Quality Assurance in Endoscopy: Which Parameters?

Ulrike W. Denzer

Clinic for Interdisciplinary Endoscopy, University Clinic Hamburg Eppendorf, Hamburg, Germany

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Summary

Background: The verbalisation of quality standards and parameters by medical societies are relevant for qualitative improvement but may also be an instrument to demand more resources for health care or be a unique characteristic. Within the health care system 3 different quality levels can be defined: structure, process and result quality. **Methods:** The current S2k guideline of the German Society for Gastroenterology (quality requirements for gastrointestinal endoscopy) AWMF registry no. 021-022 provides recommendations based on the available evidence for the structure quality (requirements for equipment, human resources) as well as for the process quality (patient preparation, conduct, documentation) and result quality (follow-up of specific endoscopic procedures). **Results:** Based on these recommendations, measurable quality indicators/parameters for the endoscopy have been selected and formulated. General quality parameters for endoscopic examinations are given as well as quality parameters for specific procedures for the preparation, conduct, and follow-up of specific endoscopic interventions. **Conclusion:** Only the regular review of processes and courses by means of defined measurement parameters builds up the basis for corrections based on facts. In addition, the implementation of recommended standards may be an instrument in demanding more resources from the health care system and, therefore, should be embedded as routine.

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Introduction: Quality Concept and Total Quality Management – Development and Meaning in the Health Care System

Terms such as quality management (QM) and total quality management (TQM) do not primarily evolve in the health care system but rather originate in the industry. These considerations are based on the so-called PIMS (Profit Impact on Market Strategy) study from the 1980s that showed that clients attach more importance to the fulfilment of their requirements concerning the product than to the pure costs. This led to the idea to put the client at the centre of the company and the development, manufacturing, and sales processes. In this context, quality not only refers to the product but also to the complete company and its employees. This requires a strategic business planning of the management [1].

In the 1990s, this quality concept was also transferred to the health care system. It is based on the legal requirement to implement and further develop an internal quality system within the health care system (Code of Social Law, SGB section 135a). The purpose is not only the initially focused systematic improvement of the medical quality but also the improvement of the satisfaction of patients and employees, and, finally, a qualitative improvement, which is relevant for the revenue of the specific medical institution as a whole. The increased demands regarding efficient work resulted in major support for, and advancement of, the implementation of the quality management system within the health care system.

However, the verbalisation of quality standards and parameters by medical societies may also be an instrument in the demand for more resources for the health care (e.g. staff, devices and space) or a unique characteristic. They include for example the quality requirements regarding a certified formation of centres (e.g. intestine centres, pancreatic centres) and the fulfilment of specific quality requirements by measurable, defined quality parameters (e.g. quality assurance agreements for the colonoscopy according to section 135, subsection 2 SGB V for the office-based sector).

Table 1. General quality indicators for the endoscopy [3]

<i>Pre-procedural</i>	
Documentation of an adequate indication for the intervention	
Timely conducting and documenting the patient information and informed consent	
Conducting a standardised risk assessment before the endoscopic intervention	
Administration of an antibiotic prophylaxis in a given indication	
Management of anticoagulating medication before an endoscopic intervention	
Conducting and documenting a team time out	
<i>Intra-procedural</i>	
Photo documentation of landmarks and pathological findings during an endoscopic intervention	
Collection and documentation of the duration of an endoscopic intervention (time recording)	
Conducting and documenting a continuous vital sign monitoring	
<i>Post-procedural</i>	
Conducting a standardised discharge management	
Compiling complete report documentation	
Compiling and documenting follow-up recommendations	
Documentation of accessories and instruments	
Documentation of intra- and post-procedural complications	
Documentation of the frequency of intra- and post-procedural complications (intervention-specific complications)	

Quality Levels within the Health Care System: Structure, Process and Result Quality

According to Donabedian [2], 3 different quality levels within the healthcare system can be defined: structure, process and result quality. The structure quality includes the available requirements for patient care pertaining to human resources, premises and techniques. Process quality is related to any processes regarding the treatment of the patients and the organisational and even medical aspects. The result quality derives from the structure and process quality; here, an improvement or worsening of the outcome parameters is documented and reviewed by measurement of target parameters individually formulated for the specific departments.

