

# Pancreatic exocrine insufficiency and pancreatic enzyme replacement therapy

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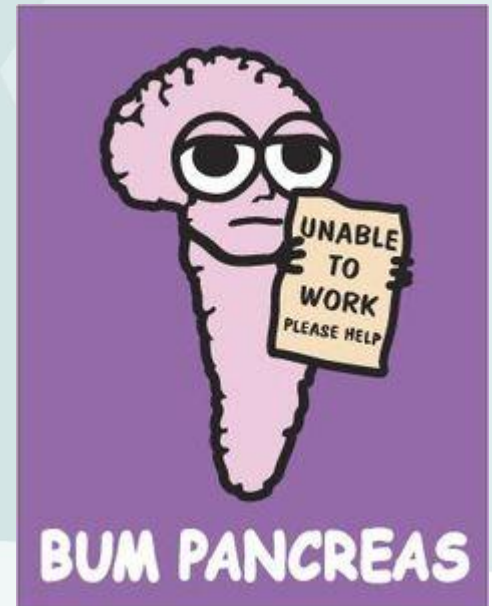
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Declaration of interests: Honoria received for speaking from Mylan, Sanofi, Vitaflo, Nutricia Clinical Care, Abbott Nutrition and Merck.

# 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



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# 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



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# Definition

“...deficiency or absence of digestive enzymes leading to maldigestion of food and consequently malabsorption of nutrients” (Whitcomb et al, 2010)

“Exocrine pancreatic insufficiency results from a progressive loss of acinar pancreatic cells which leads to the secretion of an insufficient amount of digestive enzyme into the duodenum.” (Pezzilli et al, 2013)

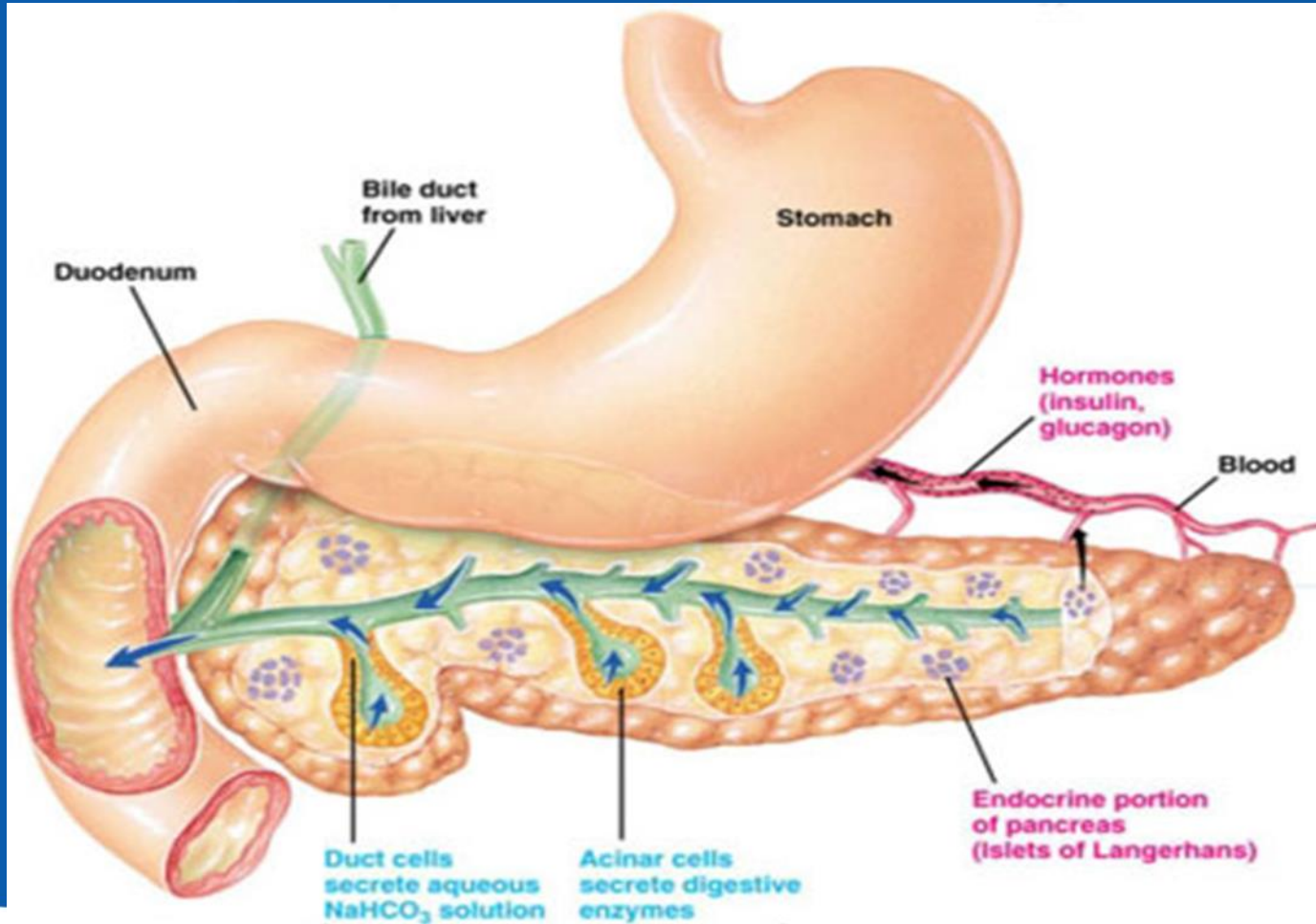
“....pancreas is unable to deliver sufficient amounts of digestive enzymes to the small intestine, leading to maldigestion” (Sikkens et al, 2012)

