaemia in patients with diabetes*

- (O'Keefe et al, 2001, Genova Diagnostics, 2008, Friess & Michalski, 2009)

Diagnosis

Pancreatic pathology	+	Clinical symptoms	=	Likely PEI
Pancreatic pathology	+	Diagnostic test	=	Likely PEI
Clinical symptoms	+	Diagnostic test	=	Consider PEI and investigate for pancreatic pathology

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Recommendations for practice

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Implications

- 37.5 % of readmissions after pancreatic surgery caused by malnutrition and dehydration (Grewal et al, 2011)
- Sarcopenia independently associated with PEI (Shintakuya et al, 2017)
- “difficulty with digestion” is most common symptom in long term (Cloyd et al, 2017)
- PEI guidance primary unmet need in pancreatic cancer (Gooden & White, 2013)

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Study Overview

RICOCHET 1: A National Prospective Audit of the Diagnostic Pathway for Suspected Pancreatic Cancer

<50% patients on PERT

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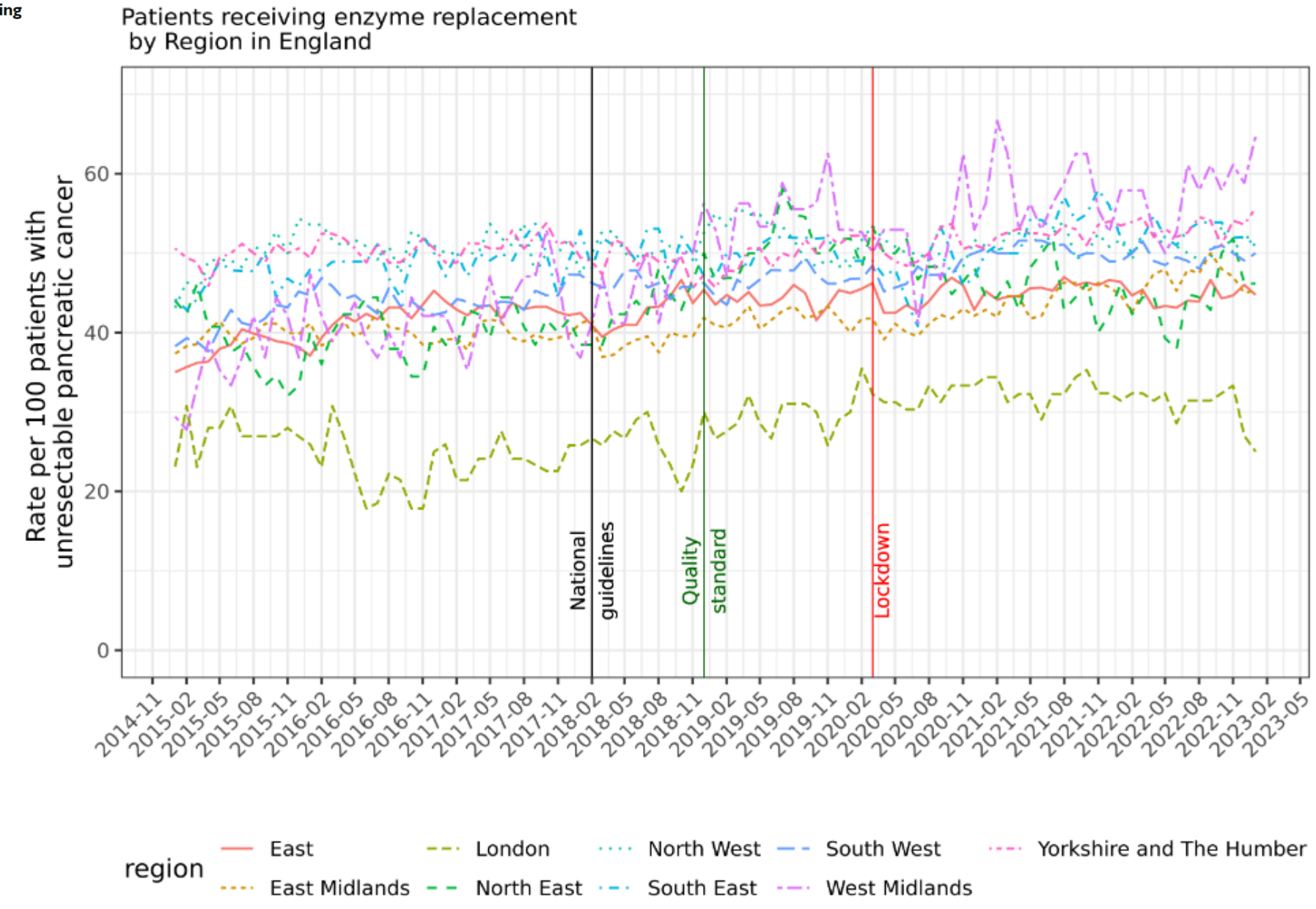
Ricochet study (2021)