The parameters of the structure and process quality are normally defined in specifications once and shall be reviewed and updated regularly. The documentation of the quality of results is much more comprehensive as it includes, in case of specific indicator diseases, the continuous registration of the results, e.g. those of the therapeutic endoscopy. This is often only possible with time- and staff-intensive follow-up documentation and patient post-enquiries. Based on the collected facts, it is possible to establish and undertake the required changes regarding the structure and process quality (even in the economic aspect).

The current S2k guideline of the German Society for Gastroenterology ‘Qualitätsanforderungen in der gastrointestinalen Endoskopie (Quality requirements for gastrointestinal endoscopy)’ AWMF registry no. 021–022 [3] provides recommendations based on the available evidence for the structure quality (premises/requirements for equipment, human resources) as well as for the

process quality. The process quality includes topics regarding the patient preparation before the endoscopy (information, handling of anticoagulation medication, antibiotic prophylaxis) and recommendations for the preparation, conduct, and follow-up of specific endoscopic procedures and of the documentation.

Based on these recommendations, measurable quality indicators/parameters for the endoscopy have been selected and formulated, and are presented here. Please refer to the corresponding guideline chapters for a detailed justification and statement [3].

General Quality Parameters

The general quality parameters for endoscopic examinations are summarised in table 1 [3]. The American Society for Gastrointestinal Endoscopy (ASGE) supports the achievement of a quality goal of usually >98% with regard to the application of general quality indicators [4]. The German guideline mainly foregoes indicating defined cut-off values, particularly for quality parameters that are generally accepted, legally claimed, and logical (evidence level III; expert opinion) even without any study-based evidence.

Pre-Procedural Quality Parameters

Documentation of an Adequate Indication for the Intervention

A documented indication is required for an endoscopic examination or intervention to be performed. The British ‘Report of National Confidential Enquiry into Patient Outcome and Death (NCEPOD) – Scoping our Practice’ [5] examined 1,818 deaths within 30 days following a therapeutic endoscopy. In 14% of the patients, the indications were evaluated as inadequate and in 9% as not indicated. Adequate indications exist if a diagnostic or therapeutic consequence results from the examination or if a therapeutic procedure has primarily been considered. Individual indications can be found in disease-specific guidelines and in the recommendations of the German Society for Gastroenterology, Digestive and Metabolic Diseases (DGVS) [6] and other professional societies [7]. Chapter 4 of the guideline ‘Quality Requirements for Gastrointestinal Endoscopy’ [3] lists the indications in relation to the specific endoscopic interventions.

Timely Documentation of the Patient Information and Informed Consent

The German Federal Court of Justice (BGH) states that every medical intervention, even if it is done legally, is a personal injury according to section 223 and subsequent sections of the Criminal Code (StGB). A punishable offence and civil liability can only be omitted if the patient has provided an effective consent. For patients to be able to effectively consent to an intervention while respecting their freedom to make own decisions, they must be informed in detail about the risks related to the medical intervention and be able to consider the principles of the case law [8]. The central function of the informed consent is, therefore, to explain the

form, meaning, course, and consequences of a planned intervention to the patient and to document this accordingly. Patients must be informed in a timely manner so that they can decide on their own whether the intervention should be performed ([3] chapter 3.1).

Conducting a Standardised Risk Assessment before the Endoscopic Intervention

In the scope of the WHO initiative ‘Safe surgery saves lives’, in 2008 a 19-topic checklist was published providing a 3-level safety check (before the initiation of the anaesthesia, before the incision, and after the completion of the OP) [9]. In 2009, a multicentre study was performed worldwide and examined the efficacy of this WHO checklist [10]. The WHO checklists were used for 3,755 patients before the surgery and for 3,955 patients after the surgery. The complications occurring within a time window of 30 days after the OP were used as an indicator. Using the WHO checklist, it was possible to achieve significant reductions in severe complications, infections, lethality, and mortality in these patients. This can also be transferred to endoscopic interventions, for which the preparation of the patient should also be done by applying a standardised risk assessment identifying the patient’s risks related to the intervention and sedation.

