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THE PANCREAS UNIT IN THE DEPARTMENT OF GASTROENTEROLOGY. ORGANISATIONAL AND FUNCTIONAL STANDARDS FOR A PATIENT-CENTERED PRACTICE

Study population

The Spanish Association of Pancreatology (AESPANC), the Spanish Association of Gastroenterology (AEG) and the Spanish Society of Digestive Diseases (SEPD) have drawn up a consensus document on the standards and recommendations related to the organisation, structure, service portfolio, care processes, training and research that a Pancreas Unit must meet in order to be certified.

Methods

A steering committee was set up to develop the standards proposal and make strategic decisions for the project.

Criteria for the structure, organisation and functioning of the Pancreas Unit were established according to the scientific evidence.

The draft standards for pancreas units were submitted to the boards of AESPANC, AEG and SEPD for comment and approval.

Outcomes

The standards developed should be reviewed after no more than five years on the basis of scientific developments in pancreatic disease.

Providing indicators of health outcomes, including patient-reported outcomes (PROMs), and evidence on the association of structural and activity standards with health outcomes is identified as a relevant challenge.

Domínguez-Muñoz J.E., et al.

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Pancreas units within gastroenterology departments. Organizational and operational standards for a patient-centered service

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Artificial intelligence: the authors declare that they did not use artificial intelligence (AI) or any AI-assisted technologies in the elaboration of the article.

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Lay summary

The Asociación Española de Pancreatología (AESPANC), Asociación Española de Gastroenterología (AEG), and Sociedad Española de Patología Digestiva (SEPD) have developed a consensus document on the characteristics and recommendations that are deemed essential for the organization of pancreas units within gastroenterology services (GSs). The goal is to facilitate that such units develop their care activities with efficiency and quality. The consensus document defines pancreas units and lays down the characteristics they should have in terms of organization, structure, care services on offer, and teaching and research activities. Some of these characteristics are mandatory requirements whereas others represent recommendations. Compliance with these characteristics will render Pancreas Units eligible for excellence certification. These characteristics will be updated according to advances in the understanding of pancreatic disease. Finally, pancreas units must define indicators allowing to assess their results and their impact in terms of health.

ABSTRACT

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The Asociación Española de Pancreatología (AESPANC), Asociación Española de Gastroenterología (AEG), and Sociedad Española de Patología Digestiva (SEPD) have developed a consensus document on the standards and recommendations they consider essential for the organization of pancreas units (PUs) within gastroenterology services (GSs) in order to conduct their activities in an efficient, high-quality manner. The consensus document defines PUs and lays down standards relating to their organization, structure, service portfolio, processes, and teaching and research activities. Standards have been categorized as mandatory (requirements to be met to qualify for certification by the scientific societies responsible for the standards) or recommendations. Standards should be updated at most within five years based on the experience gained in Spanish PUs and the advance of knowledge regarding pancreas disease. Development of health outcome indicators, including patient-reported outcome measures (PROMs), is considered a relevant challenge, as is evidence on the association of PU structure and activity standards with health outcomes.

Keywords: Pancreas units. Care processes. Quality standards. Clinical protocols. Certification.

INTRODUCTION

The relevance of pancreatic conditions in terms of incidence, prevalence, severity and financial impact, and the challenge their diagnosis and associated therapeutic decisions commonly represent in clinical practice warrant the need to develop pancreas units (PUs) (1,2). In fact, while acute pancreatitis is one of the most common reasons for hospital admission in gastroenterology services (GSs) in developed countries (3), pancreatic cancer is one of the main causes of cancer-related death and a major clinical challenge for the upcoming years (4). Furthermore, the high morbidity and mortality of acute pancreatitis (3,5,6), the high risk for complications and mortality of chronic pancreatitis (7), the high mortality rate of pancreatic cancer, similar to its incidence (4), and difficult decision-

making in patients with pancreatic cystic neoplasms are all well-known (8).

By accepting the necessary multidisciplinary approach to these conditions, the gradual development of medical and minimally invasive therapies over the past few years has resulted in an increased need for both specific education and training of gastroenterologists, and specific resources and management at GSs. The role of gastroenterologists has become highly relevant in the diagnosis and treatment of pancreatic conditions.