- 45% of unresectable patients prescribed PERT
- 74.4% potentially resectable patients prescribed PERT
- 96.9% of pancreatic head resection patients prescribed PERT
- PERT prescription was more likely if:
  - Seen by a dietitian (p = 0.001)
  - Seen in a specialist centre (p= 0.049 – HPB; p=0.009 – pancreas)
  - Seen by a clinical nurse specialist (p = 0.028)

The impact of the COVID-19 pandemic on prescribing of pancreatic enzyme replacement therapy for people with unresectable pancreatic cancer in England.A cohort study using OpenSafely-TPP

Agnieszka Lemanska, Colm Andrews, Louis Fisher, Ben Butler-Cole, Amir Mehrkar, Keith J Roberts, Ben Goldacre, Alex J Walker, The OpenSAFELY Collaborative, Brian MacKenna

doi: https://doi.org/10.1101/2022.07.08.22277317



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Sarcopenia and outcome…..

Nutrition 32 (2016) 1231–1237

Contents lists available at ScienceDirect

Nutrition

journal homepage: www.nutritionjrnl.com

ELSEVIER

Applied nutritional investigation

A high visceral adipose tissue-to-skeletal muscle ratio as a determinant of major complications after pancreatoduodenectomy for cancer

Marta Sandini M.D. [a], Davide P. Bernasconi Ph.D. [b], Davide Fior M.D. [c], Matilde Molinelli M.D. [a], Davide Ippolito M.D. [c], Luca Nespoli M.D. [a], Riccardo Caccialanza M.D. [d], Luca Gianotti M.D., Sc.D. [a,*]

Influence of cachexia and sarcopenia on survival in pancreatic ductal adenocarcinoma: A systematic review

I. Ozola Zalite [a], R. Zykus [b], M. Francisco Gonzalez [c], F. Saygili [d], A. Pukitis [a,e], S. Gaujoux [f,g], R.M. Charnley [h], V. Lyadov [i,*]

CrossMark

Impact of Sarcopenic Obesity on Failure to Rescue from Major Complications Following Pancreaticoduodenectomy for Cancer: Results from a Multicenter Study

Nicolò Pecorelli, MD[1], Giovanni Capretti, MD[2], Marta Sandini, MD[3], Anna Damascelli, MD[4], Giulia Cristel, MD[4], Francesco De Cobelli, MD[4], Luca Gianotti, MD, ScD[3], Alessandro Zerbi, MD[2], and Marco Braga, MD[1]

August 01.

1605-012-1923-5.

Impact of Sarcopenia on Outcomes Following Resection of Pancreatic Adenocarcinoma

Muscle Index

eatic Fistula

Development After Pancreaticoduodenectomy

HIROAKI YAMANE[1], TOMOYUKI ABE[1], HIRONOBU AMANO[1,2], KEIJI HANADA[3], TOMOYUKI MINAMI[3], TSUYOSHI KOBAYASHI[2], TOSHIKATSU FUKUDA[4], SHUJI YONEHARA[5], MASAHIRO NAKAHARA[1], HIDEKI OHDAN[2] and TOSHIO NORIYUKI[1,2]

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UK management

Pancreatic enzyme replacement therapy

- Multiple disease aetiology
- Co-morbidities
- Altered dietary intakes
- Altered meal patterns
- Healthy eating *vs*. nutritional support