**Failure of the pancreas to secrete sufficient enzymes to achieve normal digestion**





# 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



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# Causes of PEI

- Lack of Healthy Pancreatic Tissue (Primary Insufficiency)
  - Pancreatic Resection
    - Chronic Pancreatitis
  - Recovering Acute Pancreatitis
    - Pancreatic Cancer
  - Pancreatic Trauma
    - Cystic Fibrosis
- Lack of Pancreatic Stimulation (Secondary Insufficiency)
  - Gastric Resection
  - Duodenal Resection
- Some work suggests insufficiency in Coeliac Disease, Diabetes, Irritable bowel syndrome, intensive care, inflammatory bowel disease and the elderly



# 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



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# Pancreatic Function Tests

## Faecal Elastase

- <200ug/g moderate PEI
- <100ug/g severe PEI
- 200 – 500ug/g (low sensitivity/specificity)
- >500ug/g: Consider age; Dilutional samples (watery / large volume stool); Sample collection technique

## 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



# Clinical symptoms (1)

## Steatorrhoea

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

## LIMITATIONS

- NOT PRESENT in low fat diet
- MASKED by constipating drugs
- VERY LATE symptom



# 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

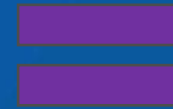


Likely PEI

Pancreatic  
pathology



Diagnostic  
test



Likely PEI

Clinical  
symptoms



Diagnostic  
test



Consider PEI and  
investigate for  
pancreatic  
pathology



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# Malignant disease

## Survival

- RCT (unresectable ca pancreas)– no benefit; but predominantly tail of pancreas disease (Woo et al, 2016)
- Survival benefit(Dominguez-Munoz et al, 2018, Roberts, 2019)
- ESPAC studies show the benefit of completing the full chemotherapy regime – performance status....

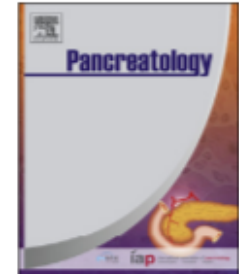




Contents lists available at ScienceDirect

## Pancreatology

journal homepage: [www.elsevier.com/locate/pan](http://www.elsevier.com/locate/pan)



# Enzyme replacement improves survival among patients with pancreatic cancer: Results of a population based study

K.J. Roberts <sup>a,\*</sup>, C.A. Bannister <sup>b</sup>, H. Schrem <sup>c</sup>

<sup>a</sup> Honorary Reader and Consultant Surgeon, Institute of Immunology and Immunotherapy, University of Birmingham, UK

<sup>b</sup> Digital Health Laboratories, UK

<sup>c</sup> Consultant Surgeon, Dept Visceral, General and Transplant Surgery, Hannover Medical School, Germany



