

SPECIAL ARTICLE

Quality indicators in digestive endoscopy: introduction to structure, process, and outcome common indicators

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ABSTRACT

The general goal of the project wherein this paper is framed is the proposal of useful quality and safety procedures and indicators to facilitate quality improvement in digestive endoscopy units. This initial offspring sets forth procedures and indicators common to all digestive endoscopy procedures.

First, a diagram of pre- and post-digestive endoscopy steps was developed.

A group of health care quality and/or endoscopy experts under the auspices of the *Sociedad Española de Patología Digestiva* (Spanish Society of Digestive Diseases) carried out a qualitative review of the literature regarding the search for quality indicators in endoscopic procedures. Then, a paired analysis was used for the selection of literature references and their subsequent review.

Twenty indicators were identified, including seven for structure, eleven for process (five pre-procedure, three intra-procedure, three post-procedure), and two for outcome. Quality of evidence was analyzed for each indicator using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) classification.

Key words: Quality indicators. Endoscopy. Digestive system.

INTRODUCTION

It is well known that, in order to assess and improve care quality, the latter term must be first defined (1) and its dimensions identified (2), including effectiveness, efficiency, safety, accessibility, and patient-centered service (Table I). Once these dimensions, their requirements for each undertaken activity, and the target results are established, designing things so that they may be completed at the first go (for instance, by describing procedures to be implemented and their requirements) significantly facilitates work.

In order to acknowledge the quality level achieved, and to start making improvements if needed, consistent information is necessary on the most relevant aspects of the care

provided, which may be summarized as indicators. Quality indicators may be divided up into three categories: “structure”, “process” and “outcome or results” (3). “Structure” includes all things related to the stable attributes wherein care is provided, both material and organizational; “process” includes all things that are done for patients and the skills involved; and “outcome” denotes any health status changes that may be attributed to the received care, as well as patient satisfaction.

In this setting, the *Sociedad Española de Patología Digestiva* (SEPD) understood that quality indicators associated with digestive endoscopy procedures should be analyzed and assessed, both overall and specifically (the goal of this first report) for the three main procedures in terms of volume and impact: gastroscopy, colonoscopy, and endoscopic retrograde cholangio-pancreatography (ERCP). In a second stage, echoendoscopy and balloon enteroscopy will also be analyzed. The reason is none other than to safeguard practice quality in the field of gastroenterology in Spain by providing quality indicators adapted to our setting and according to evidence levels.

The overall goal of this project is to suggest quality and safety procedures and indicators useful to facilitate quality improvement in digestive endoscopy units. This paper puts forth procedures and indicators common to the various digestive endoscopy tests.

METHODS

The study was structured in two clear-cut stages. First, a multidisciplinary task force was set up and headquartered at the *Hospital Clínico Universitario Virgen de la Arrixaca* (HCUVA), which reviewed the literature and the design of diagnostic esophagogastroscopy, colonoscopy,

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Table I. A multi-dimensional quality model with its corresponding indicators

| Quality dimension | Definition | Examples of indicators |
|-----------------------|---|---------------------------------------|
| Effectiveness | Extent to which digestive endoscopy improves health status in the target population | Complete colonoscopy |
| Efficiency | Relates digestive endoscopy results to incurred costs | All polyps smaller than 20 mm excised |
| Safety | Absence of unnecessary, actual or potential damage associated with digestive endoscopy | Adverse effects after endoscopy |
| Patient-centered care | Extent to which patient expectations are met | Satisfaction |
| Accessibility | Ease of access to digestive endoscopy despite barriers (organizational, financial, cultural, emotional) | Waiting times |

and ERCP procedures. In a second stage proposals were reviewed and discussed by an expert panel selected by the SEPD until a final version was produced. Then data sheets were developed for each proposed indicator to assess these procedures.

Search strategies and study selection

Two broad, systematic literature searches were performed. The first one was for clinical practice guidelines (CPGs), the second was for original and review papers. CPGs related to digestive endoscopy were obtained from three international sources (Agency for Healthcare Research and Quality [AHRQ], National Institute for Health and Care Excellence [NICE] and Scottish Intercollegiate Guidelines Network [SIGN]) and one Spanish source (*GuíaSalud*), as well as from reviews in the web sites of the main endoscopy and gastroenterology societies (American Society for Gastrointestinal Endoscopy [ASGE], American Gastroenterological Association [AGA], European Society of Gastrointestinal Endoscopy [ESGE], *Sociedad Española de Endoscopia Digestiva*, SEED [SEPD], and *Asociación Española de Gastroenterología* [AEG]). Originals were searched in the Web of Knowledge (WOK), PubMed, and Cochrane databases using the following strategy. All documents were selected that were published between January 1, 2006 and August 10, 2016 and included any of the following descriptors: [*digestive endoscop**, *gastrointestinal endoscopy*, *colonoscop**, *gastroscoop**, *oesophagoscoop**, *endoscopic retrograde cholangiopancreatography*] and [*informed consent*, *quality*, *safety*, (*security*), *assessment*, *assurance*, *indicators*, *criteria*]. (Active filters: *clinical trial*, *controlled clinical trial*, *meta-analysis*, *randomized controlled trial*, *review*, *guideline*, *practice guideline*, *publication date from 2006/01/01 to 2016/08/10*; *humans*; *adults*; *language: English, Spanish*).

A review of the references included in the selected, analyzed originals, published guidelines and meta-analyses was also performed, and previously overlooked references of interest were selected.

Once the search protocol was completed, eligible papers were split in two groups (n1: other procedures [non-colonoscopy], and n2: colonoscopy).

