1. Introduction

Colonoscopy is the current standard method for evaluating the colon. Recent surveys have shown that the proportion of individuals aged 50 years or older who have undergone colonoscopy within the last 10 years is growing and currently ranges from 6%–25% in various European countries to 62% in the United States [1, 2]. Bowel preparation for colonoscopy is a complex undertaking, involving diet modifications and laxative choice according to patient needs. An adequate level of cleansing is critical for the efficacy of colonoscopy. Two key quality indicators of colonoscopy, cecal intubation rate and polyp detection rate, are associated with the quality of bowel cleansing [3, 4]. An inadequate level of bowel cleansing also results in further costs as the examination has to be re-scheduled or alternative investigations have to be organized [5]. Furthermore, the discomfort and inconvenience of bowel preparation may affect the acceptability and uptake of colonoscopy in screening programs [6]. The aim of this evidence-based and consensus-based Guideline commissioned by the European Society of Gastrointestinal Endoscopy (ESGE) is to provide caregivers with a comprehensive review of the various regimens available and with practical advice for bowel preparation before colonoscopy.
2. Methods

The ESGE commissioned this Guideline. The guideline process included meetings, telephone conferences, and online discussions among members of the committee during October 2011 and January 2012. Subgroups were formed, each in charge of a series of clearly defined key questions (Appendix e1, available online). The committee chairs (C.H., J.M.D.) worked with the subgroup leaders (M.B., M.F.K., M.P., B.R., B.S.) to identify pertinent search terms that always included, as a minimum, “bowel preparation” as well as terms pertinent to specific key questions. Searches were performed in Medline. Articles were first selected by title; their relevance was then confirmed by review of the corresponding manuscripts, and publications with content that was considered irrelevant were excluded. A repository of selected literature was made available to all members of the guideline development group. Evidence tables were generated for each key question, summarizing the level of evidence of the available studies. For important outcomes, articles were individually assessed by using the Grading of Recommendation, Assessment, Development and Evaluation (GRADE) system for grading evidence levels and recommendation strengths [7]. The GRADE system is clinically oriented as the grading of recommendations depends on the balance between benefits and risks or burden of any health intervention (Appendix e2, available online). The different subgroups developed draft proposals that were presented to the entire group for general discussion during a meeting held in February 2012 (Dusseldorf, Germany). Further details on the methodology of ESGE guidelines have been reported elsewhere [8]. In June 2012, a draft prepared by J.M.D. and C.H. was sent to all group members. After agreement on a final version, the manuscript was submitted to the journal Endoscopy for publication. The journal subjected the manuscript to peer review, and the manuscript was amended to reflect reviewers’ comments. The final revised manuscript was agreed upon by all the authors. This Guideline was issued in 2013 and will be considered for review in 2016, or sooner if new evidence becomes available. Any updates of the Guideline in the interim period will be noted on the ESGE website: http://www.esge.com/esge-guidelines.html.

3. Recommendations and statements

Evidence statements and recommendations are stated in italics, key evidence statements and recommendations are in bold.

The ESGE recommends a low-fiber diet on the day preceding colonoscopy (weak recommendation, moderate quality evidence).

The potential benefit of a restricted diet before colonoscopy has not been well studied but such diets have been used in most studies. In a retrospective cohort study of 789 patients [9], adherence to the prescribed low-residue diet during the 2 days preceding colonoscopy was an independent predictor of adequate bowel preparation. In a subgroup analysis of a randomized controlled trial (RCT) that allocated patients to low-volume vs. high-volume polyethylene glycol (PEG), patients randomized to low-volume (bisacodyl and 2 liters [L] PEG) more frequently had poor colon cleanliness if they were allowed a normal diet compared with clear fluids only (44.0% vs. 68%, respectively; P<0.001); no difference was found in patients taking 4L of PEG [10]. However, this aspect of bowel preparation is likely less important than the timing of bowel preparation as an RCT has found that split-dose 4-L PEG and no dietary restriction provides better quality colon cleansing than single-dose 4-L PEG with a liquid diet on the day preceding colonoscopy [11]. Two RCTs have compared a clear liquid vs. a low-fiber diet on the day preceding colonoscopy in a total of 414 patients taking identical purgatives for bowel preparation [12, 13]. Both RCTs found that a low-fiber diet was better tolerated than a clear liquid diet; furthermore, satisfactory colon cleanliness was more frequent in patients randomized to non-clear-liquid diets compared with a clear liquid diet (in one of the RCTs the difference was statistically significant in the mid colon only) [13].