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# Trial design

Retrospective observational study

PDAC 1998 – 2015

Excluded those with concurrent pancreatitis, PERT prior to diagnosis

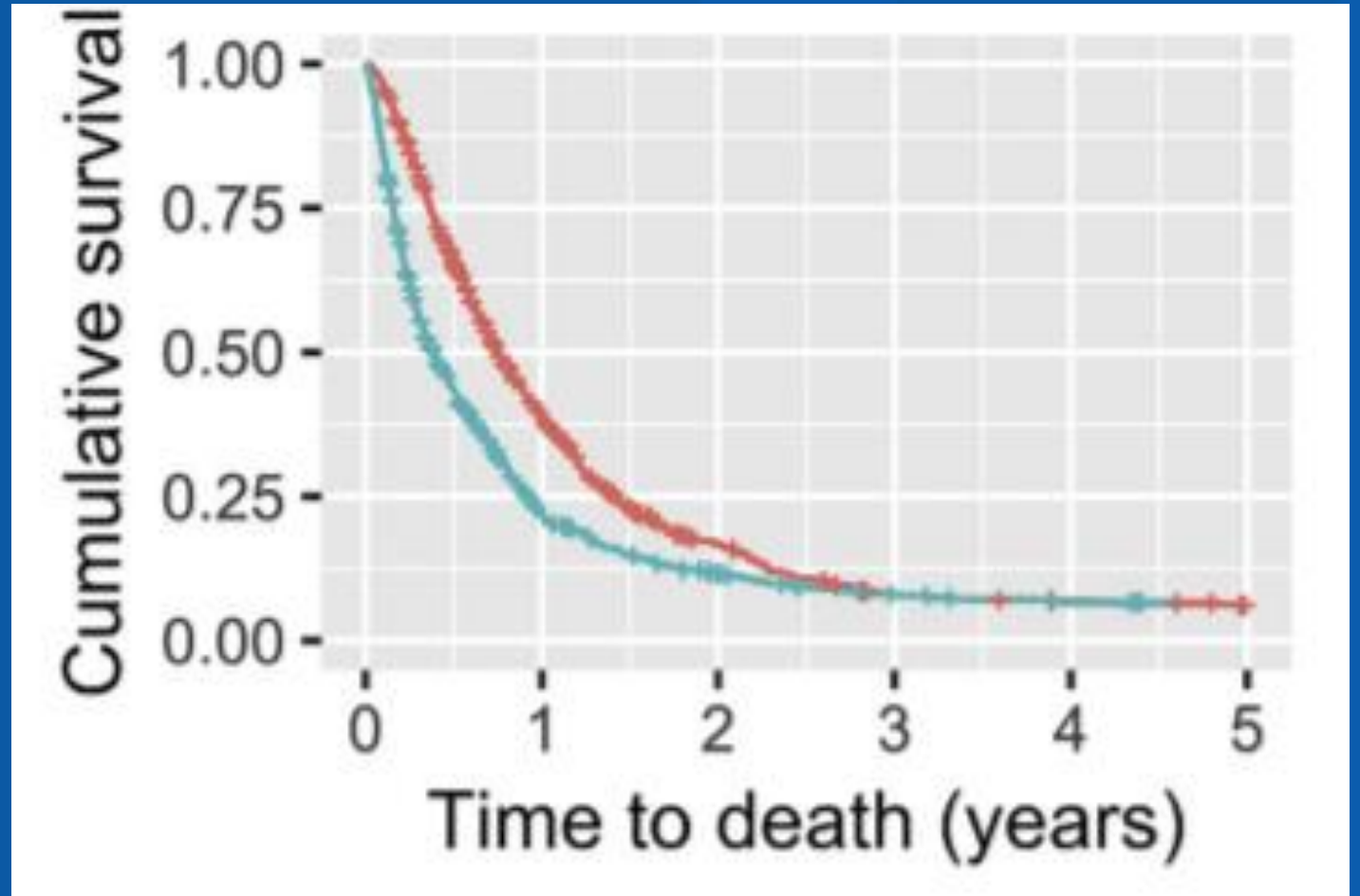


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# All patients

**PERT**

**Non PERT**

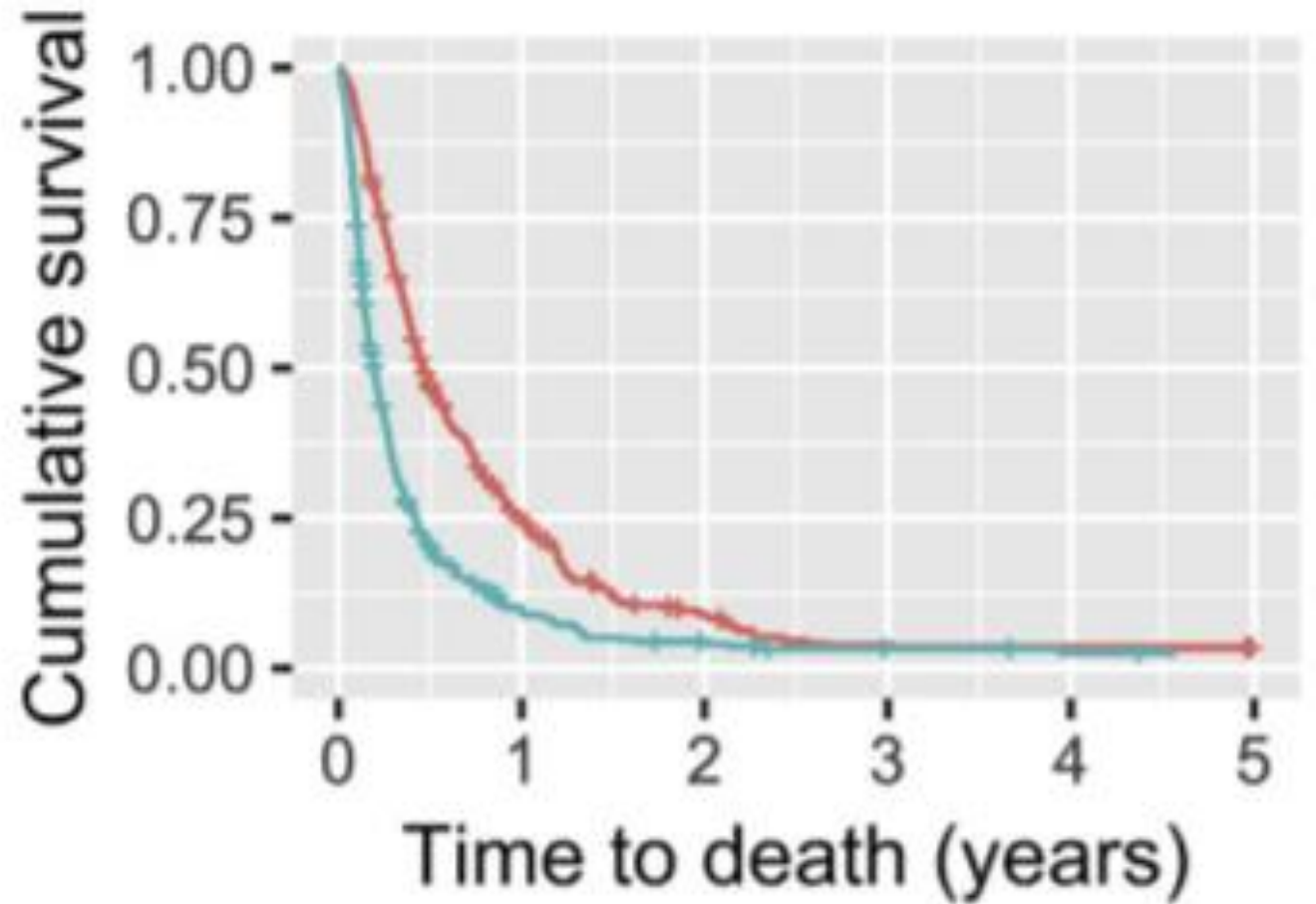


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# No surgery, no chemo