The documents selected were reviewed and analyzed separately by two reviewers. Each pair of reviewers screened their studies using any of the following criteria:

- The document includes recommendations on appropriate preparation, execution, and follow-up.
- The document includes or suggests quality indicators for structure, process or outcome.

Studies selected by just one reviewer were collated by the rest in order to decide their final selection status.

A table listing information on structure, process or outcome indicators, and whether such information was explicit, was developed to uniformly examine each document. Furthermore, the table included the type of each referenced study (clinical trial, observational study, meta-analysis, etc.), which was identified as pertaining to endoscopy in general, gastroscopy, colonoscopy or ERCP, with the rest of procedures being set aside. Document suitability for the intended goal (analysis of endoscopy-related quality indicators) was also discussed.

Endoscopy procedure design

Based on the collected literature and the authors' experience, the activities needed for each procedure were recorded and sorted out. In the case of procedures common to all endoscopic studies, the logical differences in structure, function, and organization among clinical digestive endoscopy units restrict development down to a minimum. Similarly, a description of specific techniques to be used in selected situations was excluded, as it was not contemplated in the ongoing work. Results were plotted in flow charts or parallel line diagrams. Proposals put forth by the group were reviewed and discussed by an expert panel selected by the SEPD until a final version was produced.

Construction of indicators

In order to obtain valid indicators, the quality of the available knowledge was assessed regarding the activities involved in the procedures and the documents select-

ed after the search. To this end, the quality of knowledge grading scheme available within the GRADE model was used. In the GRADE system the quality of “evidence” (this term will be hereafter used without quotation marks to denote the “best proof-based knowledge available”) is initially classified as high or low, according to its origin in experimental or observational studies; then, quality is rated as high, moderate, low or very low depending on a number of considerations regarding items that may downgrade or upgrade baseline quality (4,5).

To ensure reliability and to facilitate the estimation of the chosen indicators in clinical units, each of them is associated with a data sheet including: use environment (procedures wherein it is used); denomination; calculation formula; indicator type according to Donabedian’s model (3); time relationship with test (pre-procedure, procedure, post-procedure); quality dimension involved; justification, exclusions, and clarifications; and supporting evidence level.

RESULTS AND DISCUSSION

Search results

A total of 617 references were identified in the various databases according to the designed search strategy. Once duplications were excluded, a total of 123 references were discarded when titles/abstracts were examined (wrong references, abstract only, obvious poor quality, unavailability, older than 2006, dealing with pediatric, veterinary or non-digestive endoscopic topic, language other than Spanish or English).

Post-hoc, 19 additional references were selected from the references found in other already published papers, reviews, meta-analyses, and clinical practice guidelines.

For the paired analysis, we examined a total of 513 papers (n_1 : 253; n_2 : 260) in full text format, including both randomized and non-randomized clinical trials, as well as 224 full articles on high-quality case series, reviews, and meta-analyses (n_1 : 117; n_2 : 107).

Results are plotted in figure 1.

Common procedures

Two common procedures were implemented: admission to unit on the day scheduled for endoscopy, and discharge from unit after the procedure. The inclusion of speed-up procedures and waiting list management was dismissed on the grounds mentioned under “Methods”.

The *admission procedure* (Fig. 2) is intended to confirm that the patient is fully eligible for endoscopy, to ascertain the type of sedation that will be used, and to provide the necessary pre-procedural nursing care. It lasts from the time the patient presents to the endoscopy unit until endoscopy insertion. It includes the following activities:

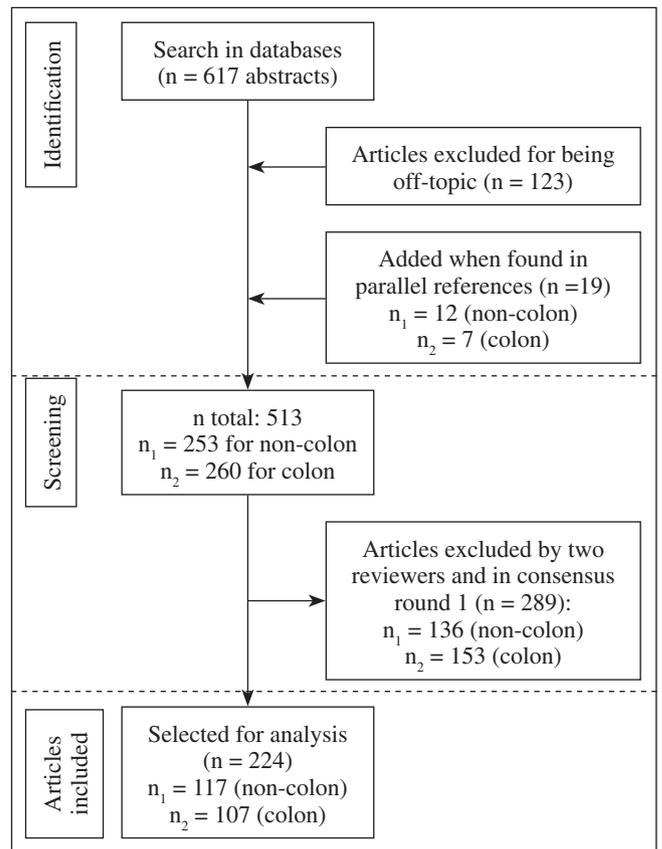


Fig. 1. Study selection flow.

- Before entering the room:
 - Confirm appointment and agenda availability (time/ room) and mark as present.
 - Confirm adequate preparation (see indicator below).
 - Check out informed consent.
- In the endoscopy room:
 - The endoscopist must:
 - Confirm informed consent and clarify last-minute concerns.
 - Open up the appropriate form within the medical record.
 - Offer sedation if applicable, with its related informed consent.
 - Confirm key history data such as allergies, use of antithrombotic drugs, or sedation contraindications.
 - The nurse must:
 - Insert a peripheral venous access, install a pulse oximeter, and provide oxygen through nasal prongs if sedation deeper than topical is required.
 - Administer appropriate sedation.