The ESGE does not make any recommendations regarding the use of low-fiber diet for more than 24 hours prior to the examination (insufficient evidence to make a recommendation).

Some endoscopists routinely prescribe a low-fiber diet during the 3 days preceding colonoscopy rather than on a single day because of the slow transit time in some patients. However, no study has compared the use of a 1-day vs. a 3-day regimen.

The ESGE recommends against the routine use of enemas in addition to oral bowel preparation (strong recommendation, moderate quality evidence).

A single RCT has compared patients who did or did not have an enema routinely added to standard bowel preparation. The addition of an enema did not result in improved bowel cleansing. However, the acceptability to patients of an identical bowel preparation in the future was lower in patients who had received an enema [14]. Another RCT found no significant difference when different purgatives were prescribed in the groups that did or did not receive the enema [15].

The ESGE does not recommend the routine use of prokinetic agents as adjuncts to bowel preparation (weak recommendation, moderate quality evidence).

Several prokinetic agents have been tested in RCTs as adjuncts to bowel preparation:

- Metoclopramide, domperidone, cisapride and tegaserod did not improve the tolerability of bowel preparation or the quality of bowel cleansing [16–20].
- Two other prokinetic agents, mosapride (an agonist for 5-hydroxytryptamine4 [5-HT4] receptors) and itopride (an antagonist for dopamine receptors and acetylcholinesterase) were found to significantly reduce adverse bowel symptoms including nausea, vomiting, bloating, and abdominal pain (the state of bowel cleansing was similar in all groups) [21]. These results, however, should be confirmed by other groups of authors before a recommendation can be made.

The ESGE suggests adding simethicone to standard bowel preparation (weak recommendation, high quality evidence).

Bubbles and foam are frequently encountered during colonoscopy (32%–57% of patients). This may hamper visualization of the mucosa [22, 23]. Simethicone is an inexpensive substance that reduces the surface tension of air bubbles. It is not absorbed into the bloodstream and it is therefore considered safe.

In a meta-analysis [24] of seven RCTs comparing bowel preparation (PEG or oral sodium phosphate [OSP]) with vs. without simethicone [22, 23, 25–29], the amount of bubbles was more frequently unacceptable in patients who had not received simethicone (odds ratio [OR], 39.3; 95% confidence interval [95% CI] 11.4–135.9). No difference in colon cleanliness was found. Be-
cause bubbles can be removed during colonoscopy, it is uncertain how the addition of simethicone to bowel preparation affects the efficacy of colonoscopy for detecting lesions. Only one of the seven RCTs included in the meta-analysis compared the detection of lesions in patients who had received simethicone or not; it was underpowered to detect such a difference [22]. Dosage of simethicone varied between studies, the most common being 120–240 mg or 45 mL of a 30% solution given with the evening and morning doses of a purgative. A compound preparation of PEG and simethicone is available in some countries.

The ESGE recommends a split regimen of 4 L PEG solution (or a same-day regimen in the case of afternoon colonoscopy) for routine bowel preparation. A split regimen (or same-day regimen in the case of afternoon colonoscopy) of 2 L PEG plus ascorbate or of sodium picosulphate plus magnesium citrate may be valid alternatives, in particular for elective outpatient colonoscopy (strong recommendation, high quality evidence). In patients with renal failure, PEG is the only recommended bowel preparation. The delay between the last dose of bowel preparation and colonoscopy should be minimized and no longer than 4 hours (strong recommendation, moderate quality evidence).