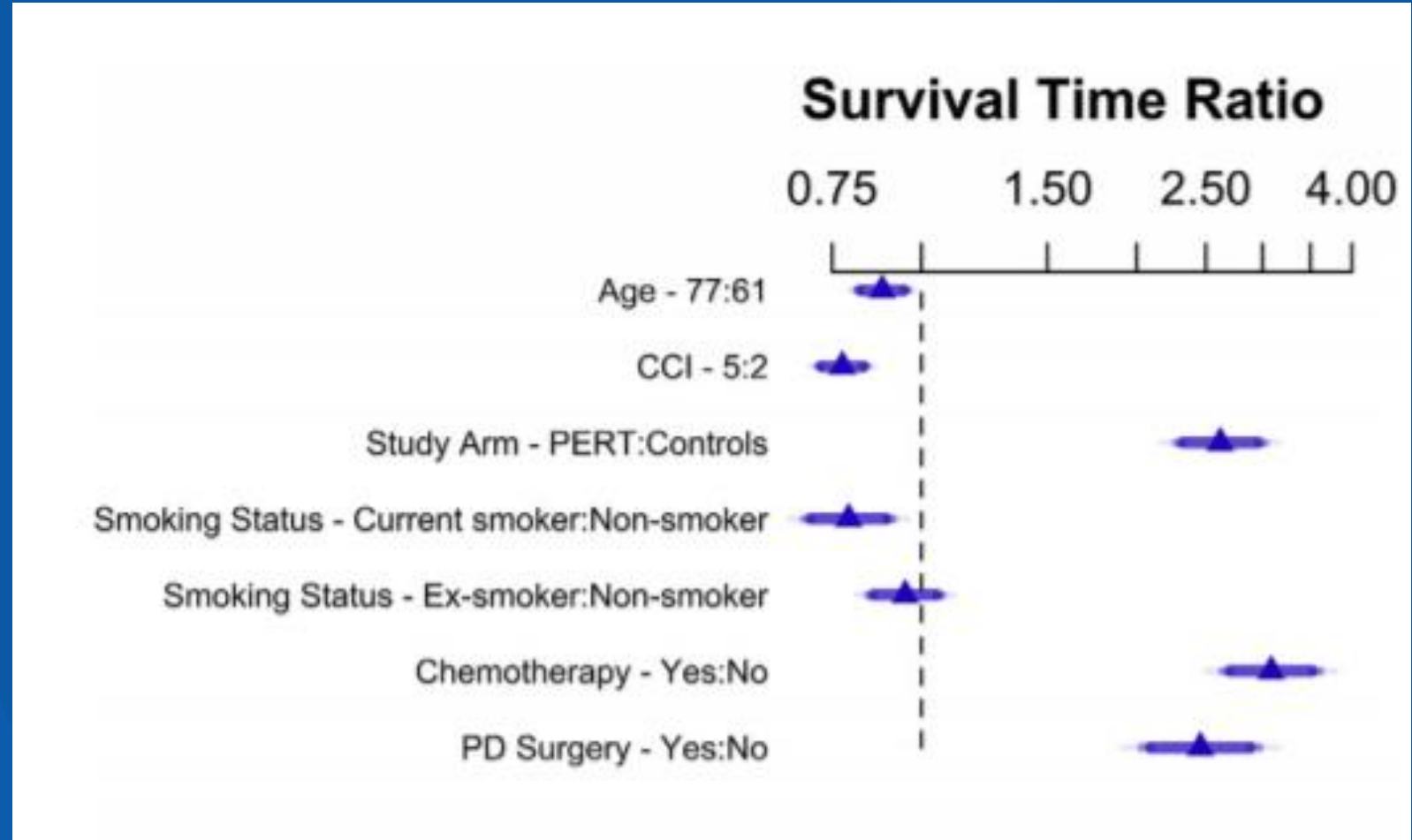
**PERT**

**Non PERT**



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# Factors influencing survival



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Roux Group  
Training | Education | Research



Pancreatic  
Cancer  
UK

BCTU  
Birmingham Clinical Trials Unit



AUGIS  
Association of Upper Gastrointestinal Surgery of  
Great Britain and Ireland