The *discharge from endoscopy unit process* is intended to adequately document the procedure’s course, findings, and potential incidences; to ensure the necessary care until

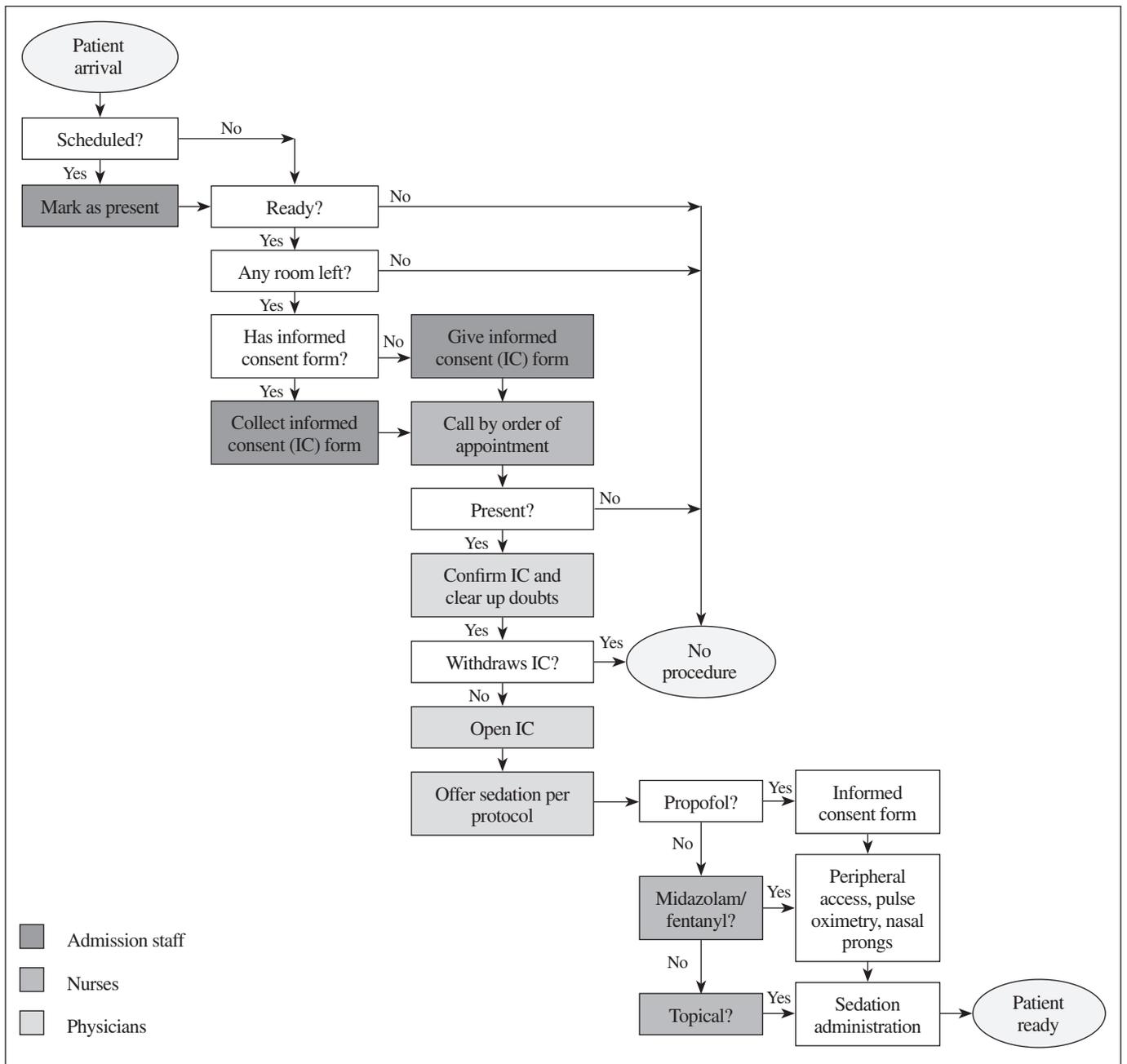


Fig. 2. Admission procedure.

the patient leaves the unit; and to prepare the endoscopy room for a new procedure. It lasts from endoscope withdrawal to patient leaving the unit (Fig. 3). It includes the following activities:

- Ancillary personnel must clean out the equipment and recondition the endoscopy room.
- The endoscopist must write a medical report (see indicator below) and make sure it is included in the patient's medical records.
- After patient transfer to the care room nurses must monitor vital signs, assess level of consciousness, and

provide appropriate post-procedural care (see indicator below).

- Patients must receive a copy of the endoscopy report before leaving the unit.

Indicators

Twenty indicators have been included, of which seven refer to structure, two refer to outcome, and eleven are related to process. Table II lists all indicators used.