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Poll

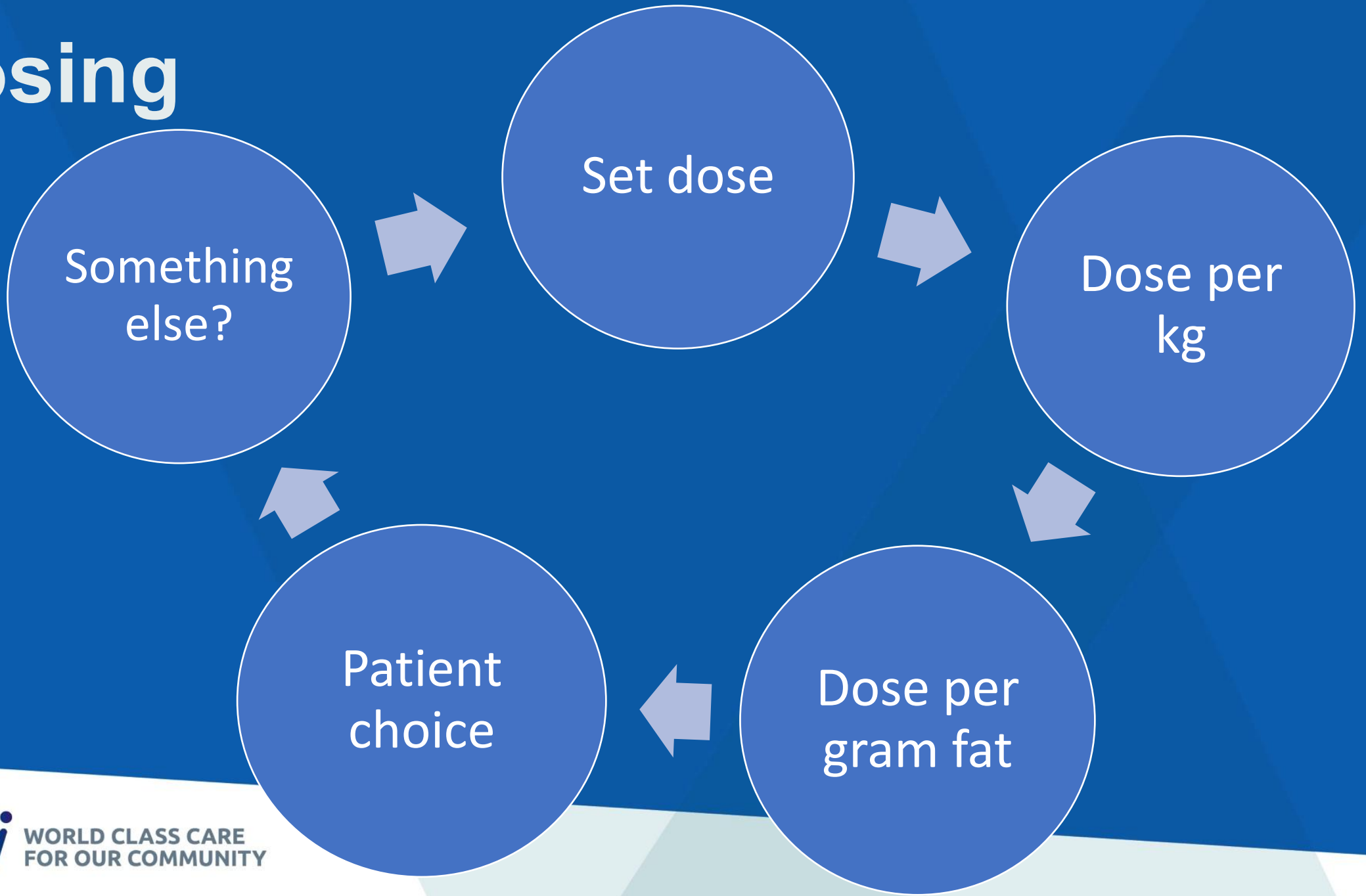
What is a suitable starting dose for PERT?

1) 5,000 units with meals
2) 10,000 units with meals
3) 22-25,000 units with meals
4) 44-50,000 units with meals

How do the products compare?

	Amylase	Protease	Lipase
Pancrex V capsule (125mg)	3300	160	2950
Creon micro (1 scoop)	3600	200	5000
Pancrex V capsule (340mg)	9000	460	8000
Creon 10,000	8000	600	10000
Nutrizym 22	19800	1100	22000
Creon 25,000	18000	1000	25000
Pancrex V powder (1g) TUBE FEEDS	30000	1400	25000

Dosing



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Comparison of weight-based doses of enteric-coated microtablet enzyme preparations in patient with cystic fibrosis

N = 21

Population: Cystic Fibrosis

Open label crossover: 500u/kg with meals and 250U/kg with snacks compared to 1500u/kg with meals and 750u/kg with snacks.

Diet : 100g fat / day

CFA: increased from 86% to 91% ($P<0.05$)

(Beker et al, J.Paed Gastrol Nutr. 1994 Aug;19(2):191-7).

RESEARCH ARTICLE

Clinical validation of an evidence-based method to adjust Pancreatic Enzyme Replacement Therapy through a prospective interventional study in paediatric patients with Cystic Fibrosis

Joaquim Calvo-Lerma[1,2]*, Jessie Hulst[3], Mieke Boon[4], Carla Colombo[5], Etna Masip[1], Mar Ruperto[6], Victoria Fornés-Ferrer[1], Els van der Wiel[3], Ine Claes[4], Maria Garriga[6], Maria Roca[1], Paula Crespo-Escobar[1], Anna Bulfamante[5], Sandra Woodcock[3], Sandra Martínez-Barona[1], Ana Andrés[2], Kris de Boeck[4], Carmen Ribes-Koninckx[1], on behalf of MyCyFAPP project[¶]

PLOS ONE | https://doi.org/10.1371/journal.pone.0213216 March 12, 2019

NHS
Royal Surrey
NHS Foundation Trust

- Multicentre trial
- Cystic fibrosis cohort
- Diet – 40% Lipid; 40% CHO and 20% Protein
- 1622 – 2573kcal/day

