A Case-Based Exploration of Exocrine Pancreatic Insufficiency Webinar

Live Webinar: Thursday May 13, 2021 (1:00-2:00 pm EDT)

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This complimentary webinar has been made possible through with the generous support of Alcresta Therapeutics, Inc. Please note that Alcresta Therapeutics, Inc. provided financial support but did not have any input into the information presented in this webinar.

Course Description:

Do you have questions about Exocrine Pancreatic Insufficiency? Join Meghana Sathe, MD as she explores the pathophysiology of EPI and the normal function of the pancreas.

Course Objectives:

After completing this continuing education course, the learner should be able to:

1. Review normal anatomy of the pancreas.
2. Differentiate between endocrine and exocrine pancreatic function.
3. Focus on the pathophysiology of exocrine pancreatic insufficiency (EPI).
4. Discuss diagnostic approaches to EPI.
5. Review management of EPI with pancreatic replacement therapy (PERT) including oral PERT and in-line lipase only digestive cartridge.

Speaker Disclosures: Meghana Sathe, MD is a consultant for Alcresta Therapeutics and PBM BC Holdings. She is a representative for the Cystic Fibrosis Foundation, Children's Hospital of Philadelphia and the Academy of Nutrition and Dietetics. She has certified that no conflicts of interest exists for this program.

Professional Approvals: Becky Dorner & Associates, Inc. has been a Continuing Professional Education (CPE) Accredited Provider (NU004) with the Commission on Dietetic Registration since 2002.

This course is intended for: RDNs and CDEs/CDCES	**CDR Activity Type and Number:** Activity Type: 171 Live webinar 175 Recorded Webinar Activity number: 163010 163011 Recorded Webinar
Course CPE Hours: 1.0	**CDR Level:** 2
Suggested CDR Performance Indicators: 4.1.2, 4.2.7, 8.1.4, 8.3.1	

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Note: Numerous Other Learning Needs Codes and Performance Indicators May Apply.

How to Complete a CPE Course:
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Expiration Date for Recorded Webinar: May 6, 2024.

Questions? Please contact us at info@beckydorner.com

Becky Dorner & Associates

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Under "Tests/Certificates", you will see the tests for all products you have purchased or have been sent. You should see the course under Send or Use Additional Tests/Certificates. Click on "Use". Move up a little and click on Start to begin the process. If you are interrupted and cannot finish the test, you can save the test and come back to it at any point in time to finish it.

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Today's Webinar

Audio and Webinar
- Please refer to handout for instructions.

Handouts
- Emailed to the person who registered for the program.

Questions
- Use GoToMeeting to ask questions.

The program will last about 60 minutes.

Credit Hours/Certificate:
- Please refer to your handouts for detailed information.

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Today's Webinar

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ALCRESTA THERAPEUTICS

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Disclosures
Dr. Sathe is a consultant for Alcresta Therapeutics and PBM BC Holdings. She is a representative for the Cystic Fibrosis Foundation, the Cystic Fibrosis Foundation Data Safety Monitoring Board, Children's Hospital of Philadelphia, and the Academy of Nutrition and Dietetics. Dr. Sathe has certified that no conflicts of interest exists for this program.

Meghana Sathe, MD

- Pediatric Gastroenterologist
- Associate Fellowship Director of the Pediatric Gastroenterology and Nutrition Fellowship program at University of Texas Southwestern (UTSW)/Children's Health
- Co-director of the Pediatric Cystic Fibrosis Center and Therapeutic Development Center at UTSW/Children's Health
- Represented in the first DIGEST class as a mentee and now a current CRSP mentee
- Co-PI for GALAXY study looking at gastrointestinal manifestations of CF at baseline
- Passionate about training fellows in GI who have a special interest in CF care

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A CASE-BASED EXPLORATION OF EXOCRINE PANCREATIC INSUFFICIENCY

Meghana Sathe, MD
Associate Professor of Pediatric Gastroenterology, Hepatology & Nutrition
Associate Director of Pediatric Gastroenterology & Nutrition Fellowship
Co-Director Pediatric of Cystic Fibrosis Center and Therapeutic Drug Center