GBIHPBA  
Great Britain & Ireland Hepato Pancreato Biliary Association



bsg  
BRITISH SOCIETY OF  
GASTROENTEROLOGY



# 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 ( $p = 0.028$ )



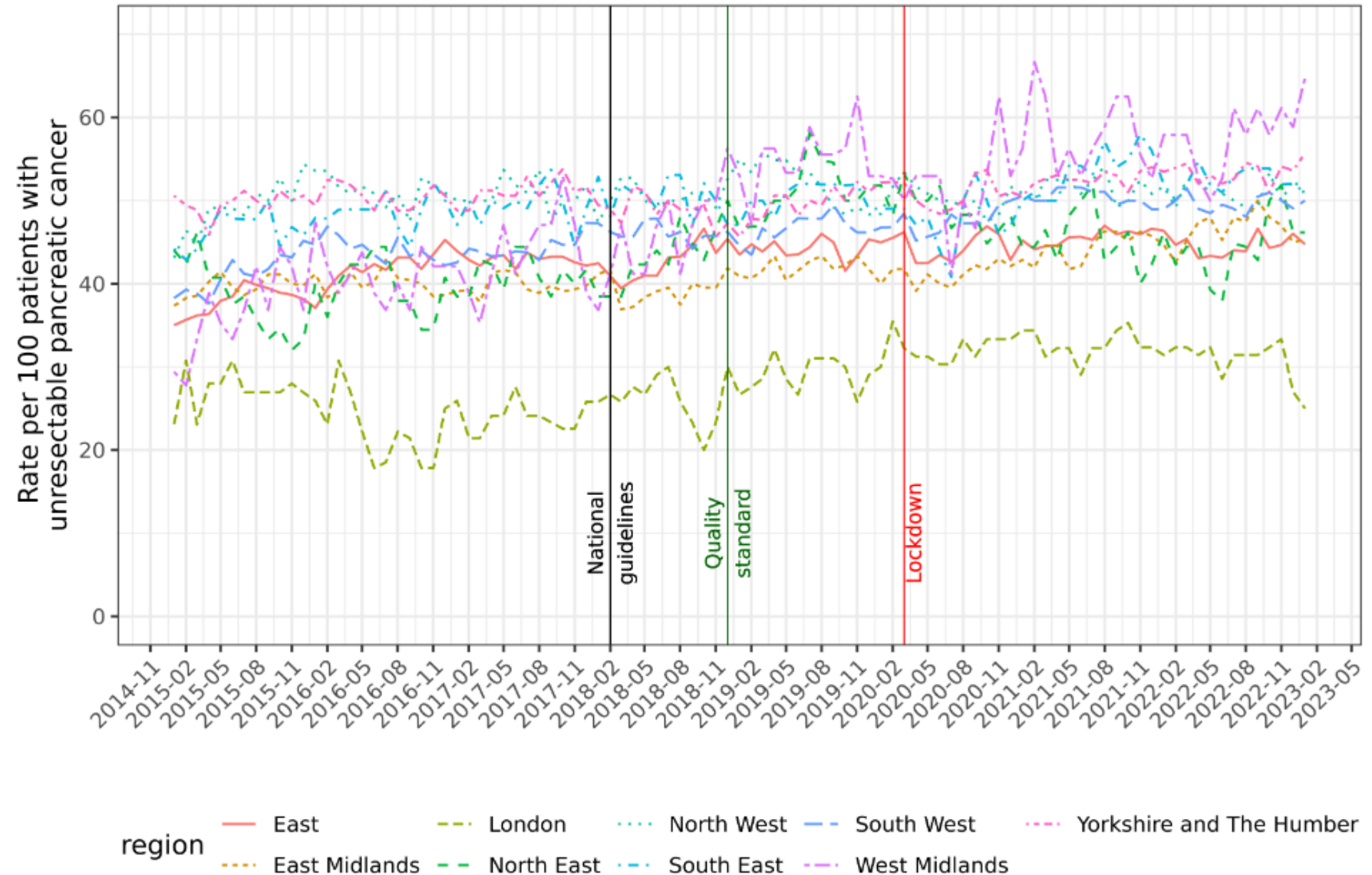


**The impact of the COVID-19 pandemic on prescribing of pancreatic enzyme replacement therapy for people with unresectable pancreatic cancer in England. A cohort study using OpenSafely-TPP**

Agneszka 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>

**Patients receiving enzyme replacement by Region in England**



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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)



# Sarcopenia and outcome.....



Applied nutritional investigation

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

Marta Sandini M.D.<sup>a</sup>, Davide P. Bernasconi Ph.D.<sup>b</sup>, Davide Fior M.D.<sup>c</sup>, Matilde Molinelli M.D.<sup>a</sup>, Davide Ippolito M.D.<sup>c</sup>, Luca Nespoli M.D.<sup>a</sup>, Riccardo Caccialanza M.D.<sup>d</sup>, Luca Gianotti M.D., Sc.D.<sup>a,\*</sup>

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

I. Ozola Zalite<sup>a</sup>, R. Zyklus<sup>b</sup>, M. Francisco Gonzalez<sup>c</sup>, F. Saygili<sup>d</sup>, A. Pukitis<sup>a,e</sup>, S. Gaujoux<sup>f,g</sup>, R.M. Charnley<sup>h</sup>, V. Lyadov<sup>i,\*</sup>

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

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

**Impact of Sarcopenia on Outcomes Following Resection of Pancreatic Adenocarcinoma**

**Development After Pancreaticoduodenectomy**

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



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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