Administration of an Antibiotic Prophylaxis in a Given Indication

The rate of infections with multidrug-resistant pathogens is increasing worldwide. In particular, the increase in resistant intestinal pathogens needs to be mentioned (multi-resistant Gram-negative (MRGN) pathogens). Thus, a moderate, evidence-based use of antibiotics is also required for prophylaxis. However, the bacteraemia rate caused by gastrointestinal endoscopies/interventions is clearly below those caused by daily activities, such as chewing (up to 70%) or brushing the teeth (up to 50%), without proof of an increased rate for endocarditis or prosthesis infections [11–14]. On the other hand, the administration of an antibiotic (AB) prophylaxis decreases morbidity and mortality for targeted indications and is a measurable parameter. The current guideline ([3] chapter 3.3) provides concrete indication-related recommendations for conducting AB prophylaxis in the endoscopic field.

Management of an Anticoagulant Medication before an Endoscopic Intervention

If a patient scheduled for an endoscopic intervention is under medication with anti-platelets and/or oral anticoagulants, it is essential to balance the individual risk of bleeding while performing the endoscopic intervention under the existing medication against the individual risk for a thromboembolic complications by stopping the medication. This also applies for a bridging and renewed administration of the medication. The procedure should also be documented. In difficult individual cases, a consultation with the treating cardiologist/anticoagulation specialist is useful. The current guideline also provides concrete recommendations for the handling of new oral anticoagulants (NOAK) ([3] chapter 3.2).

Conducting and Documenting a Team Time Out

The team time out (verification process done immediately before starting the procedure) is a useful instrument to prevent an adverse event and complications, and to enable a smooth, target-oriented intervention [9, 10]. Directly before the endoscopic intervention, details of the patient’s risk, preparation, and intervention are queried in a summarised form and documented. The US guidelines on the sedation and care record also mention the team time out as an additional review instrument beyond the pre-endoscopic risk assessment [15, 16]. An example for the ‘Endoscopy team time out form’ can also be found in the current guideline ([3] chapter 3.4).

Intra-Procedural Quality Parameters

Photo Documentation of Landmarks and Pathological Findings during an Endoscopic Intervention

Image documentation needs to be standardised and patient-related. Image documentation should include the following: i) images with ‘landmarks’ of the examined structures; ii) images of all of the pathological findings; iii) images of all of the therapeutic interventions with documentation from before and after the intervention, optionally also during the intervention. These 3 forms of image documentation are also mentioned in the international guidelines of the ESGE and ASGE as a quality attribute [4, 17]. Furthermore, the image documents should be stored according to the legal requirements and, if applicable, should be submitted to the competent self-governing bodies for quality control reasons [18].

Collection and Documentation of the Duration of an Endoscopic Intervention (Time Recording)

The time recording of the examination and intervention process includes the time spent for the intervention itself and the time spent on the corresponding preparation and follow-up. The input of time and personnel for each endoscopic intervention should also be shown ([3] chapter 2.3). This has already become a self-evident fact in the surgical field and it is an important basis for adequate imbursement. The time recording of an endoscopic intervention is mentioned in the current guideline as a ‘target’ recommendation. The time recording programs used should preferably be equipped with a time stamp function (time-based record).

Conducting and Documenting Continuous Vital Sign Monitoring

Please refer to the S3 Guideline ‘Sedation regarding the Endoscopy’ [6].

Post-Procedural Quality Parameters

Conducting a Standardised Discharge Management

The German S3 guideline on sedation [6] recommends documenting specific parameters in a structured way before the transfer or discharge of the patients. Corresponding checklists objectively ensure reproducible processes and further support patient safety.