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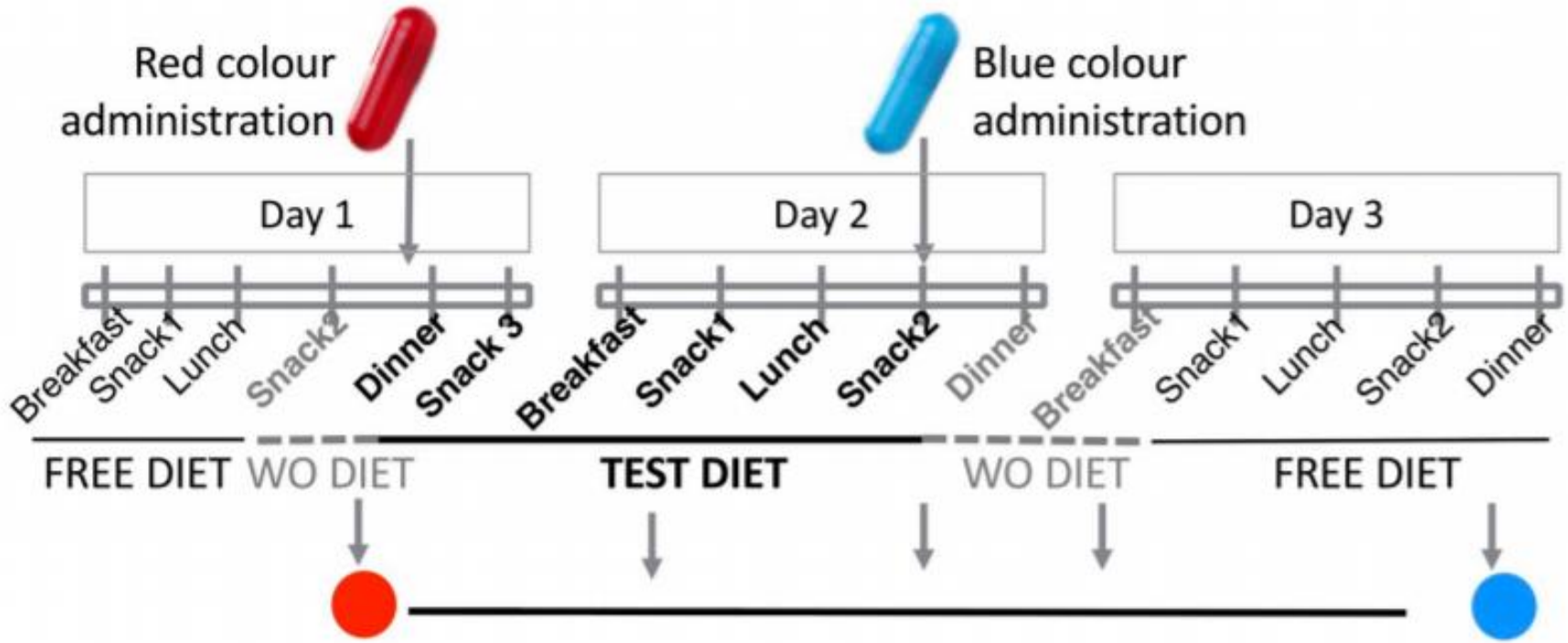

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$$IOD = \frac{g(90\%_{clinical\ target\ CFA}) - \beta_0 - (\beta_1 \cdot transit\ time) - (\beta_3 \cdot age) - (\beta_4 \cdot PPI\ intake)}{\beta_2}$$

Table 3. Beta regression model to assess the influence of the study variables on CFA, including the dose of enzymes (TOD) and the individual factors intake of proton pump inhibitors (PPI), age and transit time.

	(exp)Estimate	Confidence Interval CI 95%	p-value
(Intercept) (β_0)	2.839	[0.223, 36.147]	0.42
TOD (β_2)	0.999	[0.998, 1.000]	0.13
PPI intake (β_4)	1.367	[0.885, 2.115]	0.09
Age (β_3)	1.013	[0.961, 1.069]	0.62
Transit time (β_1)	1.815	[1.177, 2.797]	0.007

Transit time played a significant role in results: longer the transit time the greater the CFA

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And it is not just fat….

Medium-Chain Triglyceride Absorption in Patients with Pancreatic Insufficiency

S. CALIARI, L. BENINI, C. SEMBENINI, B. GREGORI, V. CARNIELLI & I. VANTINI
Division of Gastroenterologic Rehabilitation, University of Verona, Verona, and Dept. of Pediatrics, University of Padua, Padua, Italy

4 way Crossover trial: LCT vs. MCT +/- 50,000 units lipase
N= 6, all male Chronic Pancreatitis patients
All had severe exocrine insufficiency (CFA < 80%)
(1 x distal panc, 1 x total gastrectomy, 1 x distal gastrectomy, 1x whipple, 2 on insulin.)

