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DOI: 10.17235/reed.2020.6778/2019
Link: PubMed (Epub ahead of print)

Please cite this article as:

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Digestive units in the National Health System of the 21st century. Organizational and management standards for a patient-centered service

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Received: 02/12/2019
Accepted: 02/12/2019
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ABSTRACT
The Spanish Society of Digestive Pathology has set a consensus document on the standards and recommendations for gastroenterology units (GU). These standards are considered as relevant in the organization and management of the unit to develop their activities with efficiency and quality. Four key groups of processes have been identified: a) care for the acutely ill adult patient; b) outpatient digestive endoscopy; c) in-hospital support to other services and outpatient clinics; and d) management of patients with chronic complex digestive pathology. Standards for organization and management of the
unit were classified within the group of support processes, and training and research as strategic processes. Standards have also been developed for some functional and monographic units such as endoscopy, hepatology and inflammatory bowel disease; as well as for certain procedures including endoscopic retrograde cholangiopancreatography, colonoscopy and gastroscopy. The standards will be set for other units and procedures as they are developed. The standards developed must be reviewed within a maximum period of five years.

**Keywords:** Spanish Society of Digestive Pathology. Gastroenterology units. Clinical process management. Standards. Quality.

**INTRODUCTION**

The RECALAD project found a high variability in the activity and outcome of digestive units (DU) between hospitals and the health services of the autonomous communities (1). The variability found by RECALAD is hardly justifiable only by epidemiological conditions or random variations and should be partially attributed to the variability in clinical practice, including the organization and management of the quality of healthcare in the DU. The Spanish Society of Digestive Pathology (SEPD) has performed a project to develop the quality standards of the DU, which can be consulted in its full version on the website of the SEPD. The objective of this paper is to describe the aims and methodology of the project, as well as to illustrate some of the most relevant aspects of the standards developed.

Prior to these SEPD standards, the Spanish Ministry of Health published the standards and recommendations for digestive units, which were prepared in collaboration with the SEPD and other medical scientific societies and experts (2). The SEPD has also published quality standards for digestive endoscopy (3), colonoscopy (4), gastroscopy (5) and endoscopic retrograde cholangiopancreatography (6). Following the terminology of the Spanish Ministry of Health document, the term “units” was used instead of the most common “services”. This is more comprehensive and includes units and clinical management areas
or other organizational forms in the provision of digestive system services. Healthcare unit is defined as “an organization of healthcare professionals that offers multidisciplinary healthcare services, which meet functional, structural and organizational requirements, guaranteeing the safety, quality and efficiency for patients with a specific set of clinical conditions that condition the organizational and management specificities of the unit itself”. The DUs are those healthcare units that are specifically dedicated (specialized resources) to patients with diseases of the digestive system (Chapter 11 K00-K95, of the International Classification of Diseases - 10th Review Clinical Modification).

OBJECTIVES
The objectives of the DU Standards are:
– Identifying the functions and the organization of the DU.
– Defining standards of organization and management of DU.

FOCUS AND METHODOLOGY
The SEPD established three levels of participation: the Standards Committee, the Board of Directors of the SEPD and consultation (web) of the Heads of the DU. Once an agreement was reached within the Committee and the proposal was approved by the SEPD Board of Directors, it was presented on the SEPD website to request input from the heads of service. The Institute for Healthcare Improvement (IMAS Foundation) provided technical and methodological support.
In order to adapt the standards to the diversity of organizational configurations and complexity of DU, the standards have been set for different organizational levels:
– Digestive Unit.
– Monographic digestive units.
– Processes.
– Procedures.
The standards developed do not cover all units, processes and procedures within the scope of the DUs, focusing on the most relevant and/or those with quality standards
already developed by the SEPD (2-6) or developed by national (7,8) and international medical societies (9-18). The process of developing standards for DU units, processes and procedures should be progressive, based on the scientific evidence available and the standards should be reviewed periodically. The scope of the standards will also be expanded to cover a greater number of monographic units, processes and procedures. In this first approach, standards have been developed for the Digestive Unit, Digestive Endoscopy Unit, Hepatology Unit and Multidisciplinary Inflammatory Bowel Disease Unit. Other standards for processes that have been identified as “key” to the unit and some of the most common endoscopic procedures have also been defined. These standards may be used to certify the quality of the DU by the SEPD.