**Polyethylene glycol (PEG) vs. oral sodium phosphate (OSP)**

Six meta-analyses, published over a 14-year period (1998–2012), have compared various purgatives for pre-colonoscopy bowel preparation [30–35]. They included between eight and 104 controlled studies and all but one [30] included RCTs exclusively. Among five meta-analyses of head-to-head comparisons of PEG vs. OSP [30,31,33–35], three concluded that satisfactory (excellent or good) colon cleansing is significantly less frequent with PEG compared with OSP (70%–77% vs. 75%–82%) [31,33,34]. The two remaining meta-analyses found no statistically significant difference between PEG and OSP for overall colon cleansing [30,35]. These two meta-analyses included the highest number of studies because one of them was the most recent [35], and the other one was not restricted to RCTs [30]. A sixth meta-analysis has also included trials that were not head-to-head comparisons. Its main finding was that OSP tablets provide a very high proportion of satisfactory colon cleansing (88%); however, no statistically significant difference was found compared with other regimens [32]. Safety concerns prevent us from recommending routine use of OSP (see below). All the meta-analyses found a significant heterogeneity among trials; this is likely explained by various factors, including variations in the timing of bowel preparation, in dietary instructions, in scales used to assess colon cleanliness, and possibly in the use of adjunctive agents.

**Magnesium citrate with stimulant laxative**

In the UK, magnesium citrate is frequently used as a low-volume bowel preparation in combination with a variety of stimulants. Magnesium citrate combined with sodium picosulphate (Picolax or Picoprep) was compared with PEG and OSP in one meta-analysis (six studies, total of 966 patients) [34]. Compared with PEG, magnesium citrate plus sodium picosulphate provided satisfactory colon cleansing in a similar proportion of patients, with less frequent adverse events (mostly nausea, vomiting, abdominal pain, and sleep disturbances; OR 3.82, 95% CI 1.60–9.15) but OSP produced better colon cleansing than magnesium citrate plus sodium picosulphate.

Various preparations containing magnesium have been tested; Appendix e3 (available online) summarizes eight RCTs that compared such preparations with OSP or PEG in a total of 1780 patients [36–43]. When the results of all RCTs were pooled, no significant difference was found between the different regimens in terms of colon cleanliness. In those trials comparing magnesium-based bowel preparation with PEG preparation, clinical side-effects were not significantly different but willingness to repeat the same bowel preparation was higher in the magnesium-based group (a single RCT analyzed that outcome) [38]; mucosal inflammation/ulcerations were significantly more frequent with magnesium-based bowel preparation in the single RCT that assessed that outcome [36]. In two single-blinded RCTs, magnesium citrate combined with 2 L PEG provided similar colon cleanliness to 4 L PEG but with higher patient satisfaction and willingness to repeat the same bowel preparation [44,45].

**Low-volume PEG**

Various combinations of low-volume (2 L) PEG with an additional laxative have been tested; Appendix e3 (available online) summarizes 11 RCTs that compared such combinations vs. a standard volume of PEG (4 L). Five RCTs (a total of 1997 patients) used a commercially available formulation of PEG with ascorbate (Moviprep; Norgine Pharmaceuticals) [46–50]. No significant difference was found between the low-volume formulation and 4 L PEG in terms of colon cleanliness for the whole colon. However, cleanliness in the right colon (assessed in a single study) was less frequently satisfactory with 2 L PEG than with 4 L PEG (54% vs. 82% of patients, respectively; P < 0.0001) [48]. Of note, cleanliness in the right colon may be particularly important in the screening setting [51,52]. Willingness to repeat identical bowel preparation was reported in two RCTs; it tended to be higher with the low-volume formulation as compared with the 4-L PEG (73% vs. 65%, respectively; P = 0.079) [47,48]. One of the limitations of these RCTs is that the majority (77.6%) of patients had elective outpatient colonoscopy, which is a predictor of satisfactory colon cleansing.

The other six RCTs (a total of 1437 patients) used agents other than ascorbate as additional laxatives, including senna, bisacodyl, magnesium, or olive oil [10, 53–57]. Satisfactory colon cleansing was less frequent with the low-volume PEG vs. the 4-L PEG (61% vs. 76%, respectively; P < 0.0001). The RCT that used magnesium or olive oil as additional laxatives suggested that olive oil combined with 2 L PEG provides better cleansing in the right colon than 4 L PEG (no difference was noted in the left colon), as well as higher patient willingness to repeat identical preparation; these results should be taken with caution as only 80 patients were randomized to one of these two regimens [53].