May 13, 2021

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OBJECTIVES

- Review normal anatomy of the pancreas
- Differentiate between endocrine and exocrine pancreatic function
- Focus on the pathophysiology of exocrine pancreatic insufficiency (EPI)
- Discuss diagnostic approaches to EPI
- Review management of EPI with pancreatic replacement therapy (PERT) including use of oral PERT and in-line lipase only digestive cartridge

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THE NORMAL PANCREAS

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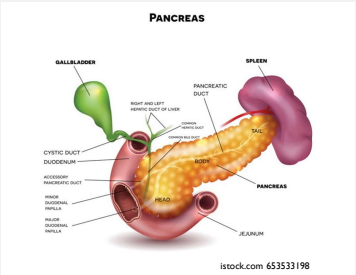
ANATOMY OF THE PANCREAS



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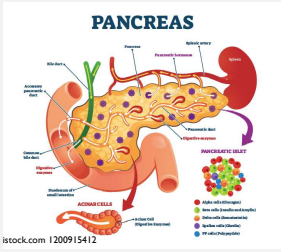
ENDOCRINE PANCREATIC FUNCTION

Located within the islets of Langerhans
- A cells – produce glucagon
- B cells – produce insulin
- D cells – produce somatostatin
- F cells – pancreatic polypeptide

Regulates glucose levels in the body



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Wyllie & Hyams, 3rd edition, Chapter 68 (1005-1041).

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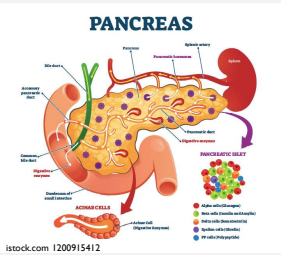
EXOCRINE PANCREATIC FUNCTION

Produces and stores pancreatic enzymes
- Pancreatic enzymes help digest food (carbohydrates, protein, and fats) into absorbable parts

Releases and delivers pancreatic enzymes to the small intestine where digestion takes place

Produces bicarbonate
- Contributes to the pH of the small intestine

Delivers bicarbonate to the small intestine



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Wyllie & Hyams, 3rd edition, Chapter 68 (1005-1041).

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FOCUS ON: THE EXOCRINE PANCREAS

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TYPES OF EXOCRINE PANCREATIC CELLS

Acinar cells
- Proteins and digestive enzymes are synthesized
- Enzymes are sorted and packaged into zymogen (inactive precursor enzyme) granules
- Proteins are involved in transportation of zymogen granules
- Receptors for secretagogues – CCK (cholecystokinin),VIP (vasoactive intestinal peptide)

Centroacinar or duct cells
- Secretion of HCO_3 rich fluid
  - 1 L of pancreatic juice is secreted into the small intestine per day
- Receptors for secretin

Wyllie & Hyams, 3rd edition, Chapter 68 (1005-1041).

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PANCREATIC ENZYMES

Digestive enzymes
- Proteolytic (protein), lipolytic (fats), amylolytic (carbohydrates)

Pro-enzymes
- Zymogens → need the alkaline solution within the pancreatic ducts and duodenum to activate

Trypsin inhibitors

Wyllie & Hyams, 3rd edition, Chapter 68 (1005-1041).

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BICARBONATE

HCO_3 neutralizes gastric acid
- Needed for pH optima of pancreatic enzymes and micelles

HCO_3 secretion ⟹ Fluid secretion

HCO_3 allows mucins to unfold / hydrate

Promotes bacterial killing

Wyllie & Hyams, 3rd edition, Chapter 68 (1005-1041).

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REGULATION OF PANCREATIC SECRETION

Interdigestive (Basal and fasting states)
- Pancreatic secretion of enzymes and bicarbonate follow the migrating myoelectric complex (MMC) within the intestine
- Every 60-120 minutes, there is an increase in gastric acid, bile and pancreatic secretions within the duodenum to "clear" residual food

Digestive (Postprandial)
- Cephalic
- Gastric
- Intestinal

Wyllie & Hyams, 3rd edition, Chapter 68 (1005-1041).