Compiling Complete Report Documentation

The completeness of the documentation of medical data is based on the one hand on legal implications [19, 20], but is also the basis for a quality control [21]. The documentation of the complete treatment process should include the following aspects:

- (1) Patient identification
- (2) Examination indication
- (3) Identification of examining physician and assistant staff
- (4) Device type and identification (serial number)
- (5) Medication relating to the documentation requirements according to the S3 sedation guidelines
- (6) Time recording of the examination and intervention process
- (7) Completeness and assessability of the examination
- (8) Endoscopic findings according to standard classification system (normal result, pathological result)
- (9) Endoscopic diagnosis and therapy
- (10) Coding of the International Classification of Diseases (ICD) and the Operational and Procedure Key (OPS) by means of stored suggested diagnoses with ICD and OPS code
- (11) Documentation of the instruments and materials used
- (12) Relevant image files.

Compiling and Documenting Follow-Up Recommendations

Another important quality attribute is the set of recommendations regarding the follow-up with information on monitoring, transition to a normal diet, possible continuation of anticoagulants, and the further proceeding.

Documentation of Accessories and Instruments

The documentation of the instruments and materials used and an identification of the disposable material used via barcodes must be performed according to the standard. This ensures a traceable documentation of the materials with respect to the hygiene requirements ([3] chapter 6; [22–24]) and the withdrawal modalities.

Documentation of the Frequency of Intra- and Post-Procedural Complications

The documentation of intra-procedural complications is an important quality attribute for the intensity of the monitoring and further therapy of the patient, if applicable. The documentation of the frequency of specific intervention-specific complications (intra- and post-procedural) is another quality parameter. To document valid data, an active follow-up of the patient may be required, in particular regarding the documentation of late complications (e.g. telephone contact after an ambulatory polypectomy). Examples for intervention-specific complications are stated in chapter 4 of the guideline [3] under the individual procedures.

Quality Indicators/Parameters for Specific Procedures

Beyond the general quality parameters (table 1), the quality parameters for specific procedures (supplementary table 1; available at <http://content.karger.com/ProdukteDB/produkte.asp?doi=443653>)

have been derived from the recommendations of the S2k guideline [3] for the preparation, conduct, and follow-up of specific endoscopic interventions.

Oesophagogastroduodenoscopy

Intra-Procedural

Complete Oesophagogastroduodenoscopy

A complete oesophagogastroscope includes the evaluation of the oesophagus starting from the upper oesophagus sphincter up to the duodenum part II and is a quality attribute [25].

Diagnostic and Follow-Up of Pre-Malignant Lesions in the Oesophagus, Stomach and Duodenum Using High-Solution Video Endoscopy

Most of the studies on the diagnostic work up of pre-malignant lesions in the upper gastrointestinal tract investigated the additional use of contrast enhancement and magnification compared to SD (standard white light) or HD (high definition) endoscopy. Studies using HD endoscopy failed to show a significant benefit for additional chromoendoscopy (real or virtually) in the detection of dysplasia in squamous cell carcinoma and Barrett's oesophagus [26–29]. The current ESGE guideline does not classify the white light endoscopy (SD) as sufficiently exact in differentiating and diagnosing pre-neoplasm conditions and lesions (*Helicobacter pylori* (HP) gastritis, atrophic gastritis, intestinal metaplasia); thus, the use of the best available endoscopy technique and the collection of sampling biopsies in the endoscopic monitoring are requested for patients with a precancerous condition ([3] chapter 4.1; [30]).

Guideline-Adequate Biopsy Collection from Inflammatory, Pathological or Pre-Malignant Lesions

Endoscopically suspect lesions include changes of the mucous membrane caused by inflammations, ulcers, tumours, and infections. The diagnostic and monitoring of precancerous conditions relates to Barrett's oesophagus but also to the atrophic gastritis with or without intestinal metaplasia [30, 31]. In these cases, the recommendations for the indication and sampling of endoscopic biopsies refer to the current guidelines of the professional society [6].