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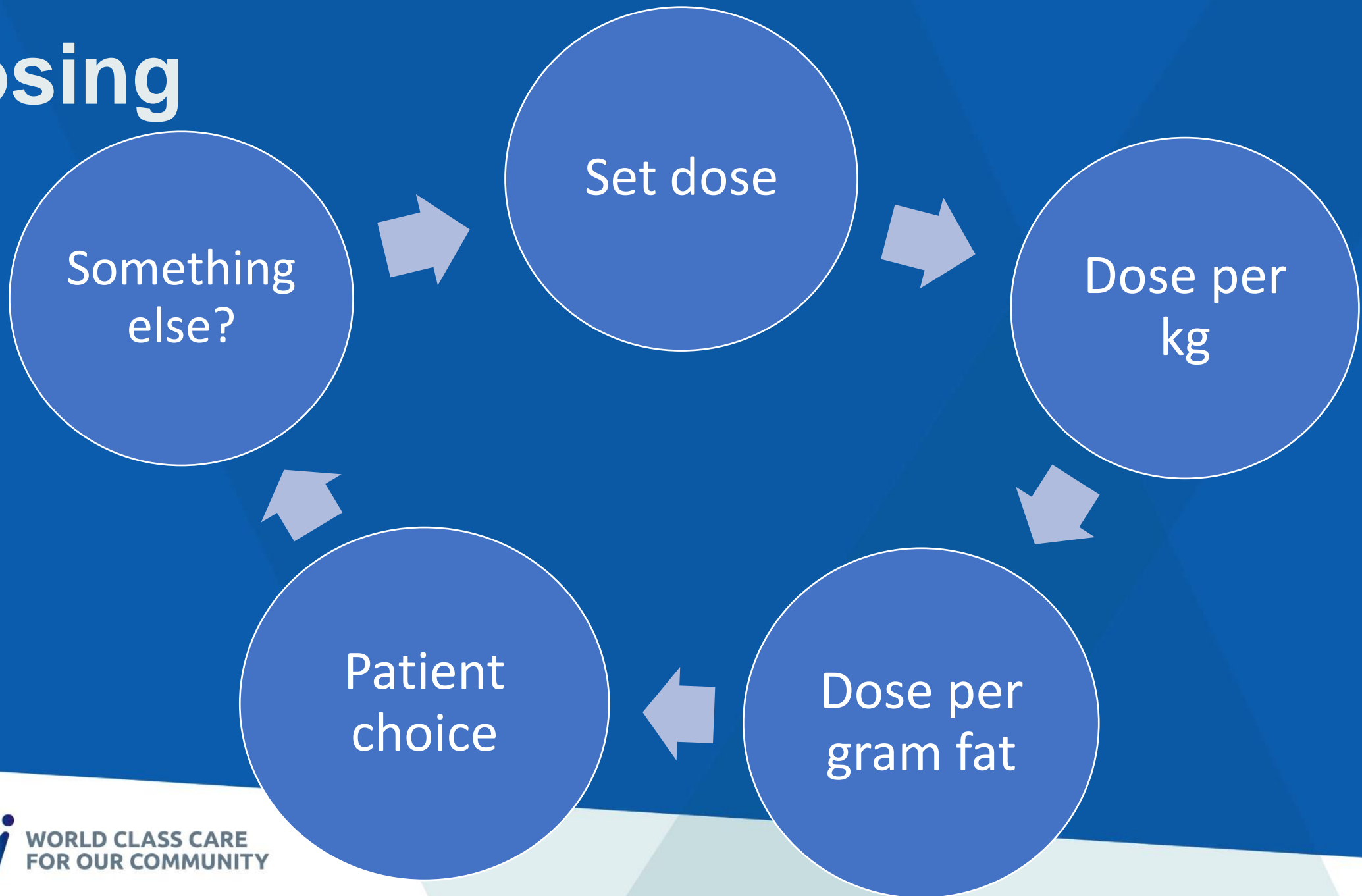


# How do the products compare?

	Amylase	Protease	Lipase
Creon micro (100mg)	3600	200	5000
Pancrex V capsule	9000	460	8000
Creon 10,000	8000	600	10000
Nutrizym 22	19800	1100	22000
Creon 25,000	18000	1000	25000
Pancrease HL	22500	1250	25000
Pancrex V powder (1g)	30000	1400	25000
Creon 40,000	DISCONTINUED		