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POSTPRANDIAL PANCREATIC SECRETION

Cephalic (20%)
- Mediated via the vagus nerve in response to sight, smell, taste, and thought of food
- Release a significant quantity of enzymes and lesser amount of bicarbonate
- Rise in plasma gastrin, CCK and secretin and elevation of inhibitory hormones pancreatic polypeptide and leptin

Gastric (10%)
- Increasing rate of pancreatic secretion as stomach distends

Intestinal (70%) – MOST IMPORTANT PHASE
- When food, chyme and gastric juice enter duodenum
- Major neurohormonal mediators – CCK and secretin

Wyllie & Hyams, 3rd edition, Chapter 68 (1005-1041).

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PANCREATIC STIMULATORY & INHIBITORY FACTORS

Stimulatory	Inhibitory
• Cholecystokinin (CCK) • Secretin • VIP • Gastrin-releasing peptide (GRP) • Insulin • Gastrin • Nitric Oxide (NO) • Serotonin • Substance P • Pancreatic phospholipase A2 • Natriuretic peptides (ANP, CNP) • Melatonin • Adenosine	• Somatostatin • Pancreatic polypeptide (PP) • Peptide YY • Neuropeptide Y • Calcitonin gene-related peptide (CGRP) • Glucagon • Serotonin • Enkephalins • Leptin • Ghrelin

Wyllie & Hyams, 3rd edition, Chapter 68 (1005-1041).

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CASE 1

20-year-old male with history of chronic recurrent pancreatitis presents to your clinic for follow-up with new onset of abdominal pain, gas, and bloating. In addition, he is having diarrhea every time he eats, worse with burgers and tacos, which are his staples. He is most concerned that it smells terrible. He is hoping to move in with his girlfriend and needs to figure out what is going on before he moves in. You note that he has lost 10 pounds since his last visit, which he comments is unintentional. In fact, he has been trying to gain weight. Which of his symptoms make you suspicious of exocrine pancreatic insufficiency?

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CASE 1

A. Gas and bloating
B. Foul-smelling stool with greasy meals
C. Weight loss
D. All of the above

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EXOCRINE PANCREATIC INSUFFICIENCY (EPI)

Defined as inadequate function or decreased number of pancreatic enzymes in the duodenal lumen → Maldigestion and Malabsorption

- Fats
- Proteins
- Carbohydrates

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Symptoms noted once there is loss of 90% of exocrine pancreatic enzyme function

Wyllie & Hyams, 3rd edition, Chapter 68 (1005-1041).
J Pancreas. 2019;20(5):126-129.
Nutr Clin Pract. 2019;34(1):S27–S42.

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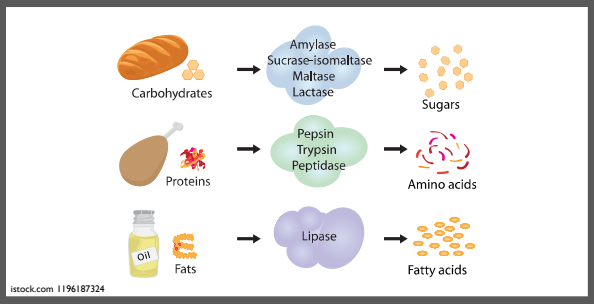

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PATHOPHYSIOLOGY OF EPI

Inadequate production and delivery of pancreatic enzymes

Pancreatic duct obstruction

- Impacting delivery

Decreased enzyme activity in the bowel

- Decreased hormonal stimulation
- Rapid transit
- Inadequate mixing of chyme
- Acidic pH in proximal duodenum

J Pancreas. 2019;20(5):126-129.
Nutr Clin Pract. 2019;34(1):S27–S42.