DIGESTIVE UNITS

DU can have a relatively simple organization and portfolio of services (medical care and endoscopy) or a very complex system that integrates multiple monographic/functional units into its portfolio of services (hepatology, inflammatory bowel disease, digestive ultrasound, etc.). The convention established by the SEPD to define a DU is that it has at least one endoscopy unit and has a minimum of six gastroenterologists with a recognized specialty title.

HEALTHCARE PROCESSES. MAP OF PROCESSES FOR DIGESTIVE UNITS

The proposal for standards was organized by identifying the key, strategic and support processes of the DU. The most common way to define a service’s process map is to relate it to the healthcare modalities; that is, with the structure where they are carried out (hospitalization, outpatient clinics, etc.) (19). The SEPD has sought to link, as far as possible, these standards to the healthcare processes attended in the DU, identifying the following processes (Fig. 1):

1. Key healthcare processes:
   - Acutely ill adults in the hospital.
   - Outpatient digestive endoscopy.
Outpatient services (includes consultation for other medical specialties).

Specialized healthcare for chronic complex patients.

2. Support processes: organizational and management of the DU.

3. Strategic processes:
   - Training.
   - Research

STANDARDS

The standards developed for the DU and for the Digestive Endoscopy Unit, which make up the nucleus of what has been defined as the Digestive Unit, are displayed in tables 1 and 2, respectively. The whole document, including monographic unit standards, outpatient digestive endoscopy process and the most frequent endoscopic procedures, can be found on the SEPD website (20). The standards have been organized following the Donabedian classification, differentiating standards of structure, process and, as far as possible, outcomes (21,22).

The standards for the process “acutely ill hospitalized patient” have been based on those developed by the Ministry of Health “Nursing Unit at Polyvalent Hospitalization Services for Acute Patients” (23) and the NICE guide to standards for acute and critical patient care (24), including the implementation of “track and trigger” systems (25).

The process of complex chronic patient healthcare involves various healthcare modalities, including hospitalization (21) and the day hospital (26). This is aimed at systematic care for patients in which chronicity coexists on numerous occasions with dependence and fragility associated with advanced stages of life (27). International experience shows that the systematic care of patients with chronic diseases reduces frequentation and hospital stays, and decreases the rate of urgent consultations and the consumption of medicines (28-31). The standards for providing systematic care to these patients is based on the Spanish Strategy for Addressing Chronicity in the National Health System (32). Patients who may benefit from systematic care to the chronic complex patient are those with a high frequency of hospital readmissions (three or more per year) or emergency
consultations (decompensated patients with hepatic cirrhosis with outpatient paracentesis, chronic hemorrhages with multiple transfusions, etc.). Figure 2 schematically shows the management of the cirrhotic patient at the day hospital (8).

The standards of the outpatient digestive endoscopy process share many aspects with those of other outpatient interventional procedures (33), including the use of safety checklists of the procedure. These are based on those set by the SEPD for the various endoscopic digestive procedures (4-6). The DU must have an organizational structure appropriate for their complexity and functions. The key issues are: having a manager (with a dedication depending on the complexity of the healthcare team), having a portfolio of services, an organization and management manual and a system of indicators, including those of quality and safety, focused as far as possible on health outcomes. The DU should draw up an annual report, and have a complication register and a scorecard to track their performance. DUs should avoid low-value interventions, such as those proposed by the SEPD (34) and comply with the legal obligations related to the information systems. It is recommended to follow the recommendations for the hospital discharge report in medical specialties (35).

The standards developed for the Digestive Endoscopy Unit are conceived as a “healthcare unit” integrated into the DU with a manager. Furthermore, the unit will have developed its portfolio of services, organization and management manual and annual report, etc. These elements can be integrated into the DU where it is included. Digestive endoscopy specialists should perform at least 200 gastroscopies and 200 colonoscopies per year. In relation to the structure and equipment of these units, the standards include those proposed by the SEPD (3). Proposed performance indicators for the digestive endoscopy units are the hospital readmissions rate, visits to the hospital Emergency Unit or stays in the day hospital during the seven days after procedure and the modification, interruption or termination of scheduled procedures due to sedation-related endoscopic events (36).

REVIEW

The SEPD document must be reviewed within a maximum period of five years, as well as
updated to the extent that standards are available for other monographic units, digestive processes and procedures.