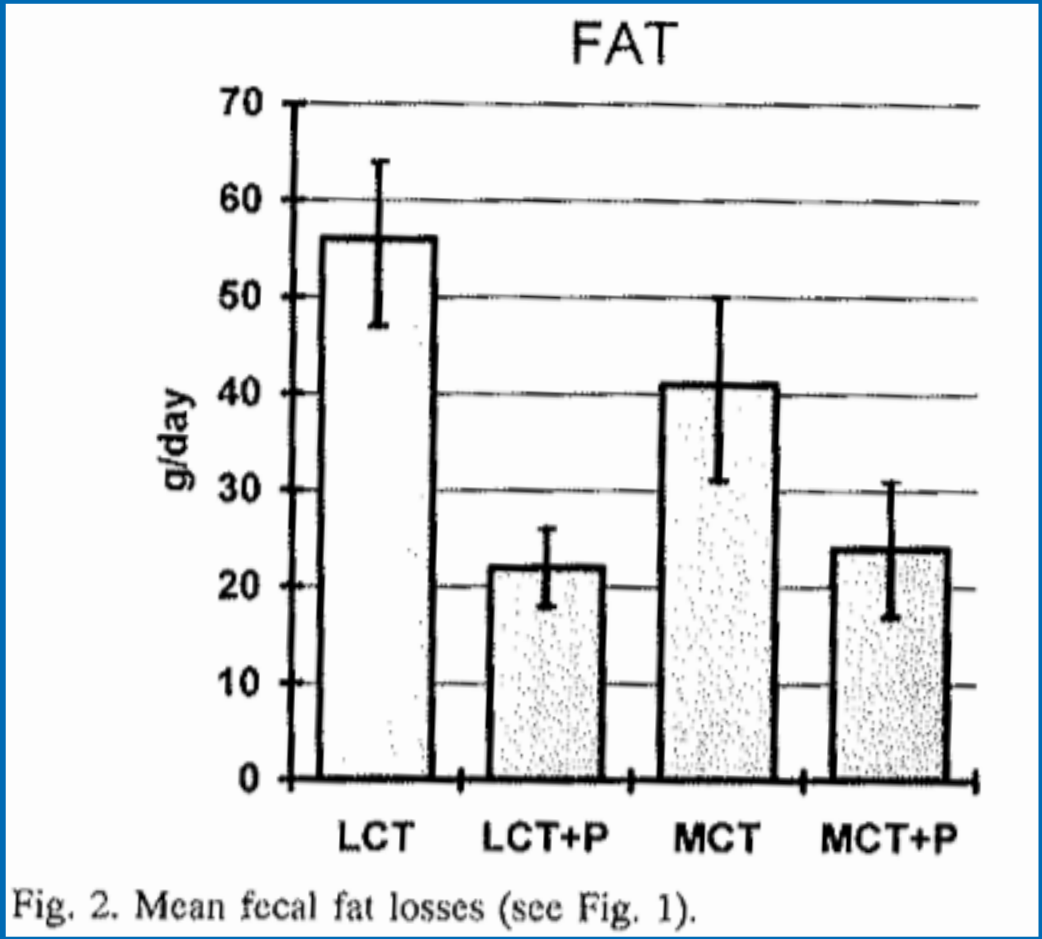

Fig. 2. Mean fecal fat losses (see Fig. 1).

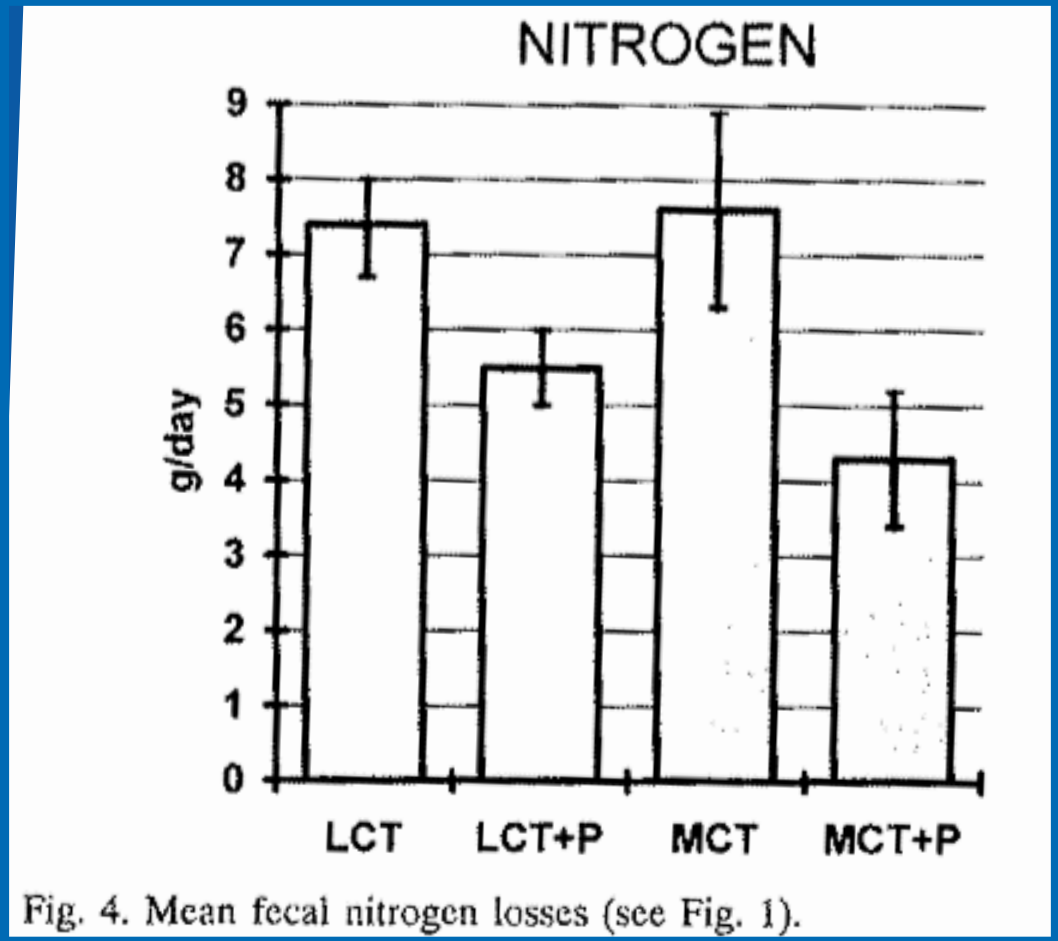

Fig. 4. Mean fecal nitrogen losses (see Fig. 1).