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CAUSES OF EPI

Etiology	Mechanism
Cystic Fibrosis, chronic ancreatitis, diabetes mellitus	Decreased pancreatic enzyme production and delivery
Tumors	Pancreatic duct obstruction
Celiac disease, Crohn's, Schwachman-Diamond Syndrome, Johanson-Blizzard Syndrome, Pearson's Syndrome, pancreatic agenesis	Decreased endogenous pancreatic enzyme stimulation and production
Gastrectomy, gastric bypass, extensive small bowel resection	Motility disorder (decreased contact time, decreased interaction with chyme, decreased stimulation of pancreatic enzymes)
All infants up to 6 months	Lack of lipase and amylase synthesis
Hereditary hemochromatosis	Iron deposition in pancreas
Zollinger-Ellison syndrome	Inactivation of pancreatic enzymes due to increase in gastric acid

J Pancreas. 2019;20(5):126-129.
Nutr Clin Pract. 2019;34(1):S27–S42.

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CASE 2

30-year-old male with history of EPI and a history of non-compliance with medication presents to clinic with a complaint that he is having difficulty driving at night. What vitamin deficiency related to his EPI is likely responsible for his troubles?

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CASE 2

A. Vitamin A
B. Vitamin D
C. Vitamin E
D. Vitamin K
E. Essential Fatty Acid Deficiency

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CLINICAL MANIFESTATIONS OF EPI

Steatorrhea

- Oily, foul smelling stools

Abdominal Symptoms

- Diarrhea
- Bloating
- Abdominal Pain
- Flatulence
- Rectal prolapse

Fat-Soluble Vitamin Deficiency (A, D, E, K)

- Vitamin A deficiency = Increased intracranial pressure (ICP) and night blindness
- Vitamin D deficiency = Bone disease
- Vitamin K deficiency = Coagulopathy
- Vitamin E deficiency = Neuromuscular abnormalities and hemolysis

Nutr Clin Pract. 2019;34(1):S27–S42.

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CASE 3

A 2-year-old with a new diagnosis of Schwachman-Diamond Syndrome was referred to your clinic by Hematology/Oncology and now presents for evaluation of poor weight gain. Mom wants to know how you determine whether he has pancreatic insufficiency.

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CASE 3

A. 72-hour fecal fat test
B. Fecal elastase-1
C. Immunoreactive trypsinogen
D. Empiric trial of pancreatic replacement therapy (PERT)

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HOW TO DIAGNOSIS EPI

Best Test: Fecal fat balance studies

Endoscopic Pancreatic Function Test (ePFT)
- Requires direct duodenal intubation, stimulation with secretin or cholecystokinin, followed by collection of pancreatic secretions for pH and enzyme analysis

Serum Immunoreactive Trypsinogen

Fecal Elastase-1: Easy to obtain, most often used today

J Pancreas. 2019;20(5):126-129.
Nutr Clin Pract. 2019;34(1):S27–S42.
JPGN. 2021;72: 144–150.

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FECAL FAT BALANCE STUDY

72 hour of dietary intake and stool collection
- Malabsorption is considered >7g/day
  - >10g/day for formula fed infants
  - >2g/day for breastfed infants
- Expressed as fat absorption coefficient or coefficient of fat absorption(CFA):
  - Difference between quantity of fat ingested and quantity of fat in feces
    [(Fat ingested – Fat excreted) / Fat ingested] x 100%
  - 90-95% in healthy children and adults
- Major limitation of test is collection process in home setting

J Pancreas. 2019;20(5):126-129.
Nutr Clin Pract. 2019;34(1):S27–S42.

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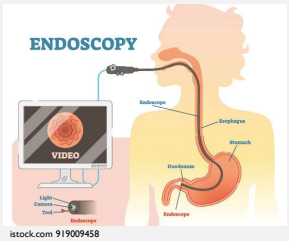
ENDOSCOPIC PFT



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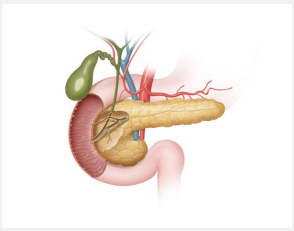
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JPGN. 2021;72: 144–150.