REFERENCES


### Table 1. Digestive Unit standards

<table>
<thead>
<tr>
<th>STANDARDS</th>
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<tbody>
<tr>
<td><strong>Digestive Unit (DU)</strong></td>
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<tr>
<td><strong>Organization and management</strong></td>
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<tr>
<td>1. The DU must have at least one endoscopy unit and a staff of at least six specialists in gastroenterology with a recognized specialty title</td>
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<tr>
<td>2. The DU must be assigned a responsible, gastroenterologist specialist, with a dedication depending on the complexity of the care team</td>
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<tr>
<td>3. The DU must have an Organization and Management Manual, which describes the DU organization, portfolio of services, staff assigned to the DU, competencies and responsibilities of the staff, healthcare protocols and the information system and scorecard.</td>
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<tr>
<td>4. The DU service portfolio should specify the functional units of the DU and the techniques/procedures performed in the DU</td>
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<td>5. The DU should develop an Annual Report that describes the activity developed and future strategy</td>
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<td>6. The DU/center must have a complication registration system</td>
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<tr>
<td>7. The DU should hold a multidisciplinary meeting periodically (at least twice a year) with the professionals/units who usually collaborate with it (e.g. nursing, hospital pharmacy/clinical pharmacology, etc.), in which possible incidences and opportunities for improvement of care are discussed</td>
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<tr>
<td>8. The DU should have a structured system of clinical sessions. At least one every week</td>
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<tr>
<td>9. The DU should provide a system of indicators, including quality and safety indicators, focused, as far as possible, on health outcomes and track them by means of a scorecard</td>
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<tr>
<td>10. The DU should avoid low-value interventions, keeping the list of these interventions up-to-date and available to all members of the unit to avoid their practice. The list should include those proposed by the EDPS</td>
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<tr>
<td>11. The registration report must comply with the requirements of Royal Decree 69/2015 of 6 February regulating the Register of Activity of Specialized Health Care</td>
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### STANDARDS

#### Digestive Unit (DU)

12. The DU should have a complaint record and develop a system for improving services based on complaints

#### Processes

**Acutely ill patient hospitalized**

13. The history of admission into a DU of an emergency patient must describe with enough detail the reason for admission, antecedents, examination, relevant results of the tests performed and a diagnostic trial

14. The DU should standardize communication between professionals in the transfer of the patient between different care units, avoiding transfers between hospitalization units. It is recommended to establish criteria of admission of the patient in the DU, agreed with the other units involved in the care of the patient hospitalized by digestive pathology

15. The transfer of patients from critical care units to the DU between 22:00 and 07:00 hours should be avoided as far as possible. If it is done during this time interval, it should be documented as an adverse incident

16. The DU should protocolize and develop clinical pathways for at least the three most prevalent processes and ensure their use from the start of care at the specialty ward

17. The DU must assign a referring physician during the period of hospitalization that the patient must recognize as responsible for his/her care

18. The DU must ensure that the activities described in the nice guide 50 (Acutely ill patients in hospital. Recognition of and response to acute illness in adults in hospital) are carried out upon admission

19. The daily ward round is essential. It is recommended that it includes Saturdays, Sundays and holidays

**Nursing staff in the DU wards should be planned according the burden of patients by levels of care**
<table>
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<tr>
<td><strong>Digestive Unit (DU)</strong></td>
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<tr>
<td>20. The discharge process should be standardized to ensure the availability of key information regarding discharge diagnostics, test results performed, treatment plan, care and medications</td>
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<tr>
<td>21. The discharge report should contain an action plan with a reference to therapeutic objectives and clinical follow-up. The discharge report should be made available to professionals responsible for continuity of care (Primary Care physician and nurse)</td>
</tr>
<tr>
<td>22. The discharge report should include the reconciliation of the medication, adjusting all the drugs carried by the patient to avoid repetition or forgetfulness</td>
</tr>
<tr>
<td><strong>Consulting support process for primary care and other specialties</strong></td>
</tr>
<tr>
<td>23. Stable communication systems with Primary Care, first-person or not, should be put in place to enable integrated care</td>
</tr>
<tr>
<td>24. The DU should establish fast-track circuits for the diagnosis of patients with rapid deterioration of their condition or a seemingly more serious condition. To do this, the DU might agree short delay times with diagnostic services (image, endoscopy, etc.) for serious pathologies. Abdominal mass or abdominal pain of unknown origin after the initial study may be considered as fast-circuit consultations for the DU</td>
</tr>
<tr>
<td>25. It is recommended that the DU have stable systems of not-in-person interconsultations capable of avoiding emergency consultations or unnecessary patient displacement</td>
</tr>
<tr>
<td>26. The consultation should include a complete history, systematic (untargeted) exploration and request for appropriate studies and generate a report at the end of the consultation/interconsultation process with a basic outline including studies, diagnostic guidance and the plan/treatment to be followed</td>
</tr>
<tr>
<td><strong>Care for the complex chronic patient and continuity of care</strong></td>
</tr>
<tr>
<td>27. It is recommended that the DU have a structured system of the relationship with the Primary Care teams within the hospital’s area of influence, aimed at the shared management of complex chronic patients.</td>
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</table>
### STANDARDS