As an antecedent to the development of PU standards the Ministry of Health initiative in collaboration with the Spanish Asociation of Gastroenterology *(Asociación Española de Gastroenterología - AEG),* Spanish Society of Gastroenterology *(Sociedad Española de Aparato Digestivo - SEPD),* and other scientific societies should be mentioned, which resulted in the document *Estándares y Recomendaciones de las Unidades del Aparato Digestivo* (9). SEPD has developed quality indicators for gastrointestinal endoscopy (10), colonoscopy (11), enteroscopy (12), gastroscopy (13) and ERCP (14). AEG has developed indicators for colonoscopy (15,16) and gastroscopy (17), and in 2019 published quality standards for GSs (18). The Spanish Working Group of Crohn´s disease and ulcerous colitis *(Grupo Español de Trabajo de Enfermedad de Crohn y Colitis Ulcerosa - GETECCU)* in 2014 identified quality indicators for integral care units (19), which were revised in 2021 by incorporating indicators derived from the *patient reported outcomes measures* (PROM) and *patient reported experience measures* (PREM), issued by the International Consortium for Health Outcomes Measurement (ICHOM) (20). The Catalan Society of Digestology *(Sociedad Catalana de Digestología)* and the Catalan Society of the Pancreas *(Sociedad Catalana del Páncreas)* have published an interdisciplinary position statement on chronic pancreatitis care (21,22) advocating for the implementation of specialist pancreatology units. SEPD developed the RECALAD project, which analyzed the structure, activity and results of GSs (23), revealing that 30 % of these, in a sample of 40 units, included a pancreas and biliary tract unit.

The development of standards for PUs is framed within the continuous improvement

process of participating scientific societies, a setting with a notorious dearth of information regarding activity and particularly results, as well as the analysis of the association of resources and activity with health results. As may be seen in the attached figure, pancreas disease (acute pancreatitis and pancreatic cancer) patient discharges from general hospitals within the National Health System have increased by 18 % during the period 2016-2021, with acute pancreatitis having an overall in-hospital mortality rate of 5.3 %. One of the goals of these PU standards is to overcome the current inadequacy of information.

The objectives of the PU standards document include:

- To identify the functions and related organization of pancreas units within the hospital setting in a multidisciplinary yet gastroenterology services-centered manner.
- To define structure, activity and outcome standards for PUs.
- In the near future, to serve as the basis for PU certification in accordance with the aforementioned standards.

METHODOLOGY FOR THE DEVELOPMENT OF PU STANDARDS

A steering committee was set up including representatives from AESPANC, AEG and SEPD. The committee prepared the standards proposal and made the strategic decisions concerning the project. The committee had methodological and logistic support available, based on the GSs standard development experience (18).

- The scientific societies representatives within the project's steering committee provided the structural, organizational and functional criteria for PUs based on the available scientific evidence, and the decisions to include these as standards were made via consensus.
- The PU standards draft, once prepared by the steering committee members, was subjected for feedback and approval by the AESPANC, AEG and SEPD governing

bodies, and contributions were incorporated into the final PU standards document (Table 1).

STANDARDS

Definition of pancreas unit within a GSs

A PU is defined as a healthcare professional organization that, within a gastroenterology service or unit (GS), provides care specifically for patients with pancreatic disease while meeting the functional, structural, and organizational requirements laid down in the present standards. These standards are designed to guarantee appropriate safety, quality and efficiency conditions to care for patients with pancreas disease.

PUs provide diagnostic, therapeutic, and preventive services for pancreatic conditions, either directly or via support units, in compliance with the following attributes:

- A manager.
- Allotted human and physical resources (premises, equipment).
- A portfolio of offered services (techniques, procedures).
- Target clients (patients and/or other responsibility units).
- Information system with process and result indicators (control panel).

Organization

- A PU should be included in a GS with at least hospitalization and gastrointestinal endoscopy resources available (18).
- A PU must have a manager appointed, namely a gastroenterologist with specific training in and dedication, even if part-time, to pancreatic diseases.
- A PU should have mechanisms in place to facilitate prompt access for patients who may need it.