Caliari et al, 1996

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Recommended dose

STARTING DOSE....

44 - 50,000 units with meals

22 - 25,000 units with snacks

25 - 50,000 units with supplements

Will need higher dose with larger meals

Increase until symptom control

Poll

Which of these do you NOT need to take PERT with?

1) Cup of tea and two bourbon biscuits

2) Mug of peppermint tea

3) Milkshake

4) Cup of milky coffee

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NICE National Institute for Health and Care Excellence

NICE guideline

Pancreatic cancer in adults: diagnosis and management

NICE guideline

Published: 7 February 2018

nice.org.uk/guidance/ng85

1.6 Nutritional management

1.6.1 Offer enteric-coated pancreatin for people with unresectable pancreatic cancer.

1.6.2 Consider enteric-coated pancreatin before and after pancreatic cancer resection.

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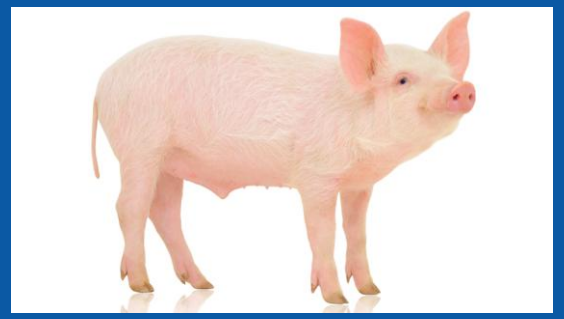
Recommendations for clinical practice

CONSENT



Timing

- Mix with food
- Allow for slow meals / multiple courses / gastric emptying

Dose

- Minimum starting dose 50,000u with meals; 25,000u with snacks
- Increase until symptom control
- Snacks *vs*. meals
- Nutritional supplements

Prevent denaturation

- <25ºC
- ?Proton pump inhibitor?
- Avoid swallowing with hot food/fluids

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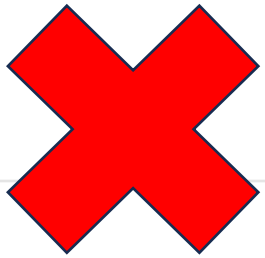
BMJ Open Gastroenterology

Consensus for the management of pancreatic exocrine insufficiency: UK practical guidelines

Mary E Phillips [1], Andrew D Hopper,[2] John S Leeds [3], Keith J Roberts [4], Laura McGeeney,[5] Sinead N Duggan,[6] Rajesh Kumar[7]

Contra-indications

For Pancrease HL®



Should not be used in children aged 15 years or less with cystic fibrosis

For Nutrizym 22® gastro-resistant capsules

Should not be used in children aged 15 years or less with cystic fibrosis

Cautions

Can irritate the perioral skin and buccal mucosa if retained in the mouth; excessive doses can cause perianal irritation

Side-effects

Common or very common

Abdominal distension; constipation; nausea; vomiting

Uncommon

Skin reactions

Frequency not known

Fibrosing colonopathy

Contraindications and side effects

- **CONTRAINDICATIONS**
  - CONSENT: Porcine content
  - Pork allergy / previous intolerance
- **SIDE EFFECTS**
  - Nausea
  - Gout (uric acid)
  - Fibrosing colonopathy
- **PREGNANCY & BREASTFEEDING:**
  - Essential fatty acids are needed for brain and retinol development in the first 8 weeks of pregnancy – DO NOT STOP PERT

What do you NEED to know :PEI

- Exocrine insufficiency is progressive, and doses escalate with time
- A few patients need really high doses (>150,000 units with a meal = >25 capsules / day = 9-10 x 100 cap tubs per month)
- Significant pill burden
- Micronutrient deficiency common
- Enzymes denatured by excess temperature and acid
- Treat like insulin – different doses for different patients for different meals

Case 1

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- 64-year-old female
- Locally advanced pancreatic cancer
- Biliary stent in situ
- On FOLFIRONOX chemotherapy
- 15% weight loss since diagnosis 5 months ago
- Struggling with reflux and indigestion but eating well despite this.
- Managing yoga 2x week but struggling with fatigue
- Bowels open once a day

Poll

Is this patient at risk / potentially suffering from malabsorption?