**Split-dose regimen**

In general, split dosing of bowel preparation is recommended: a meta-analysis of five RCTs found that, compared with the administration of the full dose of PEG on the day before colonoscopy, a split-dose regimen of PEG significantly improved the percentage of patients with satisfactory colon cleanliness, significantly increased patient compliance, and significantly decreased nausea [58]. It has also been suggested that more flat polyps are detected with split-dose vs. single-dose bowel preparation but the RCT that found this difference used a variety of purgatives (PEG and OSP) [59].
The most feared complication following OSP intake is kidney injury. The largest report of kidney injury (21 patients) described the development of acute renal failure within a few weeks after colonoscopy, which modestly improved over time and required renal replacement therapy in four of the patients [85]. A meta-analysis of seven controlled studies (12,168 patients) that compared the effect of OSP vs. another bowel preparation on kidney function found no statistically significant association between OSP and kidney injury [86]. However, these studies were usually not powered to detect rare, serious complications and tended to exclude individuals at risk for complication development by tight control of inclusion criteria. Moreover, between January 2006 and December 2007, 171 cases of renal failure were reported to the United States Food and Drug Administration (FDA) following the use of OSP and 10 following the use of PEG [87]. A retrospective, population-based national analysis in Iceland estimated that the risk of biopsy-proven acute phosphate nephropathy is approximately 1 per 1000 OSP doses sold [88]. Another severe complication of OSP for bowel preparation consists of acute disruption of electrolyte homeostasis, including hyperphosphatemia, hypocalemia, hypokalemia, and hyper- or hyponatremia. The spectrum of clinical presentation varies from mild symptoms related to hypocalemia to death [87].

The ESGE suggests that oral sodium phosphate can only be advised in selected cases of specific needs that cannot be met by alternative products (e.g., patient unable to tolerate other agents) and only in individuals assessed by physicians to be at low risk of oral sodium phosphate-related side-effects. An evaluation of the kidney function should be available before prescribing oral sodium phosphate (weak recommendation, low quality evidence). If oral sodium phosphate is used for bowel preparation, 90 mL (solution) or 32 tablets each containing 1.5 g sodium phosphate (48 g total), both in a split-dose regimen is recommended (strong recommendation, high quality evidence).

Several meta-analyses showed that a higher proportion of patients takes the full amount of the prescribed preparation if OSP is prescribed compared with PEG [31–34]; in the most recent meta-analysis of RCTs, completion rate with OSP was 97% compared with 90% with 4L PEG (it was 98% with 2L PEG and 95% with a split-dose 3-L PEG regimen) [32]. Two meta-analyses also compared the tolerability of PEG vs. OSP [30,31]; the largest comparison found that, amongst 25 studies that reported tolerability, 14 studies reported that OSP was superior, 10 reported no signif-

### Same-day regimen

Scheduling colonoscopies in afternoon slots facilitates use of same-day preparation. Three RCTs investigating various timings of bowel preparation have shown that: (i) if 4 L PEG is prescribed, taking the whole dose of bowel preparation on the morning of the colonoscopy rather than on the day before colonoscopy provides better colon cleanliness, less sleep disturbance, and less bloating [60, 61], and (ii) if 2 L PEG plus ascorbate is prescribed, patient tolerance (i.e., absence of abdominal pain and of interference with the previous workday, better sleep quality) is increased by taking the whole dose of purgative on the day of colonoscopy rather than in a split-dose regimen (day before and day of colonoscopy); no difference was found in terms of colon cleanliness [62]. A prospective cohort study suggests that similarly, with sodium magnesium citrate plus sodium picosulphate, taking the whole dose of purgative on the day of an afternoon colonoscopy rather than in a split-dose regimen (day before and day of colonoscopy) provides better colon cleansing with fewer side effects, less impact on activities of daily living, and is preferred by patients [63].

### Timing of colonoscopy

The length of delay between the last dose of bowel preparation and the start of colonoscopy was found to be correlated with the quality of colon cleansing in three prospective studies involving 1546 patients in total [Appendix E3, available online] [49, 64, 65]. Various purgatives and timings of bowel preparation were used in these studies and all of them found that the delay between the last dose of bowel preparation and the start of colonoscopy was shorter in patients with a satisfactory colon cleansing. In one of these studies, it was estimated that for every additional hour that the patient waits between the end of bowel preparation and colonoscopy, the chance of having a good or excellent cleansing in the right colon decreases by up to 10% [65].