- A PU should obtain an organization and operation manual including the unit's organization chart, services portfolio, staff, job descriptions and responsibilities, care protocols, information system, and control panel, all of these meeting the requirements set forth in the standards.
- A PU should take part in a structured clinical meetings program within the GS.
- A PU should have indicators, including quality and safety indicators, as focused on outcomes as possible, and monitor these using a control panel. Outcome indicators should include patient-reported outcome measures (PROM) (24-26). A PU should also develop patient-reported experience measures (PREM). Outcome indicators should incorporate risk adjustments according to patient complexity.
- A PU of the GS should participate in a multidisciplinary pancreas committee together with the professionals/units they collaborate with on a regular basis, including at least in-hospital gastroenterologists, endoscopists, pancreatic surgeons, oncologists, radiologists and pathologists. This committee will convene with the regularity deemed necessary according to the existing workload. These meeting should address the multidisciplinary management of complex patients with pancreatic disease, and assess any potential issues and opportunities for care improvement.
- A PU should draw up annual reports including activities and forward-looking strategies.

Structure

- A PU should include at least an additional gastroenterologist with specific training in and dedication, even if part-time, to pancreatic diseases.
- A PU should have a monographic clinic developed by practitioners in the unit.
- It is advisable for a PU to also have a specific nursing clinic for patient education, PROM tracking, drug administration training, and telematic control and follow-up for patients with pancreatic conditions.

- Within a GS, a PU should be supported by a specialist biliopancreatic diagnostic and therapeutic endoscopy unit offering at least the following specific procedures:
  - Pancreatic endoscopic ultrasound including fine-needle biopsy. Also advisable is availability of advanced imaging techniques associated with endoscopic ultrasound, including elastography and contrast-enhancement.
  - Biliopancreatic therapeutic ERCP (14).
  - EUS-guided drainage of pancreatic collections.
  - Transgastric pancreatic necrosectomy or, alternatively, a minimally invasive percutaneous technique (video-assisted retroperitoneal debridement, VARD).
- Advanced pancreatic endoscopy procedures such as pancreatoscopy, pancreatoscopy-guided intraductal lithotripsy, EUS-guided transmural biliary drainage or endoscopic gastrojejunostomy may be provided in-house or at some other external unit of reference, hence a PU should prepare the pertinent referral protocols.
- The center where a PU is located should provide or have available the following supportive services and procedures:
  - Hepatic-Pancreatic-Biliary Surgery Unit to provide pancreatic bypass and resective surgical procedures.
  - Department of Endocrinology and Nutrition.
  - Intensive Care Unit.
  - Pain Care Unit.
  - Clinical Laboratory to provide nutrition marker measurements and pancreatic testing including fecal elastase.
  - Department of Pathology to provide cyto-histologic assessment for pancreatic cytology, biopsy, and surgical specimen samples by a specifically

trained pathologist who is full- or part-time dedicated to pancreatic conditions.

- Pancreatic imaging procedures including at least abdominal ultrasound, multidetector computed tomography, magnetic resonance imaging (MRI), and MRI cholangiopancreatography, with pancreas-specific protocols and a radiologist who is specifically trained in and full- or part-time dedicated to pancreatic conditions.
- Interventional radiology procedures.
- Percutaneous or transgastric celiac plexus neurolysis.
- Bone dual-energy x-ray absorptiometry.
- Availability of muscle mass quantification techniques is also advisable.

Services portfolio

- A PU should define a services portfolio detailing its care modalities, procedures, and key care processes. Such services portfolio should at least include the requirements laid down in these standards concerning care modalities, care processes, and available techniques and procedures.
- A PU should offer the following care modalities:
  - Monographic specialist outpatient clinic.
  - Hospitalization, with PU staff taking part in the management of acute or complicated pancreatic conditions in inpatients.
  - Having hospital-at-home care available is highly desirable.
- Facilities and equipments: No specific needs have been identified beyond the outpatient clinic space. However, availability of clinical/translational research laboratories is recommended.