1. Yes – treat
2. Yes – test and then consider treatment
3. No
4. Not sure

Diet history

- Breakfast: Weetabix, 2x Toast and Jam
- Lunch: Large Jacket potato with ½ tin baked beans
- Dinner: Pasta with tomato and vegetable sauce and chicken breast, Fresh fruit and sorbet and honey
- Snacks: Banana, dried fruit, low fat yoghurts
- Drinks: Black coffee, orange juice, lemonade.

- Bowels open with slightly fluffy but formed stool
- Large in volume
- Oral intake exceeds predicted energy requirements
- Most problematic symptom was fatigue
- Medication: Omeprazole, Creon 10,000 – 2 with meals, 1 with snacks, rampiril, metformin, tramadol, paracetamol.

Poll

Does this change your decision?

1. Yes – increase PERT
2. Yes – test for other causes of weight loss
3. No – this is cancer associated weight loss - cachexia
4. Not sure

Results

- No obvious steatorrhoea due to low fat diet
- Bowel motions became more solid with higher dose of PERT
- Blood glucose levels 15 - 25mmol/l
- Weight loss stopped once commenced insulin

Case 2

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Case 2

- 82-year-old male
- Metastatic pancreatic cancer – lung mets
- Having palliative chemotherapy – reduced to Gemcitabine only
- Bowels open 8 times per day – yellow, floating, loose ++
- On Creon 25,000 – 5 capsules TDS and 3 capsules PRN
- Progressive weight loss

Poll

What would you do?

1. Increase PERT
2. Test for other causes of weight loss (inc. diabetes)
3. Nothing – this is cancer associated weight loss - cachexia
4. Not sure

Investigate

- CT – stable disease – no signs of colitis
- Diet history
  - Breakfast – porridge, full fat milk and honey
  - Mid morning – fruit and nut cereal bar and oral nutritional supplement drink
  - Lunch – scrambled egg, fried bacon, tinned tomato, 2 x hash browns
  - Mid afternoon – thick and creamy yoghurt
  - Dinner – spaghetti bolognaise, garlic bread, Cornish ice cream
  - Before bed – Oral nutritional supplement drink

Poll

What would you do?

1. High energy diet - Increase PERT
2. Test for other causes of weight loss (inc. diabetes)
3. Nothing – this is cancer associated weight loss - cachexia
4. Not sure

Outcome

- No improvement with increased PERT
- Further questioning:
  - Taking PERT every 6 hours (TDS) only – not with meals.
  - Once taking PERT correctly, symptoms settled

Case 3

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Case 3

- 73-year-old male
- Localised pancreatic ductal adenocarcinoma
- Pancreatico-duodenectomy 9 months ago, completed adjuvant FOLFIRINOX
- Bowels open 4 x a day loose and watery
- Taking Nutrizym 22 – 6 capsules with meals, 3 with snacks
- Weight stable, eating well

Poll

Is this patient at risk / potentially suffering from malabsorption?

1. Yes – treat increase the dose of PERT
2. Yes – continue PERT dose and investigate other causes
3. No
4. Not sure

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- Investigate:
  - Correct technique, storage
  - No improvement with increasing doses
  - Worsening symptoms for several months
  - Bloating and wind ++ accompanying frequent loose bowel motions
  - Feels worse after eating fatty foods
  - Weight stable
  - Impact on Quality of Life

Poll

Now what would you do?