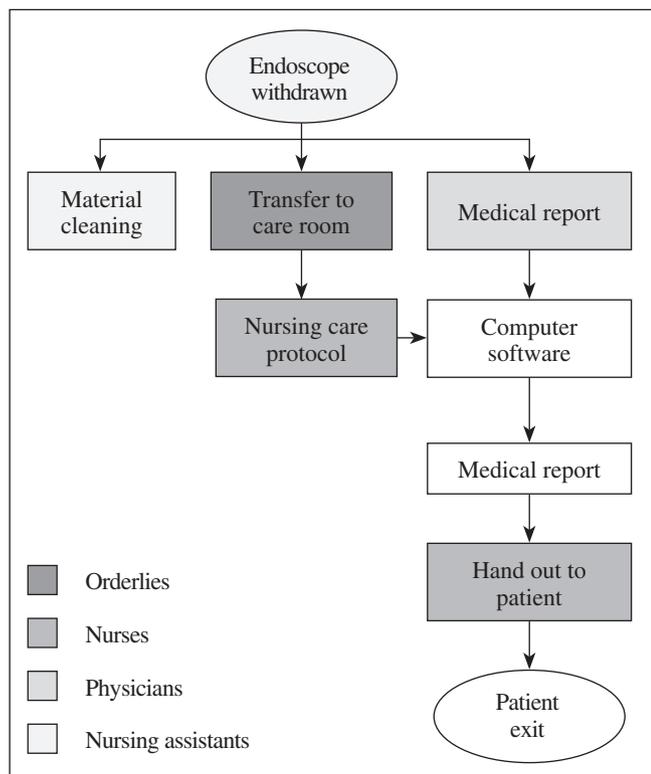


Fig. 3. Discharge process.

Table II. Quality indicators common to all endoscopic procedures

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|--|
| A. Structure |
| 01. Valid informed consent |
| 02. Antithrombotic therapy management plan |
| 03. Experienced endoscopist |
| 04. Discharge plan |
| 05. Discharge report quality |
| 06. Endoscopy equipment disinfection procedure |
| 07. Structural and functional endoscopy unit characteristics |
| B. Process - Pre-procedure |
| 01. Appropriate indication |
| 02. Signed informed consent form |
| 03. Clinical assessment |
| 04. Scheduled sedation |
| 05. Antithrombotic medication management |
| C. Process - Procedure |
| 01. Graphic documentation |
| 02. Sedated patient monitoring |
| 03. Recording of immediate adverse events |
| D. Process - Post-procedure |
| 01. Patient recovery |
| 02. Information on discharge |
| 03. Recording of delayed adverse events |
| E. Result |
| 01. Incidence of adverse events |
| 02. Perceived quality and patient satisfaction |

Structure indicators

A1. Valid informed consent

| |
|--|
| Definition and formula |
| Quality defects per document ratio – Numerator: no. of formal quality criteria unmet – Denominator: total of informed consent documents assessed |
| Type, temporal relationship, and quality dimension |
| Structure - Patient-centered care |
| Quality of evidence |
| Very low |

Providing patients with information regarding their therapy options and diagnostic choices, in an understandable manner, so that they may take part in the decision-making process involving their care, is both a duty health care professionals must fulfill (6) and a right guaranteed to patients by law (7). Hence, there is no doubt that informed consent forms are needed for digestive endoscopy procedures (8,9). These provide patients with information on the involved procedure so that an informed decision is made. Therefore, consent forms must meet formal quality requirements in order to observe legal regulations, promote readability, and improve decision making.

In this regard the criteria put forward by the Murcia Region EMCA program have proven useful in order to improve informed consent forms (10). Furthermore, it is also necessary to ensure the readability and understandability of these forms, as well as the validity of their contents (11,12). To achieve the former, the INFLESZ tool may be used, which is a validated scale to assess ease of comprehension for documents written in Spanish (scores of at least 55 are highly likely to provide the average population with an understandable text) (12), as well as other items (11). To achieve the latter it is key that texts and their supported evidence be up-to-date (13).

A2. Antithrombotic medication management plan

| |
|--|
| Definition and formula |
| The unit/service involved has a plan to manage antithrombotic and antiaggregant medication that at least formulates recommendations pointing out their strength and evidence level, and includes an explicit validity and review period Qualitative indicator of presence/absence |
| Type, temporal relationship, and quality dimension |
| Structure - Safety |
| Quality of evidence |
| Very low |

Although diagnostic endoscopies are usually considered to have a low bleeding risk, the same does not apply to some therapeutic procedures (8). In these patients the risk of thromboembolic complications associated with treatment

discontinuation must also be assessed (14), and the timing of anticoagulant and/or antiaggregant drug withdrawal and reinitiation has to be decided upon, together with the need for monitoring during said periods (15). Because of this, several guidelines approach this subject in the context of digestive endoscopy (16), and several scientific societies recommend its inclusion among quality indicators (8).

About the minimal requirements an antithrombotic medication management plan should meet, it is suggested that validity criteria, a key aspect of clinical guidelines, be ascertained (17,18) and potentially assessed by checking out that recommendations include their strength and evidence level, and the plan includes an explicit validity and review period.

A3. Experienced endoscopist

Definition and formula

Qualitative indicator of the presence/absence of the experience and training required of the endoscopist who performs the procedure (to establish for each procedure)

Type, temporal relationship, and quality dimension

Structure - Effectiveness

Quality of evidence

Low

An endoscopic procedure must reach its intended goal while minimizing the incidence of adverse events. Evidence suggests that endoscopist inexperience and insufficient training represent barriers to these ends (16,19,20).

Some scientific societies have established recommendations to assess expertise in endoscopy, which include a minimum of procedures performed to meet basic quality standards, as well as a minimum of procedures yearly (8,21,22).

Other factors to consider will depend upon the type of procedure and have to do with diagnostic or therapeutic yield and safety (23). Expertise in a given procedure does not qualify for other procedure types (20).