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Processes

- A PU should formalize its common processes.
- A PU should define the care process for patients with acute pancreatitis from presentation at the emergency room to hospital discharge.
- A PU should also design the following care protocols:
    - Follow-up of patients with chronic pancreatitis.
    - Diagnosis, optimized treatment and follow-up of patients´ exocrine pancreatic insufficiency.
- A PU should desirably define additional specific care protocols including but not limited to the following:
    - Outpatient follow-up after acute pancreatitis.
    - Therapeutic approach to local chronic pancreatitis complications.
    - Monitoring and management of patients with cystic pancreatic tumors.
    - Treatment and follow-up of patients with unresectable pancreatic cancer.
    - Treatment and follow-up of patients following pancreatic surgery.
    - Monitoring high-risk subjects for pancreatic cancer development.
    - Follow-up of adult patients with cystic fibrosis.

Training

- GS professionals responsible for PUs should participate, at least once a year, in training activities concerning pancreatic conditions. These activities include courses and/or national/international conferences with specific contents on pancreas diseases.

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Research

- PU staff should actively pursue research activities through participation in at least one research project, be it as primary investigators or collaborators.

Review

PU standards should be reviewed within 5 years, and updated as new scientific evidence emerges and experience from their implementation in GSs develops.

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Table 1. Pancreas unit standards

Type	Standards
1. Organization and management	
Mandatory	1. A PU must be integrated within a GS with at least hospitalization and GS endoscopy resources
Mandatory	2. A PU must have a manager appointed — a gastroenterologist with specific training in and full- or part-time dedication to pancreatic diseases
Mandatory	3. A PU must have mechanisms in place to facilitate prompt access to the Unit for patients who need it
Mandatory	4. A PU must develop an organization and operation handbook including the unit's organization chart, services portfolio, personnel, job competencies and responsibilities descriptions, care protocols, information system, and control panel
Mandatory	5. A PU must participate in a structured clinical meetings program within the GS
Mandatory	6. A PU must define a set of indicators, including quality and safety indicators, focused as much as possible on outcomes, and track these using a control panel
Mandatory	7. A PU must play a major role in a multidisciplinary pancreas board with the practitioners/units that commonly work together with the PU, including at least hospitalization ward gastroenterologists, endoscopists, pancreatic surgeons, oncologists, radiologists, pathologists and radiation therapists. Said board must be convened at least once monthly
Mandatory	8. A PU must prepare annual reports including its activities and forward-looking strategy
2. Structure	
Mandatory	9. A PU must have at least a second gastroenterologist with specific training in and full- or part-time dedication to pancreatic diseases
Mandatory	10. A PU must have a monographic outpatient clinic managed by its staff
Recommended	11. It is advisable that a PU also has a specific nursing clinic available
Mandatory	12. A PU must be, within the GS, supported by a specialist pancreatic diagnostic and therapeutic endoscopy unit offering at least the following specific procedures: – Endoscopic ultrasound and fine-needle procedures of the pancreas – Biliopancreatic therapeutic ERCP – EUS-guided drainage of pancreatic collections – Pancreatic necrosectomy, transgastric (or minimally invasive percutaneous)
Mandatory	13. Advanced pancreatic endoscopy techniques, including pancreatoscopy, pancreatoscopy-guided intraductal lithotripsy, EUS-guided transmural biliary drainage, and endoscopic gastrojejunostomy, may be performed in-house or at an identified external unit of reference, hence a PU must develop the pertinent referral protocols