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FECAL ELASTASE-1

Fecal Elastase-1 is an enzyme synthesized by the pancreas and passed into intestinal tract without degradation

Species-specific, so can be differentiated from PERT (porcine elastase)

Stable at room temperature
- Easily collectible at home

Good tool for dichotomous results:
Pancreatic Insufficiency (PI) vs Pancreatic Sufficiency (PS)

J Pancreas. 2019;20(5):126-129.
Nutr Clin Pract. 2019;34(1):S27–S42.

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CASE 4

A 40-year-old female with newly diagnosed EPI wants to know what the goal of starting PERT is.

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CASE 4

A. Normalize digestion
B. Provide clinical improvement in EPI symptoms
C. A and B
D. Improve pancreatic function with time so she no longer needs PERT

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EPI TREATMENT

GOALS

- Normalize digestion
  - Prevent malnutrition-related morbidity and mortality
- Alleviate EPI-related clinical symptoms

TREATMENT = Pancreatic enzyme replacement therapy (PERT)

- Lifestyle – avoidance of smoking and alcohol
- Diet – small frequent meals, normal to high fat intake, fat-soluble vitamin supplementation
- Follow-up – symptoms of maldigestion, weight & weight-for-length/body mass index (BMI), nutritional markers

J Pancreas. 2019;20(5):126-129.

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CASE 5

A 13-year-old boy with history of cystic fibrosis (CF) has been more involved in the treatment of his condition. He wants to understand what foods he must take PERT with. He knows he needs it with breakfast, lunch and dinner, but snacks confuse him. Which snack doesn't require PERT?

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CASE 5

A. Apple
B. A candy bar with chocolate
C. Protein shake
D. Trail mix

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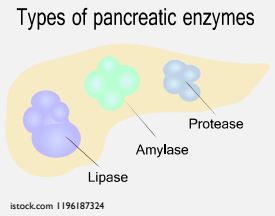
WHAT EXACTLY IS IN PANCREATIC ENZYME REPLACEMENT THERAPY?



- Lipase: breaks down fat
- Amylase: breaks down starch (sugar)
- Protease: breaks down proteins

- Some also contain:
  - Bicarbonate
  - Ursodiol (binder)

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PERT

Pancreatic enzyme replacement therapy (PERT) – extracts from porcine pancreas (pancrelipase)
- Dependent on availability of pigs
- Theoretical viral transmission
- Do not mimic native enzymes 100%
- Contain purines – possibly a risk for patients with gout, renal disease, and hyperuricemia

Enteric coated microspheric preparations or non-coated
- pH sensitive (Readily dissolve at pH >5.5 to 6)
- Non-enteric coated preparation is activated immediately

Lipase ONLY in-line digestive cartridge for enteral feedings

World J Gastroenterol. 2014;20(33): 11467-11485
JPGN. 2017;65: 97–101.

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HISTORY OF PERT

Pre 2010	2010 and After
FDA approval not required	FDA approval required
Variable consistency and activity	Consistent efficacy
Generic/OTC formulations	Prescription
Confusion overdosing & administration	Confusion overdosing & administration

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FIBROSING COLONOPATHY

Intraluminal non-inflammatory fibrosing process that affects proximal colon
- Associated with obstruction +/- pain, diarrhea and rectal bleeding
- Diagnosed with contrast study
- Confirm with colonoscopy and biopsy
- Treatment is surgical resection of fibrotic region

Occurred frequently after introduction of high dose PERT
- Great than 6,000 lipase units/kg/meal for >6 months

Now rarely seen
- New guidelines = Maximal dose of PERT 10,000 lipase units/kg/day (2,500 lipase units/kg/meal)
- New formulations that are FDA approved

N Engl J Med. 1997;336:1283-9.
J Pediatr. 1995;127:681-84.

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GUIDANCE TO PERT (FROM CFF GUIDELINES)

INFANTS: 2,000-4,000 lipase units/120ml formula OR breast milk

CHILDREN <4 years: 1,000 lipase units/kg/meal

CHILDREN >4 years: 500 lipase units/kg/meal

Maximum dose is 2,500 lipase units/kg/meal and 10,000 lipase units/kg/day
- Usually, ½ meal dose for snack

Fat-based dosing: 500-4000 lipase per gram of fat in meal

J Pediatr. 1995; 127:681-84.