A4. Discharge plan

Definition and formula

The unit/service performing the procedure has:

- A recovery area other than the endoscopy room, with all necessary equipment for post-anesthesia care
- A patient management plan to facilitate recovery from procedure completion to discharge, with an explicit validity and review period
- A plan for patient information, instruction (allowed foods, activities not permitted within the next 24 hours, etc.) and follow-up, including any adverse events that might develop and their recognition

Qualitative indicator of presence/absence

Type, temporal relationship, and quality dimension

Structure - Safety

Quality of evidence

Very low

Trained nursing staff is usually responsible for patient recovery, including patient monitoring and the assessment of patient discharge criteria. The plan must also include a report on the procedure and its ensuing process, as well as patient instructions (food ingestion, forbidden activities within 24 hours, etc.) and follow-up assessments, including potential complications and their recognition (23,24).

The duration and frequency of monitoring should be individualized according to sedation level and patient health status, and range from 30 minutes to two hours. In this respect level of consciousness as assessed by response to verbal stimuli, vital signs (heart rate, respiratory rate, oxygen saturation), and level of pain must be monitored and recorded regularly until their return to normal (20,21,25).

Standard tools such as the modified Aldrete scale (22) are available to assess recovery after sedation (respiration, oxygen saturation, blood pressure, level of consciousness, activity). At discharge, patients must be fully aware and oriented with stable, normal vital signs (heart rate, respiratory rate, blood pressure, oxygen saturation), with a score of at least 9 points in the modified Aldrete scale (23,26).

A5. Discharge report quality

Definition and formula

Quality defects per document ratio

- Numerator: no. of formal quality criteria unmet
- Denominator: total no. of discharge report documents (DRDs) assessed

Type, temporal relationship, and quality dimension

Structure - Patient-centered care

Quality of evidence

Very low

Providing accurate, timely information on the procedure performed, succinctly including all relevant data, improves patient care. Both the ASGE (8,27) and the Canadian Association of Gastroenterology (CAG) (10,28,29) recommend the inclusion of selected items in the endoscopy report: date of procedure; patient identification; endoscopist and other staff identification; relevant history and physical examination data; conditions that may interfere with the procedure or with sedation; drug allergies; medications, particularly anticoagulant and antiplatelet drugs; anesthetic risk assessment (American Society of Anesthesiologists [ASA]) (28,30); proof of informed consent; endoscopic procedure; indication; type of endoscope; medication during the procedure (analgesia, anesthesia, sedation) (31) and during recovery (if applicable); anatomical extent of the procedure; barriers and restrictions encountered during preparation and procedure (9) (type, quality); samples obtained, including type, location and sampling technique; findings, with a detailed description of present/pertinent absent lesions; diagnosis, using as much as possible stan-

standardized, coded terminology (32); therapies administered and outcomes, complications and adverse events; recommended actions (new appointments, collection of results, etc.), and recommended care.

A6. Disinfection procedure for endoscopy equipment

Definition and formula

The unit/service performing the test has a disinfection procedure for endoscopy equipment including an explicit validity and review period

Qualitative indicator of presence/absence

Type, temporal relationship, and quality dimension

Structure - Safety

Quality of evidence

Moderate

While the risk of infection is low (one case per 1.8 million endoscopies), digestive endoscopy is an invasive procedure where infection may be transmitted, hence every effort to minimize it must be in place. A consistently, appropriately executed cleaning and disinfection procedure is effective to get rid of bacteria, mycobacteria, and viruses (33,34).

To ensure adequate endoscope disinfection three steps should be followed: mechanical cleaning, disinfection, and rinsing and drying.

Guidelines and consensus documents by different societies (35-48) recommend the following:

- Perform test to identify potential loss of tightness in channels or presence of inner disruptions that may impair disinfection.
- Suction out and submerge the endoscope in an enzymatic detergent solution.
- Carefully clean and brush the whole endoscope, including valves and channels, using an enzymatic detergent (49).
- Use a device-friendly disinfectant agent of proven efficacy such as 2% glutaraldehyde, 0.4-1% glutaraldehyde-phenate, or 0.2% peracetic acid (48,50,51).
- Submerge the endoscope in disinfectant filling up the channels. Exposure duration and temperature vary according to product (52).
- If an automatic machine is used, check it is properly connected and follow manufacturer instructions.
- Replace disinfectant after its activity period regardless of minimum effective concentration.
- Once disinfected, rinse the endoscope using preferably sterile water and dry all channels with air.
- The use of 70% alcohol, followed by further air drying, may enhance disinfection efficacy.
- Store the endoscope vertically in a well-ventilated area. Valves and instrument channel cap should be stored separately (9).

- The irrigation bottle and tubing must undergo "high-level" disinfection daily (53).
- Ancillary materials potentially in contact with blood must be sterilized following careful mechanical cleaning (54).
- If any material is stored under non-sterile conditions for over 48-72 hours, reprocessing is advised in view of contamination risks (55).

A7. Structural and functional characteristics of an endoscopy unit

Definition and formula

The unit/service performing the test must meet the following structural and functional requirements according to its regulatory background

Qualitative indicator of presence/absence

Type, temporal relationship, and quality dimension

Structure - Safety

Quality of evidence

Very low

The structural and functional requirements of endoscopy units may differ to a greater or lesser extent according to location and type (10,53,56).

In this context, all of them must secure protocols, equipment, and trained, experienced personnel to provide safe, effective conscious sedation.

Endoscopy unit accreditation is directly related to the ability to provide endoscopy training (22).

In Spain, a document granted by the Ministry of Health and Consumption (57) includes the structural and functional characteristics digestive endoscopy units must have according to their defined typology (Table III). It also points out that they must be fitted with computer systems capable of processing and storing images, and of facilitating the writing of standard reports.