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Type	Standards
Mandatory	14. A center where a PU is located must perform or have available the following supportive services and procedures: – Hepatic-biliary-pancreatic surgery unit and pancreatic bypass or resective surgical procedures – Department of endocrinology and nutrition – Intensive care unit – Pain care unit – Clinical laboratory to provide measurements of nutritional markers and pancreatic function tests such as fecal elastase – Pathology department to provide cyto-histological studies of pancreatic cytology, biopsy and surgical specimen samples by a specifically trained pathologist who is full- or part-time dedicated to pancreatic conditions – Pancreatic imaging procedures including at least abdominal ultrasound, multidetector CT and MRI/MRCP using specific protocols, and a radiologist with specific training in and full- or part-time dedication to pancreatic diseases – Interventional radiology procedures – Percutaneous or transgastric celiac plexus neurolysis – Bone densitometry – Availability of muscle mass quantification techniques is also advisable
2.1. Services portfolio	
Mandatory	15. A PU must define its services portfolio, detailing care modalities, procedures, and key care processes
Mandatory	16. A PU must offer the following modalities of care: – Monographic specialist outpatient clinic – Hospitalization, with active involvement of PU staff in the management of acute or complicated pancreatic disease in inpatients – Availability of hospital-at-home care services in the center is recommended
Recommended	17. Availability of clinical and/or translational research laboratories is advisable
3. Processes	
Mandatory	18. A PU must have its common processes formalized
Mandatory	19. A PU must define the care process for patients with acute pancreatitis from presentation at the emergency room to discharge from hospital
Mandatory	20. A PU must also design the following care protocols: – Follow-up of patients with chronic pancreatitis – Diagnosis, optimized treatment and follow-up of patients with exocrine pancreatic insufficiency

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Type	Standards
Recommended	21. It is advisable for a PU to define additional specific care protocols including but not limited to the following: – Outpatient follow-up after acute pancreatitis – Therapeutic approach to local chronic pancreatitis complications – Monitoring and management of patients with a pancreatic cystic tumor – Treatment and follow-up of patients with unresectable pancreatic cancer – Treatment and follow-up of patients after pancreatic surgery – Monitoring of subjects at high risk for pancreatic cancer development – Follow-up of patients with cystic fibrosis
4. Training	
Mandatory	22. Gastroenterologists responsible for a PU must participate at least once a year in training activities related to pancreatic disease. Said activities may include courses and/or either national or international conferences with specific contents concerning pancreatic conditions
5. Research	
Mandatory	23. A PU must carry out research activities and actively participate in at least one research project, be it as primary investigators or collaborators
ERCP: endoscopic retrograde cholangio-pancreatography; FNA: fine-needle aspiration; MRI: magnetic resonance imaging; CT: computed tomography; GS: gastroenterology unit; PU: pancreas unit.	

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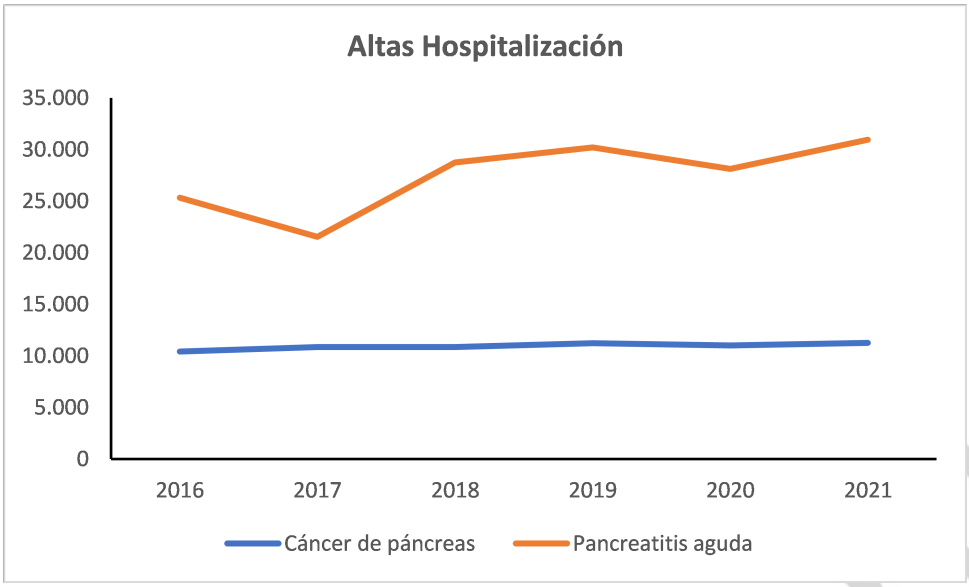

Hospital discharges

Pancreatic cancer

Acute pancreatitis

Fig. 1. Hospital discharges for pancreatic cancer and acute pancreatitis, 2016-2021.