Endoscopic Treatment of Bleeding from Oesophageal Varices

Pre-Procedural

Administration of a Vasopressin Analogue in Acute Variceal Bleeding

Antibiotic Prophylaxis in Acute Variceal Bleeding: The administration of an antibiotic prophylaxis in acute variceal bleeding significantly reduces morbidity and, therefore, should be performed ([3] chapter 3.3). A significant improvement of the initial bleeding control and 5-day haemostasis has been proved for the administra-

tion of vasopressin analogues in cases of acute variceal haemorrhage ([3] chapter 4.3.2).

Intra-Procedural

Endoscopic Band Ligation as a First-Choice Procedure for Endoscopic Treatment of Acute Oesophageal Variceal Bleeding and for Endoscopic Primary and Secondary Prophylaxis of Oesophageal Varices

Endoscopic band ligation should preferably be performed in acute oesophageal haemorrhage as the first-choice procedure. Furthermore, band ligation is the first-choice procedure in the endoscopic primary and secondary prophylaxis of oesophageal variceal bleeding ([3] chapter 4.3). For sclerotherapy with Aetoxysklerol/polidocanol, comparative studies on endoscopic band ligation have shown an increased rate of recurrent bleeding and complications (ulcers, perforation, and mediastinitis) [32–34].

Post-Procedural

Recommendation to Control and Continue the Endoscopic Band Ligation in the Primary and Secondary Prophylaxis of Oesophageal Varices

The endoscopic band ligation treatment should be periodically performed until eradication. Subsequently, regular endoscopic controls should be undertaken and, if applicable, a renewed ligation therapy if recurrent varices are found. Complete eradication of oesophageal varices with band ligation every 2–4 weeks is achieved after 2–4 sessions ([3] chapter 4.3; [32]).

Endoscopic Therapy of Non-Variceal Bleeding

Pre-Procedural

Immediate Proton Pump Inhibitor (PPI) Administration before the Endoscopy if Acute Ulcer Bleeding Is Suspected

If acute ulcer bleeding is suspected, therapy with PPI should be administered immediately, independent of the time of the endoscopy. The Cochrane meta-analysis [35] shows the benefits of this procedure with regards to the rate for bleeding stigmata and the number of the required therapeutic interventions ([3] chapter 4.4).

Intra-Procedural

Performance of a Second Endoscopic Haemostasis Procedure (Mechanical/Thermal) in Addition to Injection Therapy if a High-Risk Stigmata and Peptic Ulcer Bleeding Is Present

Several meta-analyses and a Cochrane analysis [36–40] dealing with the endoscopic therapy of peptic ulcer bleeding revealed that the combination with a second haemostasis procedure (haemoclip

or thermal procedure) is superior to the injection therapy alone with regards to the recurrent bleeding rate and the requirement to perform surgery ([3] chapter 4.4).

Post-Procedural

Recommendation of HP Testing and Continuation of a PPI Therapy for Peptic Ulcer Bleeding

In light of the data from a Cochrane analysis [41] and a meta-analysis [42], a high-dose PPI therapy cannot generally be recommended for each case of peptic ulcer bleeding, but it seems to be justified if a high-risk bleeding stigmata is present. If the HP test was not already performed during the acute endoscopy, the report should recommend it be done ([3] chapter 4.4).

Colonoscopy

Intra-Procedural

Documentation Rate of the Preparation Quality (Simplified Boston Score)

The Boston Bowel Preparation Scale is the most frequently used validated score [43, 44]. It defines the cleanliness for 3 sections of the colon with 3 levels (0 = not prepared, 1 = only small parts of the mucosa visible; 2 = mucosa predominantly visible, 3 = mucosa clearly visible) so that the result is total scores of between 0 and 9. The quality of the preparation needs to be documented not only for legal reasons. If a bowel is badly prepared, the need for repetition of the colonoscopy has to be discussed with the patient. 2 recent reviews of the literature show that there is no difference of the adenoma detection rate between a very well and well/sufficiently prepared bowel but there are differences between these 2 categories (summarised) and a badly prepared bowel, and they conclude a need for repeated colonoscopies [45, 46]. If the adenoma detection rate is taken as the main surrogate parameter for the outcome quality of the colonoscopy (as few not-detected carcinomas as possible) [47, 48], this justifies the recommendation that a repeat colonoscopy is necessary in cases of bad bowel preparation ([3] chapter 4.5.1).