# 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).



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

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

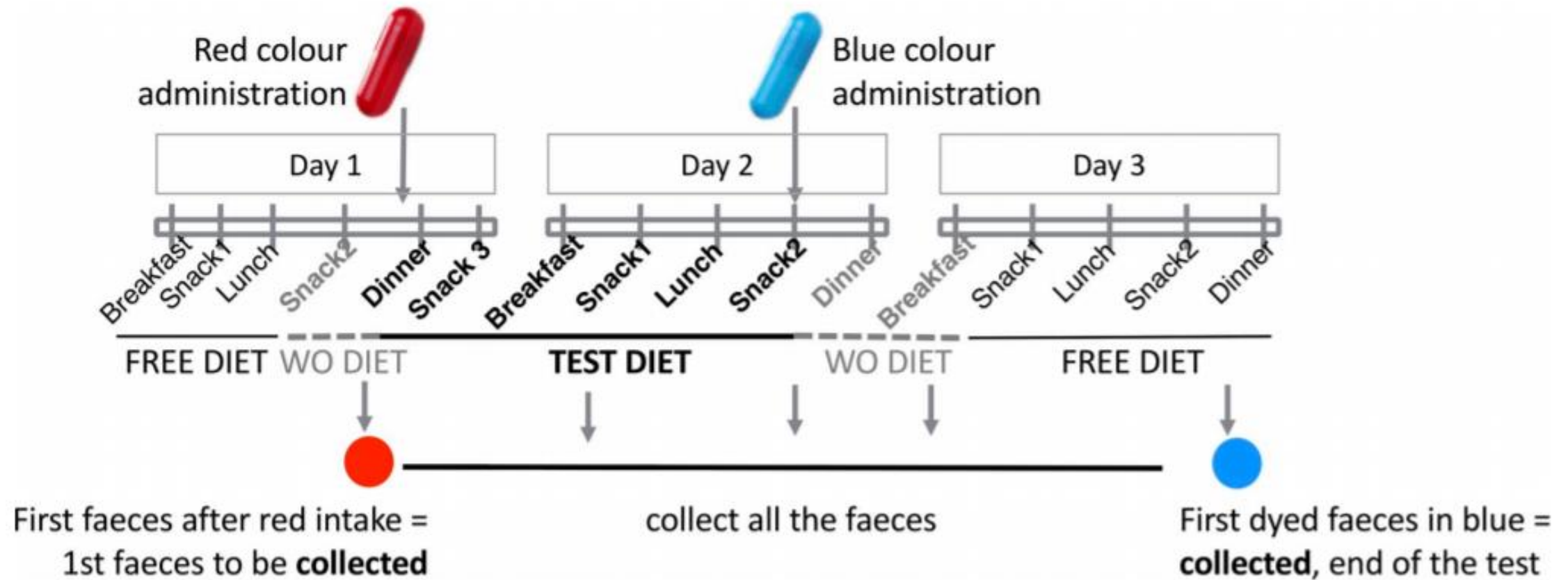


Royal Surrey  
NHS Foundation Trust

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



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

**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) ( $\beta_0$ )	2.839	[0.223, 36.147]	0.42
TOD ( $\beta_2$ )	0.999	[0.998, 1.000]	0.13
PPI intake ( $\beta_4$ )	1.367	[0.885, 2.115]	0.09
Age ( $\beta_3$ )	1.013	[0.961, 1.069]	0.62
Transit time ( $\beta_1$ )	1.815	[1.177, 2.797]	0.007

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





# 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.)



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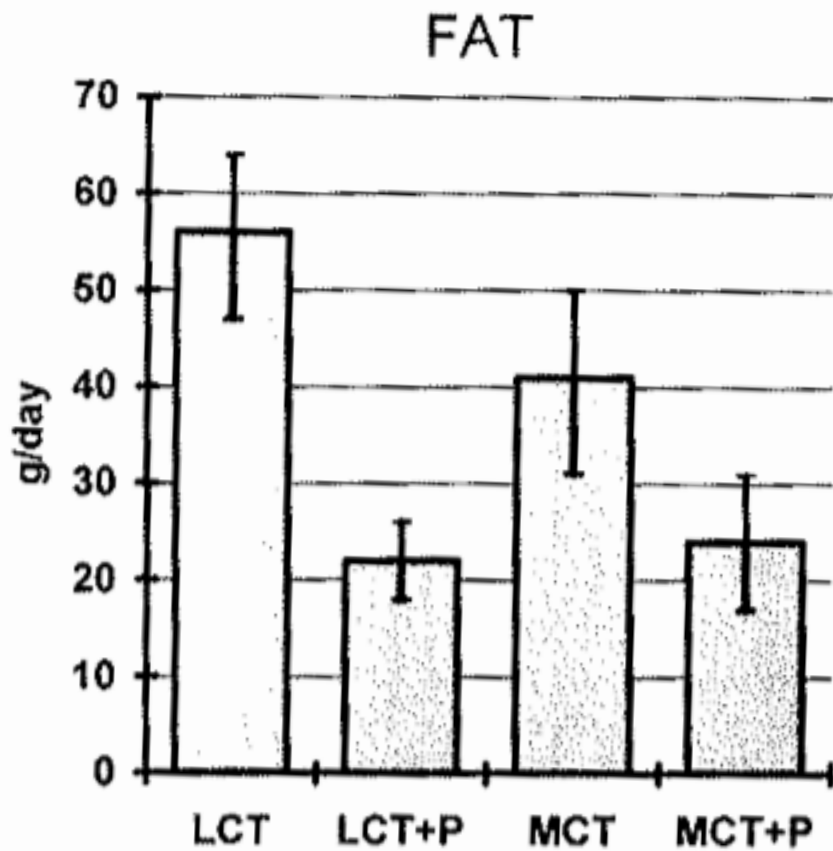


Fig. 2. Mean fecal fat losses (see Fig. 1).