#### Digestive Unit (DU)

**Training**

28. The DU should have a continuous training plan tailored to their members, based on the development of professional skills appropriate to the unit’s service portfolio

29. Each DU professional must have completed at least 40 hours (1.5 ECTS - European Credit Transfer and Accumulation System) (7.5 ECTS over a five-year period)

**Research**

30. The DU should participate in the RECALAD registry

31. Every DU should at least have one of its members as an author of an article published in one scientific indexed journal per year
Table 2. Standards of the Digestive Endoscopy Unit

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<th>Standards</th>
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<tr>
<td><strong>STANDARDS</strong></td>
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<tr>
<td>Digestive Endoscopy Unit (DEU)</td>
</tr>
<tr>
<td><strong>Organization and management</strong></td>
</tr>
<tr>
<td>1. The DEU must be assigned a responsible, digestive system specialist, with dedication depending on the complexity of the care team</td>
</tr>
<tr>
<td>2. The DEU must have an Organization and Management Manual, which describes the DU organization, portfolio of services, staff assigned to the DU, competencies and responsibilities of the staff, healthcare protocols and the information system and scorecard</td>
</tr>
<tr>
<td>3. The DEU’s portfolio of services should specify the techniques/procedures performed in the unit</td>
</tr>
<tr>
<td>4. The DEU should develop an Annual Report that describes the activity developed and future strategy</td>
</tr>
<tr>
<td>5. The DEU should hold a multidisciplinary meeting periodically (at least once a year) with the professionals/units who usually collaborate with it, in which possible incidents and opportunities for improved care are discussed</td>
</tr>
<tr>
<td>6. The DEU must have a structured system of clinical sessions (at least one per week)</td>
</tr>
<tr>
<td>7. The DEU should be provided with a system of indicators, including those of quality and safety, focused, as far as possible, on health outcomes and monitored by means of a scorecard</td>
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<tr>
<td><strong>Structure standards</strong></td>
</tr>
<tr>
<td>8. Specialists performing digestive endoscopies should perform at least 200 gastroscopies and 200 colonoscopies per year</td>
</tr>
<tr>
<td>9. The DEU must have defined a sedation analgesia/anesthesia protocol that ensures the patient safety and that specialists have the necessary competencies for airway sedation and maintenance</td>
</tr>
</tbody>
</table>
### STANDARDS

**Digestive Endoscopy Unit (DEU)**

10. Appropriate setting and facilities, which meet at least the requirements established by the EDPS

11. DEU must have a nurse responsible for patients throughout post-sedation recovery

**Process standards and proceedings**

12. The DEU must meet the standards for the outpatient digestive endoscopy process

13. The DEU must comply with the standards established for the procedures it develops

**Performance indicators**

14. The DEU should establish specific performance indicators for each procedure
Fig. 1. Digestive Unit synthetic process map/key medical care modalities of a DU.
Prevention of disease progression and decompensation

- Identifying all HCV and HBV patients with advanced fibrosis
- Treating etiology in all patients with cirrhosis with an indication for treatment
- Identifying and refer all patients with advanced alcoholic fibrosis in primary healthcare IB-4 and echo (multimodal intervention)
- Identifying all patients with EHNA and advanced fibrosis by NAFLD scoring and echo in primary healthcare. Multimodal intervention, which includes diet, exercise, endocrine-nutrition, surgery or bariatric endoscopy and drugs when available

Prevent recurrence of decompensation and readmissions

**Checklist on HD:**

- Periodic surveillance. Vital and analytical signs
- Early detection of CHC Echo on the same day or within a short time if there is no echo during the previous 3-6 month
- Schedule endoscopy if there is no VVEE or endoscopy in the last 2 years
- CPT-9 psychometric test to evaluate EH (numerical connection test). Adjustment of disaccharides or rifaximines if EH
- Urine alcohol test
- Adjusting BB for bleeding prophylaxis (carvedilol requires less titration)
- Adjusting non-selective blockers
- Adjustment of diuretics based on ascites, creatinine, HD or hyponatremia
- Norfloxacin for PBE prophylaxis
- Multidisciplinary coordination to promote and promote abstinence

Fig. 2. Management of cirrhotic patients at the day hospital.