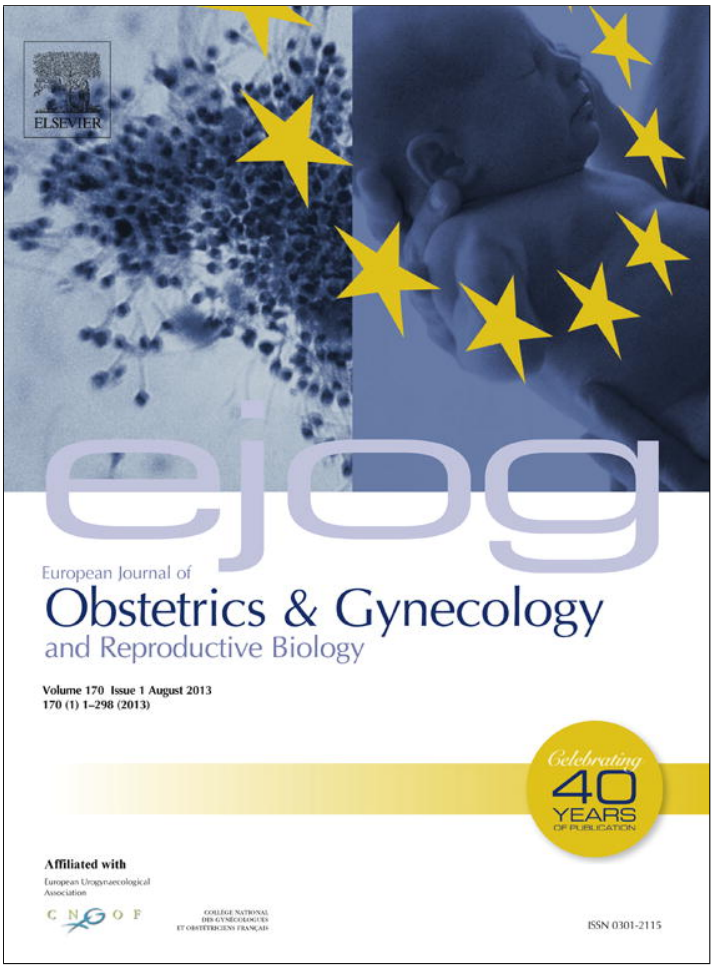

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European Federation of Colposcopy quality standards Delphi consultation

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ABSTRACT

Objective: Optimization of colposcopy practice requires a program of quality assurance including the monitoring of performance indicators. The European Federation of Colposcopy (EFC) aimed to identify a list of quality indicators for colposcopic practice, which are relevant, reproducible and practical across all of the member countries.

Study design: A five-round Delphi consultation was conducted in 30 full, 5 associate and 4 potential member countries in order to determine a core list of quality indicators including optimal target ranges.

Results: Six indicators were selected from a list of 37 proposed standards. Two further rounds of consultation were conducted to determine expert opinion on the target level for each of the standards. The six indicators identified and corresponding targets were: documentation of whether or not the squamocolumnar junction has been seen (100%); colposcopy prior to treatment for abnormal cervical cytology (100%); percentage of excisional treatments/conizations to contain cervical intra-epithelial neoplasia grade two or worse (≥85%); percentage of excised lesions/conizations with clear margins (≥80%); and two indicators concerned the number of cases to be colposcoped per year: ≥50 low-grade/minor and ≥50 high-grade/major cytological abnormalities.

Conclusions: A Delphi consultation identified six EFC quality indicators. These are a first step in an international attempt to optimize colposcopy practice throughout Europe. The current targets are based on expert opinion and may need adaptation in the future. Data are needed from European colposcopy settings to determine whether the indicators are achievable practice-based benchmarks and will help in improving and fine tuning the list of performance indicators and targets.

1. Introduction

The definition of quality assurance (QA) is the systematic monitoring and evaluation of various aspects of a service to ensure that standards of quality are met. In the context of colposcopy it is a process that needs to conducted at both the individual level, with the colposcopist and institution, and externally, at a national or regional level, to ensure the quality of service across a country.

The European Federation of Colposcopy (EFC) comprises 30 member states and five associate member countries, which cover a diverse range of populations, health care systems and clinical training practices. The aim of the EFC is to promote high quality colposcopy throughout Europe. The need for QA in colposcopy and common standards across Europe is a prime goal of the EFC and is the focus of much work in developing Europe-wide guidelines and standards [1–5]. Written policies and guidance documents, however, are unable to assess the performance and practice of individual colposcopists, and QA procedures for monitoring clinicians are needed.

Numerous issues need to be considered when developing QA guidelines and standards that are applicable to the whole EFC population. Quality indicators would have to enable systematic monitoring and evaluation of colposcopic practice and should fulfil the following criteria: pertinence, validity, reproducibility, feasibility, efficiency, ability to action and generalisability across all of

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the member countries. The QA system should also be adaptable for use in local healthcare settings, both state funded and private.