Attained Caecum Intubation Rate (Documentation of the Appendix Orifice, Caecum Base and Ileocaecal Valve)

A Canadian database evaluation of 1,260 interval carcinomas revealed that endoscopists with a high caecal rate and those with a higher polypectomy rate (related to account data) detected significantly fewer interval carcinomas and this in an almost linear correlation [49]. The EU guidelines regarding the quality of colorectal carcinoma screenings, including the prophylactic colonoscopy, suggest a cecum intubation rate of at least 90% as a quality criterion, with the exemption of obstructing processes of the colon [50]. Excluding hindering factors, as the rates vary depending on the adjustment and as it should be assumed that fewer contaminated bowels and strictures can be found during a prophylactic colonoscopy, a rate of 95% should be supported ([3] chapter 4.5.3).

Documentation of Withdrawal Time (in the Scope of the Time Recording)

With respect to the withdrawal time, several larger studies showed a positive influence of longer withdrawal times on the adenoma detection rate. Despite being high-level publications, it should be stated that these studies were possibly post-hoc analyses and not prospectively planned studies as there was no prospective time measurement, e.g. with a stopwatch, in cases involving biopsies and polypectomies. For this reason, only negative colonoscopies with no polyp findings requiring a biopsy or resection have been used for the documentation of the withdrawal time ([3] chapter 4.5.23).

Adenoma Detection Rate in Prophylactic Colonoscopy or Cases with Adequate Indications

A correlation of the adenoma detection rate (ADR, rate for patients with at least 1 adenoma) is plausible despite the limitations of the present studies. For this reason, a cut-off value of 20% is recommended for the ADR to be achieved in prophylactic colonoscopies [47]. Analysis of the literature shows, in a model calculation for interval carcinomas, a mean rate of 0.7 for non-detected carcinomas; in addition, a rate of 1.1 for the development of a carcinoma due to non-detected carcinomas has been calculated. In contrast, de novo carcinomas not having been detected nor resulting from non-detected carcinomas are evaluated as very rare [51]. It should be explicitly stated that the ADR as a quality parameter is only established for prophylactic colonoscopies, and, thus, it cannot be correlated directly to the diagnostic colonoscopy. According to the available data, symptoms such as abdominal pain (partly termed irritable colon), diarrhoea, and, in particular, constipation show a more or less similar ADR as that of the prophylactic colonoscopy ([3] chapter 4.5.3).

Documentation of the Completeness in Cases of Polypectomy (Endoscopic Evaluation)

The completeness of the polypectomy should be controlled endoscopically. In this case, the suggested follow-up intervals are given in the recommendations of the DGVS guidelines on colorectal carcinoma [6, 7]. In the case of a piecemeal resection, biopsies from macroscopically normal scar areas should also be performed during the first endoscopic follow-up. The recommendation for a biopsy even from a normal scar comes from a recently published German 2-centre study in which biopsy specimens of macroscopically inconspicuous scars showed 7% adenoma tissue at follow-up [52]; however, a recurrence was only seen in 3% of cases with a normal scar and negative biopsy ([3] chapter 4.5.3; [53]).

Post-Procedural

Completeness of Performing Histological Examination Following Polypectomy or Biopsy of Non-Ablated Polyps

Resected lesions should be sent for histological examination and the localisation should be indicated. If this is not possible in single

cases, this should be documented in the report. The histological evaluation of resected polyps should be considered as standard with regard to the current standard of knowledge. However, in Anglo-American countries, it has been suggested that due to cost reasons [54, 55] polyps should be resected but not analysed histologically ('resect and discard', shortly DISCARD). Up to now, this policy is limited to polyps of less than 5 mm for risk assessment reasons. These considerations are based on several studies of endoscopic differential diagnosis using pit patterns and a virtual chromo-endoscopy, with normally very good results [56–58]. These studies have been summarised in various reviews and 'meta-analyses', such as the recent update of the ASGE recommendation [59]. However, there is an increasing number of high-level studies showing that this does not work in many centres and under 'routine conditions' [60–63].