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CASE 6

A 5-year-old male with EPI comes to your clinic for follow-up. He has gained weight nicely since you last saw him almost 6 months ago. Mom has noticed that lately it's much harder to clean the toilet he uses; there seems to be a ring of grease around the bowl. In addition, she has noticed that he has been having more frequent, looser, foul-smelling stools. His current PERT contains 6000 lipase units per capsule. He has just mastered swallowing pills. He is currently taking 2 capsules with meals and 1 with snacks. He consistently eats 3 meals and 2 snacks. What would be the most appropriate dose adjustment?

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CASE 6

A. He doesn't need a dose adjustment. He gained weight.
B. 4 with meals, 2 with snacks, max of 25 per day
C. He doesn't need a dose adjustment. He needs to be treated for small intestinal bacterial overgrowth (SIBO).
D. 6 with meals and 4 with snacks, max of 25 per day

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CASE 6

Currently, with 2 capsules of 6000 lipase units/capsule and a weight of 15 kg, he is getting:

lipase units x number of capsules/weight in kg = lipase units/kg/meal

6000 x 2/15 = 800 lipase units/kg/meal

But he is symptomatic, so an increase in dosing is required

With 4 capsules = 1,600 lipase units/kg/meal

With 6 capsules = 2,400 lipase units/kg/meal

Max per day = (weight x 10,000) / lipase units in capsule

(15 kg x 10,000) / 6000 = 25

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CASE 7

A 42-year-old female with EPI comes in for follow-up complaining of gas and bloating. She reports compliance with taking enzymes and is taking the dose as prescribed. She has also been having some looser stools. You find out that she recently started a new job and has adopted a baby. Life is a bit more hectic these days. What question would allow you to elicit why she is suddenly having symptoms of EPI?

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CASE 7

A. When is she taking her enzymes?
B. What foods is she eating?
C. What is the baby eating?
D. Is she finding time to exercise?

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BEST PRACTICE GUIDELINES

Dosing	• Take with the 1st bite of a meal • Consider adding on during or towards end of meal – especially if long, slow meal over 1 hour • Try to mimic effects of exocrine pancreas in relation to the quantity of food and type of fat
Hydration Alkaline pH	• Ensure adequate hydration, particularly in CF patients due to impaired bicarbonate/fluid secretion • Consider acid blockade?
Common Side Effects	• Headache, dizziness, abdominal pain • Perceived constipation • Older formulations associated with hyperuricemia and hyperuricosuria

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All enzymes were required to be FDA approved between 2009-2012

Enzyme Brand	Commonalities	Differences
Creon, Zenpep, Pancreaze	Lipase, amylase, protease	Variations in size of beads
Pertyze	Lipase, amylase, protease	Ursodiol binder and Bicarbonate 4000s FDA-approved for 14 French G-tube
Viokase	Lipase, amylase, protease	ONLY tablet Not enteric coated Recommend use of proton pump inhibitor (PPI) in conjunction
Relizorb	Lipase only	Lipase ONLY in-line digestive cartridge for enteral tube feeding

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CASE 8

A 19-year-old female with long-standing history of short-gut syndrome is coming in for follow-up after 1 month of restarting gastrostomy tube feedings because she was losing significant weight since starting college. She has been trying to run the 3 cans of formula that she is supposed to and takes her PERT before starting her feeds, however, she feels extremely bloated in the morning and has to rush to the bathroom. In fact, the urgency wakes her up and she finds herself fatigued all the time. She has not been able to gain weight in the last month as it's been hard to be consistent with this new regimen. What change in her PERT might aid digestion of her feeds?