B1. Appropriate indication

Definition and formula

Percentage of cases where the reason for endoscopy is recorded in the medical history, and is also present in a list of appropriate indications

- Numerator: 100 x cases with a recorded valid indication
- Denominator: total of cases assessed

Type, temporal relationship, and quality dimension

Process - Pre-procedure - Effectiveness

Quality of evidence

Low

Table III. Structural and functional characteristics of digestive endoscopy units (DEUs) (57)

| | <i>In-hospital or independent with general/loco-regional anesthesia</i> | <i>Independent, without general/ loco-regional anesthesia</i> | <i>Satellite</i> |
|--|---|---|------------------|
| Medical staff certified to perform digestive endoscopies through a training program validated by the Comisión Nacional de Especialidades (National Specialties Commission) | Yes | Yes | Yes |
| Adequate space and facilities | Yes | Yes (less demanding) | Yes |
| Monitoring equipment (sphygmomanometer, ECG, pulse oximeter) should be checked the day before | Yes | Yes | Yes |
| At least an endoscopy post for digestive endoscopy only | Yes | Yes | Yes |
| Anesthesia delivery equipment will be readily available, with appropriate maintenance and cleaning | Yes | Yes | Yes |
| Aspiration devices available in endoscopy and recovery rooms. A backup aspiration device is required | Yes | Yes | Yes |
| Resuscitation equipment (*) | Yes | Yes | Yes |
| Means to perform cricothyroidotomy or tracheotomy | Yes | Yes | Yes |
| IV administration equipment | Yes | Yes | Yes |
| Emergency power system for illumination (**) (operating status to be checked weekly) | Yes | Yes | Yes |
| For all procedures under local/general anesthesia, an anesthesiologist will be present until consciousness is recovered by the last patient (***) | Yes | No | Yes |
| Anesthesia machine using non-explosive anesthetics only | Yes | No | Yes |
| Expired CO ₂ analyzer | Yes | No | Yes |
| Pathogen-free endoscopy room (sampling twice a year) | Yes | No | Yes |
| Instrument sterilization | Yes | Yes | Yes |
| Use of <i>Bacillus stearothermophilus</i> to verify sterilization (****) | Yes | Yes | Yes |
| Post-anesthesia recovery room with adequate space | Yes | Recovery posts | Yes |
| Oxygen and vacuum outlets | Yes | | Yes |
| Not used for other purposes | | | |
| Medication available to manage hyperthermia and anaphylactic shock | Yes | Yes | Yes |
| Emergency transfer to operating room available for potential complications | Yes | < 15 min | Yes |

(*) Defibrillator, laryngoscopes, endotracheal tubes, positive pressure-capable O₂ sources, emergency drugs, O₂ tanks. (**) Able to sustain lights for > 4 hours. (***) A DEU must necessarily provide conscious sedation strategies to relieve the pain or discomfort inevitably associated with most endoscopic techniques. An anesthesiologist (or a team of doctors and nurses specifically trained in sedoanalgesia techniques) must be present to ensure that endoscopic procedures be performed with minimal patient discomfort. (****) DEUs should set up coordination systems with the central sterilization unit to provide patients with optimal safety. They should have an adequate number of endoscopes available to allow complete disinfection processes in parallel with workload. Automatic washing systems (washing machines) should be available, as well as semiautomatic or manual washing facilities to be used for special purposes or in case of machine breakdown. Infection control standards should be followed when reprocessing endoscopes.

The test must be indicated when the information it may yield or the therapy it may provide will improve the patient's outcome with a good risk-benefit ratio, as evidence suggests this improves cost-effectiveness (8,10,53,58) and provides a reference for legal claims (30). A list of gastroscopy indications was published by the ASGE and updated

in 2012 (58). The European Panel on the Appropriateness of Gastrointestinal Endoscopy (EPAGE) II criteria are used for colonoscopy (59-64). Consensus documents also provide data for ERCP (58,65-67).

When a test is appropriately indicated, a higher rate of relevant diagnoses is obtained (68-72).

B2. Signing the informed consent form

Definition and formula

Percentage of cases with confirmed delivery and signing of a valid informed consent form (ICF)

- Numerator: 100 x cases where a valid ICF was delivered and signed
- Denominator: total of non-urgent cases assessed

Type, temporal relationship, and quality dimension

Process - Pre-procedure - Patient-centered care

Quality of evidence

Very low

Providing patients with information on their therapeutic and diagnostic options in an understandable way, so that it may be used to promote their involvement in the decision making process regarding their care (8), is both a duty for health practitioners and a right guaranteed to patients by law (7).

This indicator may be exempted in case of emergency. The signed ICF must meet formal quality requirements or be accredited by the institution where the test is performed or by its corresponding scientific society (see structure criteria) (9,10,12,53,73).

In any case, the decision to undergo endoscopy should not be made under duress, and the patient must acquiesce in writing by signing the consent form. The patient must be allowed time and opportunities to pose additional questions before making a decision (74). According to a recent systematic review (75), interventions to promote the consent process in patients undergoing surgery or other invasive procedures such as digestive endoscopy usually enhance comprehension.

B3. Clinical assessment

Definition and formula

Percentage of cases with a confirmed appropriate assessment before endoscopy

- Numerator: 100 x cases with previous appropriate assessment
- Denominator: total of cases assessed

Type, temporal relationship, and quality dimension

Process - Pre-procedure - Safety

Quality of evidence

Very low

Assessing a patient's clinical status improves test safety. This implies that all risk factors must be considered to minimize complications during the procedure. Since many adverse effects during endoscopy are associated with

sedation, it is advisable that individual risk for sedation be evaluated to adjust the regimen to be administered.