The uncertainty in differential diagnostic between hyperplastic polyps and sessile serrated adenomas complicates the topic, in particular, with regards to the prognostic meaning. Therefore, the guideline recommends sending resected lesions for histological examination indicating also the localisation.

Endoscopic Retrograde Cholangiopancreatography (ERCP)

Pre-Procedural

Post-ERCP Pancreatitis Prophylaxis in Risk Patients/Risk Interventions

The rectal application of 100 mg diclofenac or indomethacin before and after ERCP with papillotomy is well proved for the prophylaxis of a post-ERCP pancreatitis (PEP) and should be applied as standard ([3] chapter 4.8.3).

Intra-Procedural

Cannulation Success, Successful Stent Placement, Successful Removal of the Stent

Documentation of the Fluoroscopy Time and Dose: A large meta-analysis analysing more than 8,000 publications regarding quality criteria for ERCP included 52 qualitatively adequate prospective and retrospective studies [64]. The cumulative success rate for bile duct cannulation was 89.3%, and that for pancreatic duct cannulation was 85%. A pre-cut was applied in 10.5%. The stone extraction rate from the Ductus hepatocholedochus (DHC) was at 88.3%, and the rate of the successful placement of a stent into the DHC below the hilar bifurcation was 97.5%. The subgroup analysis did not result in statistically significant differences between academic and local endoscopies, and prospective and retrospective studies. There were also no differences for the participation of a trainee during bile duct cannulation, pre-cut, and stone extraction. There were no data available for the pancreatic duct cannulation and bile duct stenting in this setting. The current publication of the ASGE regarding the quality indicators in the ERCP [65] states similar intra-procedural

quality indicators, whereas here, the success rates for bile duct and pancreatic duct cannulations, DHC stentings, and stone extraction are indicated with >90%. The documentation of the fluoroscopic time and radiation dose should be performed, and is embedded in the Radiation Protection Act. For further recommendations regarding a standardised procedure in the ERCP, if applicable with derivable quality parameters, please refer to ([3] chapter 4.8.3).

Post-Procedural

Specific Complications (e.g. PEP, Bleeding after Papillotomy, Perforation)

In addition to the general post-procedural quality indicators, the documentation of specific complications for an ERCP may also serve as a quality indicator. With regard to the documentation of, for example, the PEP, the analysis should be based on the indication of the intervention (planned bile duct or pancreatic duct cannulation, naive versus pre-cut papilla, second intervention following the pre-cut) to define risk subgroups.

Diagnostic Endoscopic Ultrasound

In 2006 and 2014, a work group of the ASGE and the American College of Gastroenterology published quality indicators for endosonography, including pre-procedural, indication-related procedural and post-procedural criteria [66, 67]. The specific quality indicators suggested here for endoscopic ultrasound (EUS) and EUS-guided fine-needle aspiration (FNA) are based on those suggested by the ASGE [67], and implement the indicators documented in the endosonography registry of the German Society for Ultrasound in Medicine (Deutsche Gesellschaft für Ultraschall in der Medizin; DEGUM) [68].

Pre-Procedural

Please refer to the general quality parameters for the per-interventional antibiotic prophylaxis in cases of EUS-FNA ([3] chapter 3.3).

Intra-Procedural

Documentation of Anatomic Structures Relevant to the Indication

The indication-related completeness of an examination should be documented by an image or a video sequence and description of the relevant anatomic structures. The description of pathological results requires the indication and documentation of the anatomic localisation, measurements and sonographic structural features (echogenicity, echostructure, contour, relative tissue stiffness, and vascularisation) to enable a clinical and differential diagnostic interpretation, reproducibility, evaluation of therapeutic effects, and follow-up controls. As far as available, internationally accepted classification sys-

tems embedded in guidelines should be used. Thus, the description of pathological results using the minimal standard terminology (MST 3.0) for the gastrointestinal endoscopy of the organisation Mondiale D'Endoscopie Digestive (OMED) is useful [69].