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CASE 8

A. Increasing her PERT dose before starting the feeds
B. Having her redose her PERT in the middle of the night
C. Using the lipase ONLY in-line digestive cartridge
D. Changing her formula

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NUTRITIONAL RECOMMENDATIONS

- Energy
  - 150-200% RDA with 40% as long-chain triglycerides (LCT)
  - May require additional calories via nasogastric OR gastric feeds
- Protein
  - 100% RDA
- Fat-soluble vitamins supplementations
  - Utilizing water-soluble formulations of fat-soluble vitamins
  - Take with PERT to optimize absorption
  - Following deficiencies till correction and then monitor maintenance

Nutr Clin Pract. 2019;34(1):S27–S42.

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CASE 9

A 27-year-old male with EPI works for a construction company in Texas. He comes in for follow-up and reports that his PERT just doesn't seem to be working. This seems to happen every summer. He doesn't understand. He always takes his PERT before meals, even at work. He always has his PERT with him in the glove compartment of his truck and he keeps his lunch in a cooler right below the glove compartment, so he won't forget to take his PERT with his lunch. He is very compliant. He doesn't understand what he is doing wrong. What change in his behavior might improve the efficacy of his PERT?

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CASE 9

A. Take PERT after lunch, not before
B. Put the PERT in the cooler with his lunch
C. Just skip lunch
D. PERT never works in the summer

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FACTORS LEADING TO FAILURE OF EPI

- Nonadherence to prescribed dosing
- Expired enzymes
- Inactivated enzymes due to prolonged exposure to heat
- Highly acidic small intestinal environment
- Prolonged exposure of microspheres to alkaline foods
- Taking enzymes after eating
- "Grazing"
- Generic enzymes with lower potency
- Chewed or crushed microspheres
- Inadequate dose of enzymes reaching small intestine

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GI COMORBIDITIES LEADING TO "PERT FAILURE"

- Lactose intolerance
- Enteric infection
- Parasite – giardia
- Small intestinal bacterial overgrowth (SIBO)
  - Empiric treatment versus breath test
- Biliary disease (cholestasis)
- Clostridium difficile
- Celiac disease
- Short bowel syndrome
- Crohn's disease
- Motility disorder
- Recurrent abdominal pain / Irritable Bowel Syndrome

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SUMMARY

- EPI can be due to a range of etiologies but presents similarly which symptoms of steatorrhea, malodorous stool, weight-loss and fat-soluble vitamin deficiency
- PERT can be successful treated with addition of oral PERT prior to meals and snacks, increase of caloric intake and supplementation with water-soluble formulations of fat-soluble vitamins
- Some patients with EPI cannot consume the recommended calories for growth and development orally and require the use of supplemental enteral feedings
- The in-line LIPASE only cartridge should be utilized in conjunction with enteral feedings to optimize absorption of fats
- In patients' adherent to PERT but symptomatic, dose adjustment should be consider exploring common pitfalls leading to failure of EPI and potential GI comorbidities that may need to be evaluated for and treated

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Thank You!

Credit Hours:

- Please refer to your handouts for detailed information on how to obtain your certificate.
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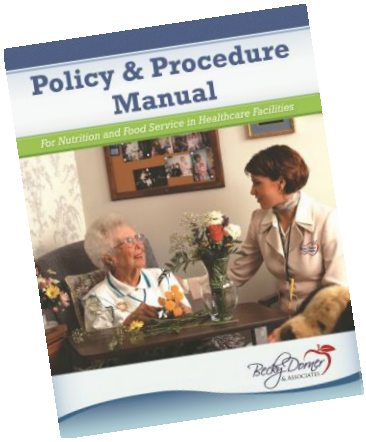

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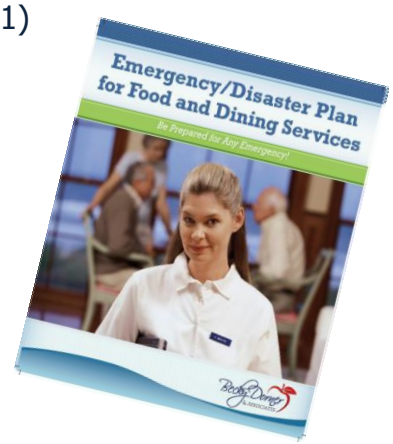

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