The following must be verified before the procedure (8,9,30,76,77):

- The patient has been informed about the procedure and has no concerns.
- Consent signed by both the patient and the physician.
- Scheduled preparation is appropriately followed.
- Fasting time as instructed.
- Antiplatelet or anti-inflammatory drugs (past seven days), or anticoagulants (past three or four days).
- Drug allergies.
- Removal of all metallic objects and dentures, when applicable.
- Issues in prior examinations, when present.
- The patient is accompanied and will not need to drive.

Another poorly clarified concept is the need to pause of the endoscopy team before a procedure in order to ensure the patient is aware of the procedure's reason, course and goals.

B4. Sedation plan

Definition and formula

Percentage of cases with a specified sedation plan before procedure onset

- Numerator: 100 x cases with specified sedation plan
- Denominator: total of cases assessed

Type, temporal relationship, and quality dimension

Process - Pre-procedure - Patient-centered care

Quality of evidence

Moderate

Sedation should be offered by levels to all patients according to their clinical status. The patient will choose one among the available options once adequately briefed, which is associated with greater satisfaction.

The level of sedation (from none to deep) to be used during the procedure must be recorded (53,78).

B5. Antithrombotic medication management

Definition and formula

Percentage of cases with antiplatelet or anti-inflammatory medication specified in the medical records, together with a risk minimization plan if present

- Numerator: 100 x cases where the use of antiplatelet or anti-inflammatory drugs is explicitly specified, together with a risk minimization plan if present
- Denominator: total of cases assessed

Type, temporal relationship, and quality dimension

Process - Pre-procedure - Safety

Quality of evidence

Very low

Diagnostic endoscopies are usually deemed to entail a low bleeding risk. This is not the case for some therapeutic procedures where a graded risk assessment applies (79). These patients must also have their risk for thromboembolic complications after therapy discontinuation assessed (8-10,14,16-18,80-82). Therefore, the timing for anticoagulant and/or antiaggregant discontinuation and reintroduction must be defined, as well as the need for monitoring during that period (79). Furthermore, decisions must be agreed with the patient (83).

C1. Graphical documentation

Definition and formula

Percentage of cases with a graphically documented test (pictures, video)

- Numerator: 100 x cases with graphical documentation (pictures, video)
- Denominator: total of cases assessed

Type, temporal relationship, and quality dimension

Process - Procedure - Effectiveness

Quality of evidence

Very low

No studies have approached the effectiveness of including graphical documentation on the procedure, but it represents a universally accepted good practice requirement. Thus, the ASGE (8) and other guidelines (9,10,53,84,85) recommend that photographs be taken of the cecum as a quality parameter for colonoscopy (86). They are also recommended for other procedures since lesion's pictures enhance patient understanding and facilitate inter-consultations and second opinions (87).

C2. Sedated patient monitoring

Definition and formula

Percentage of cases where sedated patient monitoring is recorded

- Numerator: 100 x cases with at least pulse oximetry, heart rate, and blood pressure monitoring
- Denominator: total of cases where sedation is used

Type, temporal relationship, and quality dimension

Process - Procedure - Safety

Quality of evidence

Very low

Patient monitoring improves procedure safety but not clinical outcome.

According to the ASGE (8,26,78) and CAG (10), monitored parameters should include oximetry, heart rate, and blood pressure (the latter two at intervals no longer than five minutes), which help identify potentially life-threatening cardiovascular changes during sedation (53,88,89).

Evidence is insufficient to recommend capnography for patients sedated with propofol (9,26,90).

C3. Recording of immediate adverse events

Definition and formula

Percentage of cases with recorded presence/absence of adverse events, and their nature when present

- Numerator: 100 x cases with recorded presence/absence of adverse events and their nature
- Denominator: total of cases assessed

Type, temporal relationship, and quality dimension

Process - Procedure - Safety

Quality of evidence

Very low

Patient safety requires that damaging or potentially damaging events be identified and followed up (30,91). The recording of events emerging during the procedure or before leaving the endoscopy unit is therefore key in the effective implementation of programs to improve patient safety (30).

Efforts have been made to grade the severity of adverse events (92), and to establish a coherent classification (93). The following adverse events must be included:

1. Medication-related (94):

- a) Need for cardiopulmonary resuscitation. Use of reversal medication, such as flumazenil and naloxone, to antagonize the sedative effects of benzodiazepines and opiates, respectively, which indicates excess sedation. Elective use to speed up recovery is inconsistent with better practice, and not recommendable in view of potential rebound sedation when the patient is no longer supervised (68,95,96).
- b) Hypoxemia (< 85%). The risk of sequelae from hypoxemia is poorly understood, but an association with higher risk for late adverse events and longer recovery has been reported.
- c) Hypotension (< 90/50 mmHg or ≤ 20% from baseline) or hypertension (> 190/130 mmHg or ≥ 20% from baseline) may trigger endoscopy termination, require direct intervention, have adverse consequences, and/or delay recovery.
- d) Allergic reactions including laryngospasm/bronchospasm.

2. Procedure-related (97-99):

- a) Perforation (100).

- b) Immediate bleeding after polypectomy. Uncertain clinical outcome. Some authors suggest that even with immediate hemostasis significant complications may develop, this being a risk factor for subsequent bleeding events (101).
- c) Need for admission or transfer to the Emergency Room for any procedure-emergent event.
- d) Tube impaction, which may require surgery.
- e) Persistent, severe abdominal pain requiring careful assessment to rule out perforation. In a randomized trial, 45% and 31% of patients undergoing colostomy experienced abdominal pain after one and six hours. While this pain usually subsides, in some patients it is persistent to the extent of requiring medical care. Pain from air retention during or after colonoscopy may be reduced when CO₂ insufflation (102,103) or water immersion are used (104).
- f) Instrument failures requiring a repeat procedure.