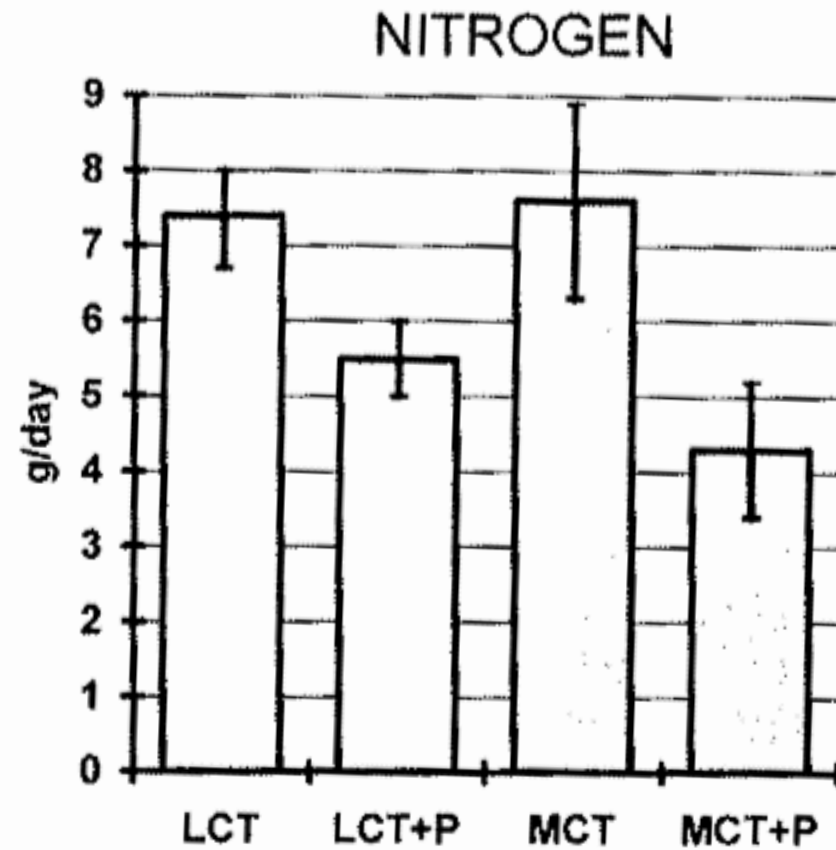


Fig. 4. Mean fecal nitrogen losses (see Fig. 1).



# Dosing used in clinical trials

Study	Cohort	Dose	Benefit
Kim et al, Clin Gastroenterol Hepatol. 2019	RCT n=304 Pancreatico-duodenectomy	40,000 units lipase with meals	Increase body weight; increased pre-albumin
Sato et al, <a href="#">Pancreas</a> . 2018 Aug;47(7):800-806	N=88 PDAC chemotherapy	48,000 units lipase with meals	No difference in nutritional markers in 8/52 trial Survival 19/12 vs. 12/12 (p=0.07)
Woo et al, <a href="#">Pancreatology</a> . 2016 Nov - Dec;16(6):1099-1105	N= 67 Unresectable PDAC	25,000 capsules x 6-9 per day	NO difference in nutritional markers or QOL in 8/52 trial
Bruno et al, <a href="#">Gut</a> . 1998 Jan;42(1):92-6	N = 21 Unresectable PDAC	50,000 units lipase with meals; 25,000 units with snacks	12% improvement in CFA; weight gain in intervention; weight loss in placebo



# 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



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# 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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## Pancreatic cancer in adults: diagnosis and management

NICE guideline

Published: 7 February 2018

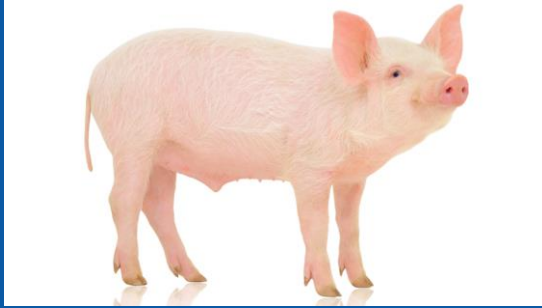
[nice.org.uk/guidance/ng85](https://www.nice.org.uk/guidance/ng85)

### 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.

# 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




- <25°C
- ?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 <sup>1</sup>, Andrew D Hopper,<sup>2</sup> John S Leeds <sup>3</sup>, Keith J Roberts <sup>4</sup>,  
Laura McGeeney,<sup>5</sup> Sinead N Duggan,<sup>6</sup> Rajesh Kumar<sup>7</sup>

# Contra-indications

---

## For Pancrease HL<sup>®</sup>

---

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

## For Nutrizym 22<sup>®</sup> 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



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# 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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- 78 year old female
- Metastatic pancreatic cancer – liver mets
- Declined palliative chemotherapy
- Bowels open once a day: type 1 (pellet type stool)
- Large volume hard stool
- Crampy abdominal pain
- 5% weight loss each month despite eating well
- Functionally well – caring for Grandchildren



# 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

- Taking high dose opioids for pain relief
- Commence laxatives
- Once bowel symptoms improved – then start PERT
- Biggest symptom was constipation



# Case 2

- 69 year old female
- Localised pancreatic ductal adenocarcinoma
- Distal pancreatectomy and splenectomy – 1cm lesion removed from tail of pancreas
- Bowels open 4 x a day loose and watery
- Gaining weight, 1-2kg per month
- Eating well



# 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



- Investigate:
  - Total specimen 2cm tail of pancreas
  - Head and body of pancreas enhances normally, no duct dilatation
  - Faecal elastase >500ug/g
  - Vitamin and mineral levels normal



# 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

# Outcome

- No nutritional compromise
- **PEI = Failure of the pancreas to secrete enough enzymes to achieve normal digestion**

## **PDAC is a Red Herring**

- Further investigations – diagnosed small intestinal bacterial overgrowth
- Symptoms resolved with antibiotics.



# 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.