There are practical difficulties with the administration of bowel preparation on the morning of an afternoon list. There are risks of incontinence when traveling to the endoscopy unit and of bronchoaspiration if deep sedation is used [66]. Such concerns should not be overemphasized because two prospective studies (total 589 outpatients) have found no significant difference in the proportions of patients who had bowel movement while traveling to the endoscopy unit if bowel preparation was administered on the day preceding colonoscopy, on the day of colonoscopy, or with split dosing (globally, such incidents occurred in 5%–16% of patients) [59, 67]. Moreover, a survey of 300 individuals showed that, after having been informed about the advantages of split dosing, approximately 80% of these individuals would be willing to get up during the night to take the second dose of a split-dose bowel preparation before early morning colonoscopy [68]. An RCT that randomized patients scheduled for early morning colonoscopy for single-dose vs. split-dose 4-L PEG found no difference in compliance between these two regimens. Adverse effects (nausea, vomiting, and bloating) were more frequent with the single-dose vs. the split-dose regimen [69]. Patients starting bowel preparation intake at 0500 on the day of colonoscopy usually report no particular difficulties [55, 64]. Finally, the American Society of Anesthesiologists recommends 2 hours as the minimum fast from intake of clear liquids before sedation or anesthesia [70].

### Other laxatives

Senna and bisacodyl have mainly been used as adjuncts to PEG [Appendix E3, available online] or to other regimens [54, 57, 71–81]. Senna has also been shown to be effective when used alone at high doses [74]. However, it appeared to be less effective and tolerable than low-volume PEG preparation, and its use was limited by abdominal cramps [74–76, 78]. Similarly, high-dose (30 mg) bisacodyl alone has been shown to have a similar effectiveness to PEG, but it was poorly tolerated because of colicky abdominal pain [57, 81]. Mannitol has also been used for bowel preparation; it seems to be as effective and as well tolerated as OSP or PEG [82, 83]. However, its use has almost been abandoned because of the explosion risk when diathermy is used during colonoscopy [84].

The ESGE advises against the routine use of oral sodium phosphate for bowel preparation because of safety concerns (strong recommendation, low quality evidence).
The ESGE recommends that oral and written information about bowel preparation should be delivered by healthcare professionals. (Strong recommendation, moderate quality evidence).

The delivery of both oral and written instructions for bowel preparation, as opposed to written instructions only, has been shown to be an independent predictor of adequate level of cleansing [102]. Nonadherence to preparation instruction appeared to predict a poor level of bowel preparation [103]. Dedicated booklets or visual aids have also been associated with an improvement in the quality of bowel preparation [104, 105].

Specific scenarios

In patients with inadequate bowel cleansing, the ESGE suggests the use of endoscopic irrigation pumps or repeating colonoscopy on the following day after additional bowel preparation (Weak recommendation, low quality evidence). For the first colonoscopy, the use of models to identify patients at increased risk of inadequate cleansing, with the aim of adapting the bowel preparation is not recommended (Insufficient evidence to determine net benefits or risks).

Inadequate colon cleanliness at colonoscopy has been reported in up to 30% of patients undergoing colonoscopy. Identification of risk factors for inadequate colon cleanliness would have the potential benefit of selecting patients who need a more intensive bowel preparation regimen. Overall, six studies attempted to identify such risk factors by multivariate analysis (Appendix e4, available online) [102, 106 – 110]. Independent risk factors that were identified in at least three of these studies include male gender, inpatient status, and older age. However, a model based on such factors correctly predicted inadequate colon cleansing in only 60% of patients [102]. Furthermore, no study attempted to apply a different regimen to patients presenting with risk factors for inadequate colon cleanliness. Previous failure to adequately prepare colon cleansing might be a better predictor [111]. In two studies, one retrospective and one prospective, including a total of 318 patients, have analyzed the outcome of a second bowel preparation after inadequate colon cleansing [111, 112]. One of these studies identified colonoscopy on the day following colonoscopy failure due to inadequate colon cleansing as the only independent factor associated with adequate colon cleansing on repeat colonoscopy. The other study lacked a control group and was limited to outpatients; it showed that an “intensive” strategy of bowel preparation (including multiple diet recommendations, bisacodyl, and a split regimen of PEG) was associated with adequate colon cleansing at repeat colonoscopy in 90% of the cases [112].

Colonoscopy reporting should include an evaluation of the quality of colon cleansing, with the adoption of a validated scale [113]; we reason that adding information in the report about the likely cause of inadequate colon cleansing would also be useful. However, a recent audit in the Netherlands found that no information was stated about adequacy of colon cleansing in 38% of colonoscopy reports [114].