EUS-FNA

Intra-Procedural

Documentation of the Needle Type, Needle Diameter, Number of Needle Passes, and Material Processing

The description of the results of an EUS-FNA should include information on the target lesion, in case of several target lesions the order of the puncture, the needle route (e.g. trans-oesophageal or trans-gastral), the needle type and diameter, the number of the needle passes, the material quality and processing. This information is, among others, important for the cytopathological diagnosis and for the estimation of the quality of the technical performance. It allows a correlation with the result quality [66, 70]. All of the mentioned intra-procedural quality indicators are evaluated in the ASGE recommendation [66] with a quality target of >98%.

Post-Procedural

Effectiveness of the EUS-FNA

The portion of malignant diagnoses in cases of EUS-FNA used for solid pancreatic masses was evaluated in a US multicentre study as a surrogate parameter of the diagnostic accuracy suitable for benchmarking. Here, the mean frequency of diagnosed pancreatic carcinomas was 71% [71]. The authors suggested that a work-up of the complete diagnostic process should be performed if the cytological diagnose rate was <52% (1st quartile) [72]. This quality parameter was used by the ASGE [72] but cannot be transferred to the German situation as the indicators for the biopsy of solid pancreatic carcinomas in Germany clearly differ from those used in routine practice in the USA [73]. The percentage of diagnostically adequate material (acceptable: ≥85%), the portion of conclusive results (diagnostic categories: malignant, neoplasm, benign) and the portion of specific diagnoses with regards to the total number of malignant findings may be used as quality parameters [72, 74, 75].

Percutaneous Transhepatic Cholangiography and Drainage (PTCD)

Pre-Procedural

Conducting an Imaging Procedure of Bile Duct Pre-PTC/PTCD

Imaging is useful for the indication for, and localisation of, enlarged bile ducts and the planning of a suitable access for the PTC, and, especially, the PTCD [76]. This, in particular, applies to the

complication rate for this method of 22% for minor, and 4.7% for severe complications (mostly bleeding). With more than 3,110 patients, one of the largest case series regarding the complication rates, in particular concerning the arterial vascular injuries, recommended conducting an imaging procedure as a mandatory requirement prior to any new insertion [77].

Intra-Procedural

PTC/PTCD Success Rate

The success rate of the PTC is 90% for cases with dilated bile ducts; for the insertion of a percutaneous drainage in dilated bile ducts success rates between 90 and 100% can be achieved. The cannulation and drainage of non-dilated bile ducts is more difficult, and related to lower success rates of approximately 70% ([3] chapter 4.12; [78, 79]).

Capsule Endoscopy

Pre-Procedural

Prevention of Capsule Retention

Capsule retention is one of the most significant complications (approximately 1–2%, [80]); it is defined as a capsule remaining in the intestine for more than 14 days. Capsule retentions are more common in some specific diseases or pre-treatments (Crohn's disease 2–3% in larger series, in some studies partly up to 13% [80–82]; tumours of the small intestine 10–25% [83]). It is possible to

prevent retentions in particular in risk groups by imaging or the use of a patency capsule [84].

Intra-Procedural

Adequate Assessability of the Small Intestine Mucosa

The adequate assessability of the mucosa for the small intestine video capsule endoscopy (VCE) and capsule colonoscopy depends on the preparation [85] and correlates with the diagnostic effect. The preparation regime and the evaluation systems of individual studies vary. Meta-analyses and studies commonly differ between an adequate and inadequate assessability [86, 87] and also partly in use of a 4-level evaluation system (excellent, good, moderate, and bad) that is similar to the Aronchick Scale [88].

Complete Small Intestine Capsule Endoscopy (Arrival at the Caecum during the Examination Time)

A complete small intestine capsule endoscopy is defined as its arrival at the cecum during the examination time [85]. The rate of incomplete examinations is 10–25% [89]. Due to the longer life-times of the current generation of capsules in combination with the real-time viewer, the number of incomplete examinations is now decreasing [90, 91].

Disclosure Statement

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