1. Increase PERT
2. Screen for diabetes
3. Request medical review – investigate further?
4. Not sure

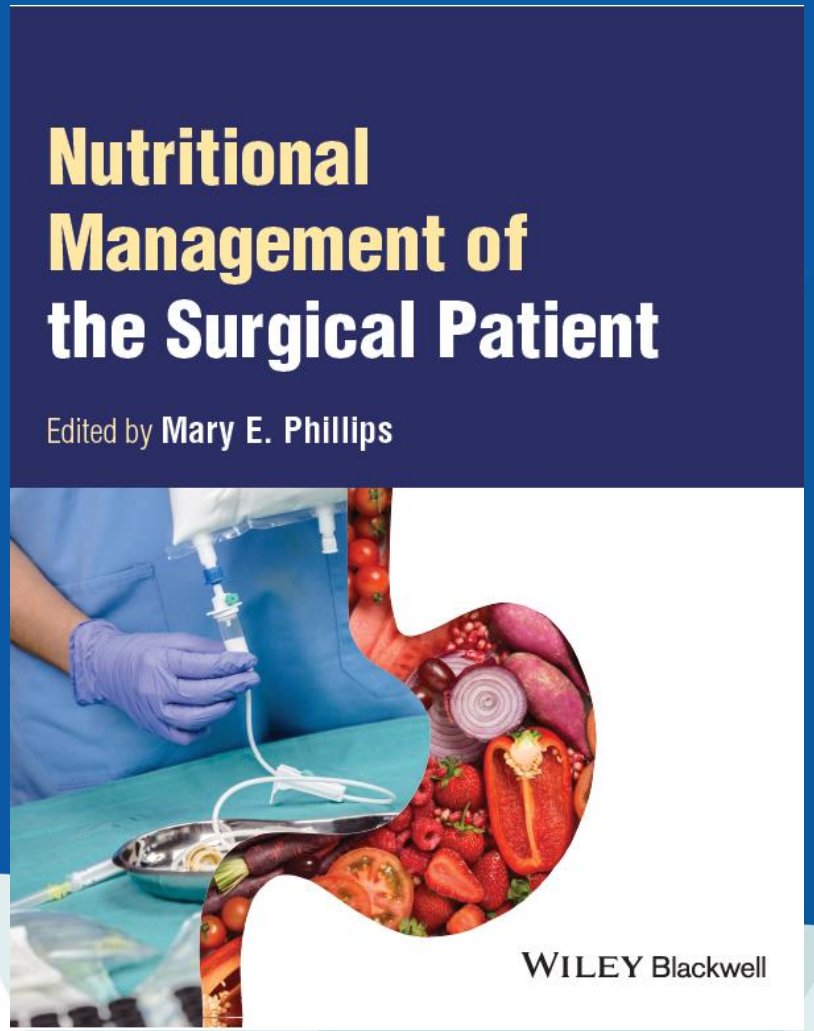
Outcome

- Colonoscopy – normal
- HbA1c 36
- CT – no disease recurrence
- Ca19-9: 7
- SeHCAT: 3% - severe bile acid malabsorption

Conclusion

- PEI is under recognised
- Many patients are on sub-optimal doses
- Appropriate therapy improves outcome
- Multiple factors play a role in dose adjustment – individual management
- Permission to dose escalate
- Other conditions can mimic PEI
- More data needed to explore relationship with survival in pancreatic cancer.

More information on managing pancreatic (and other) surgical patients



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Royal Surrey
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Commonly asked questions……

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The PERT shortage….

Community Pharmacy England

Our Work | Funding & Reimbursement | Quality & Regulations | Dispensing & Supply

SSP61 – Creon® 25000 gastro-resistant capsules further extended

Dispensing & Supply | Funding & Reimbursement | Headline | Shortages | Wednesday 15th April 2026

Update 15/04/26 – The Department of Health and Social Care (DHSC) has provided an update on the Serious Shortage Protocol (SSP) for Creon® 25000 gastro-resistant capsules (SSP061) was due to expire 17 April 2026 but has been further extended to **Friday 10 July 2026.**

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National Patient Safety Alert

Department of Health & Social Care

NHS England

Shortage of Pancreatic enzyme replacement therapy (PERT)

Position Statement: Pancreatic enzyme replacement therapy (PERT) shortage – advice for the management of adults with pancreatic exocrine insufficiency

Phillips M.E[1,3], McGeeney L.M[1], Watson K-L[2], Lowdon J[2].

Phase 1: What to do when you have a supply

- Do not stockpile
- Check expiry dates
- Put next prescription request in as soon as the last one is issued, and check it has been authorised
- Ensure your PERT is optimised – spread out the dose, store <25°C Speak to your GP about accessing imported medications so everyone is aware in case you have less than 2 weeks left

(HCP's – please add it to every letter)

iNForm your GP

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Advice to GP's & Community Pharmacists

- Prescribe one month's worth at a time
- Authorise multiple prescriptions – do not automatically reject repeat prescription requests that come in too early
- Prepare – be aware of imported procedures and set up necessary accounts with wholesalers and Pharmacies managing central stocks

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Phase 2: What to do if you think you need to increase your dose

- If you have CF – speak to your specialist centre
- Before increasing your PERT:
  - Add a PPI if not on one already
  - Check you are spacing it out throughout meals
  - Check you are storing it below 25^{o}C
- Consider peptide ONS in place of polymeric to reduce need for PERT
- Speak to your Dietitian / Doctor / Nurse Specialist if you are struggling with symptoms or your weight.

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PERT prescription management

- Reassure patients
- Ensure optimal use of existing product: timing, storage
- Prioritise Creon 10,000 and Pancrex V (8000u) for children and those unable to swallow larger capsules
- Prioritise Nutrizym 22 for those unable to tolerate Creon
- Consider PPI if not on one already
- If nutritionally well, consider using loperamide to optimise bowel symptoms rather than a dose escalation
- If gastrically fed, consider giving PERT via PEG/NG at mealtimes in those eating alongside feed.
- Consider peptide ONS in place of polymeric to reduce need for PERT

Other considerations

- Blood glucose control – higher risk of hypo's and poor correction of hypo's.
- Vitamin K – patients on anti-coagulation should be flagged to their GP as may need more regular monitoring
- Medication absorption – seizure medication, thyroxine, steroids, oral contraceptive pills. Consider a secondary form of contraception.
- Consider falls – faecal urgency in vulnerable patients

Phase 3: What to do if you have <2 weeks supply left

- Don’t panic!
- Check with manufacturer helpline to source stock:: **Creon: 0800 8086410; Nutrizym 0800 0902408**
- Speak to your Pharmacist AND GP to arrange a prescription for an import – in most ICBs this is imported Creon or PANGROL.
- If you have completely run out – make a same day emergency appointment with your GP
- If you are under the care of a local hospital, contact your team there to request an emergency rescue prescription.

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Thank you
Any questions?

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