In a recent randomized study including 42 participants, an irrigation pump (flow rate 650 mL/minute) connected to a disposable catheter inserted through the working channel of a standard colonoscope has been shown to be more effective than the use of syringes for cleansing in patients with suboptimal bowel preparation [115].

The ESGE found insufficient evidence to determine for or against the use of specific regimens in pregnant/breastfeeding women. However, if total colonoscopy is strongly indicated, PEG regimens may be considered, with tapwater enemas preferred in the case of sigmoidoscopy (Insufficient evidence to determine net benefits or risks).

Colonoscopy appears feasible and relatively safe in pregnancy when strongly indicated [116, 117]. PEG has not been extensively studied in pregnancy and it is unknown whether it can cause fetal harm; when used for treating constipation during pregnancy, it is considered relatively safe [118 – 120]. Because full colonoscopy is rarely indicated during pregnancy, tapwater enemas are recommended as bowel preparation for sigmoidoscopy. No reported series allows any evaluation of the role of bowel preparation during lactation. If bowel preparation is strictly recommended, interrupting breastfeeding during and after bowel preparation may be an option.

The ESGE suggests the use of PEG for bowel preparation in patients affected by or at risk of inflammatory bowel disease. Other agents may cause mucosal abnormalities that mimic inflammatory bowel disease (Weak recommendation, moderate quality evidence).

OSP use may be associated with development of colonic mucosal abnormalities [121]. Endoscopically, mucosal lesions, possibly associated with OSP ingestion, were visible in 24 (erosions in 3,
aphthoid lesions in 21, and ulcer in 1 patient) out of 730 patients (3.3%). Lesions were often multiple. The OSP-associated lesions were predominantly located in the distal sigmoid colon and rectum [122]. In a randomized study including 634 patients, preparation-induced mucosal inflammation was 10-fold more frequent with OSP (3.4%; OR 9.8; P < 0.03) and sodium picosulphate (3.5%; OR 10; P < 0.03) compared with PEG (0.3%) [36]. In a study in healthy rats, OSP and PEG caused significantly more colonic mucosal damage compared with a control group and the damage induced by OSP was worse than that caused by PEG [123]. In another study, no significant difference was found either macroscopically or microscopically in terms of the effects of saline, OSP, and PEG solutions in both healthy rats and rats with chemically induced colitis [124].

The ESGE recommends PEG for bowel preparation if urgent colonoscopy is scheduled for lower gastrointestinal bleeding (strong recommendation, moderate quality evidence).

The role of emergency colonoscopy in lower gastrointestinal bleeding remains controversial [125–132]. Although some studies have shown that urgent examinations performed within 12–24 h of admission improve the diagnostic yield and reduce the rebleeding/surgery rates, others have not. Urgent colonoscopy may be defined as an examination performed within 12–24 h of admission following a rapid colon purge: it is safe and may facilitate the identification and treatment of bleeding lesions [125 – 131]. In a series of 140 patients admitted with acute lower intestinal bleeding, the cecal intubation rate was 41% without full bowel preparation compared with 74% in the PEG group [132].

Use of the guideline

In addition to the legal disclaimer applicable to all ESGE guidelines [8], for the current Guideline, prescribers should adhere to general as well as specific contraindications to bowel preparation (e.g., any oral purgative is contraindicated in the case of ileus, the use of Moviprep is contraindicated in individuals with phenylketonuria, because of the presence of aspartame, and in those with glucose-6-phosphate dehydrogenase deficiency, because of the presence of ascorbate).

ESGE guidelines represent a consensus of best practice based on the available evidence at the time of preparation. They may not apply in all situations and should be interpreted in the light of specific clinical situations and resource availability. Further controlled clinical studies may be needed to clarify aspects of this statement, and revision may be necessary as new data appear. Clinical consideration may justify a course of action at variance to these recommendations. This guideline is intended to be an educational device to provide information that may assist endoscopists in providing care to patients. This guideline is not a rule and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment.

Competing interests: Michael Brethauer has received bowel preparation materials free of charge for use in clinical trials, from Falk Pharma and Ferrigno. Dr Rembacken has taken part in Advisory Board Meetings of Ferrigno and Ibsen. No competing interest has been reported by the other authors.

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Appendix e1 – e4

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