D1. Patient recovery

Definition and formula

Percentage of cases where monitoring and discharge criteria assessments are recorded

- Numerator: 100 x cases with adequate monitoring according to discharge plan
- Denominator: total of cases assessed

Type, temporal relationship, and quality dimension

Process - Post-procedure - Safety

Quality of evidence

Very low

Recovery is usually supervised by trained nurses who perform the monitoring and assess discharge criteria.

The duration and frequency of the monitoring must be tailored to each patient according to sedation level and general health status (8,9), and should range from 30 minutes to two hours.

The level of consciousness as assessed by the response to verbal stimuli, together with vital signs (heart rate, respiratory rate, oxygen saturation) and pain level, must be regularly monitored and recorded until their return to normal (10).

Standard scales (modified Aldrete) (105,106) are available to assess recovery from sedation (breathing, oxygen saturation, blood pressure, level of consciousness, activity). Patients at discharge must be aware and oriented, with normal, stable vital signs (heart rate, breathing rate, blood pressure, oxygen saturation), with a score of at least 9 points on the modified Aldrete scale (31,107,108).

D2. Information on discharge

Definition and formula

Percentage of cases where a discharge report was generated on the procedure day

- Numerator: 100 x cases with discharge report generated on procedure day
- Denominator: total of cases assessed

Type, temporal relationship, and quality dimension

Process - Post-procedure - Patient-centered care

Quality of evidence

Very low

Information on discharge must include the procedure's course and findings, process follow-up (further appointments, reviews), and patient instructions, as well as potential adverse events and how to recognize them. This is known to reduce anxiety, to enhance recall of test conclusions and recommendations, and to improve patient adherence (8,9,30).

This is verified by ascertaining a high-quality report was written, discussed, and delivered before patient leave (10,27,31,53,109,110).

D3. Recording delayed adverse events

Definition and formula

Percentage of cases where the presence/absence of delayed adverse events was recorded, together with their nature if present

- Numerator: 100 x cases with recorded presence/absence of adverse events and their nature
- Denominator: total of cases assessed

Type, temporal relationship, and quality dimension

Process - Post-procedure - Safety

Quality of evidence

Very low

Patient safety requires the identification and follow-up of damaging or potentially damaging events (91). While the recording of adverse events occurring during the procedure is widespread, the recording of those developing after leaving the Endoscopy Unit is also key for the effective implementation of programs to enhance patient safety (15,30,94,97).

According to the CAG, adverse events that should be recorded include (93):

- Death within 30 days after the procedure.
- Unscheduled admission or emergency visit within 14 days after the procedure.
- Gastrointestinal bleeding within 14 days after the procedure.

- Infection, both acute and chronic.
- Symptomatic metabolic complication (hypoglycemia or hyperglycemia, electrolyte disorders). Colonoscopy requires colon cleansing with a laxative preparation. There is evidence of associated metabolic disorders such as hypokalemia, hyponatremia, hypocalcemia, and renal failure. Phosphate-containing preparations have been associated with acute phosphate nephropathy and their use is limited. Furthermore, preparation for colonoscopy may interfere with the management of conditions such as diabetes mellitus.
- During ERCP the development of procedure-induced pancreatitis depends upon the expertise of the endoscopist and the techniques performed.

E1. Incidence of adverse events

Definition and formula

Percentage of cases with delayed adverse events, both total and per type

- Numerator: 100 x cases with adverse events
- Denominator: total procedures per observation period

Type, temporal relationship, and quality dimension

Outcome – Safety

Quality of evidence

Very low

Indicators C3 and D3 refer to the recording of immediate and delayed events (30,89,94,97,107). The purpose of such recording is twofold: on the one hand, to know the magnitude, typology, and transcendence of adverse events emerging from digestive endoscopy procedures; and on the other, to assess their potential for prevention and to establish specific improvement actions.

E2. Perceived quality and patient satisfaction

Definition and formula

- Satisfaction. An 11-item (0-10) Likert scale is suggested for measurement
- Concurrent measurement of associated perceived quality dimensions

Type, temporal relationship, and quality dimension

Outcome - Patient-centered care

Quality of evidence

Very low

A measure of care quality cannot be considered as fulfilled without an assessment of the patient perceived qual-

ity and patient satisfaction with the care received. In fact, the Institute of Medicine (IOM) highlights patient-centered care as one of the six major values of health care (108). Therefore, satisfaction measurements in the digestive endoscopy setting have been repeatedly proposed by authors and scientific societies alike (8,10,53,106,111). The above suggested measurement involves an 11-item (0-10) Likert scale that we feel better suited to Spanish context as compared to the 5- or 7-item scales usually seen in other settings and cultures. With this scale, useful measurements may be obtained to understand its evolution and set a ground for the analysis of conditioning factors such as the mean, median or percentage of excellent scores, the latter understood as the number of scores equal to or greater than 8 over the total of scores, as has already been tested in other environments (112,113).

However, measuring satisfaction is not enough. In order to implement an ongoing improvement approach and know where interventions are needed, conditioning factors must also be learned. Some derive from the other indicators suggested above. Others will have to be explored based on perceived quality items. In this respect, the Endoscopy Global Rating Scale (GRS) initiative, successfully developed in the United Kingdom, may represent a good starting point for their identification, as one dimension refers to perceived quality (114). GRS is a web-based assessment tool that provides statements requiring a yes or no answer, the usefulness of which has been tested in various settings and health systems (115,116). The six level-graded items of patient-centered care include equality and equity, opportunity (waiting times), ability to select dates (accessibility), privacy and dignity, post-procedural care, and capacity to generate return information to the endoscopy unit.

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CONFLICTS OF INTEREST

The undersigned authors signed the present paper on behalf of the *Sociedad Española de Patología Digestiva*

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