A Delphi consultation is a technique for determining consensus agreement between experts in order to develop a collective outcome [6,7]. The 1st EFC Satellite Meeting on Quality Assurance in Colposcopy determined to conduct a Delphi consultation with the objective of identifying a number of quality standards in colposcopic proficiency that could be used as a template throughout Europe as a means of promoting high quality colposcopy.

2. Materials and methods

Two senior colposcopists were contacted from each of the EFC member (Albania, Austria, Belgium, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, FYR Macedonia, Georgia, Germany, Greece, Hungary, Ireland, Israel, Italy, Kosovo, Malta, Netherlands, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Turkey, United Kingdom), associate member (Denmark, Latvia, Lithuania, Sweden, Switzerland) and potential member countries (Bosnia and Herzegovina, Bulgaria, Montenegro, Norway) and asked to participate in the study. The study was conducted using the internet-based survey tool Survey Monkey. Participants were emailed a link to each of the rounds of the survey and were given a minimum of four weeks per round in which to respond. At least two reminder emails were sent each round to encourage participation. It was possible to identify only one participant for six of the countries (Bosnia and Herzegovina, Bulgaria, Denmark, FYR Macedonia, Malta, Switzerland) and in some of the rounds responses were only received from one of the two participants. In order to ensure that each country had equal representation in the final result, the mean score given to each potential indicator was calculated by country.

In round 1 a "long list" of potential standards was compiled. The national delegates present at the satellite meeting had proposed a list of quality indicators of colposcopy which was used as the basis for this list and the participants were asked to add other standards that they felt were important. In round 2 the participants were

Table 1
Median scores attributed to each of the 37 proposed quality indicators by 30 member, 5 associate member and 4 potential member countries.

Proposed quality indicators	ECF members	Full and associate members	Full, associate and potential members
Percentage of excisional treatments/conizations containing CIN2+	5	5	5
Percentage of CIN2 or less treated primarily by knife cone biopsy	3	3	3
Percentage of excisional treatments/conizations containing no CIN	4	4	4
Percentage of CIN1 or less treated at the first visit	3	3	3
Percentage of CIN (any grade) treated primarily with local treatment (excisional treatment (LLETZ/LEEP/LASER)/ablation)	4	4	4
Percentage of cases having a colposcopic examination prior to treatment for abnormal cervical cytology	5	5	5
Percentage of excised lesions/conizations with clear margins	5	5	5
Percentage of treated CIN2+ cases with negative cytology at 6 months	4	4	4
Percentage of CIN1 or less treated primarily by hysterectomy	3	3	3
Percentage of treated CIN2+ cases with negative cytology at 12 months	4	4	4
Secondary (postoperative) haemorrhage rate	4	4	4
Percentage of local excisional treatments/conizations performed under general anaesthetic	4	4	4
Number of biopsies needed to achieve final diagnosis	4	4	4
Percentage agreement between colposcopic impression and biopsy diagnosis	4	4	4
The percentage of excisional treatments/conizations taken in one piece	4	4	4
Number of colposcopies personally performed each year for high-grade/major abnormality on cervical cytology	4	4	4
Percentage of CIN2+ treated at the first visit	4	4	4
The average number of punch biopsies performed per patient following abnormal cervical cytology	4	4	4
Percentage agreement between results of punch and excisional treatments/conizations	4	4	4
Percentage of CIN2 or less treated primarily by hysterectomy	3	3	3
Percentage of excisional treatments/conizations without malignancy/CIN2+	4	4	4
Percentage of biopsies with interpretable results	4	4	4
Percentage of CIN treated by ablative methods	4	3.75	4
Percentage of treated CIN2+ cases with positive excision margins	4	4	4
Percentage of normal colposcopy findings with positive cytology	4	4	4
Documentation of whether the squamocolumnar junction has been seen or not	5	5	5
Percentage of CIN2+ treated without prior histological diagnosis	4	4	4
Percentage recurrence rate of CIN in cases with clear margins	4	4	4
Percentage of excisional treatments/conizations with positive margins	4	4	4
Primary (perioperative) haemorrhage rate (requiring an additional haemostatic technique)	4	4	4
Percentage of second excisional treatments/conizations with positive margins	4	4	4
Number of colposcopies personally performed each year for a low-grade/minor abnormality on cervical cytology	4.5	4.75	4.75
Duration of colposcopic examination (without biopsy)	3	3	3
Documentation of colposcopic impression at initial encounter and correlation with results	4	4	4
Percentage of treated CIN2+ cases with negative HPV test at 6 months	4	4	4
Documentation of the findings of inspection of the lower genital tract (vagina/vulva/perianal area)	4	4	4
Percentage of CIN1 or less treated primarily by knife cone biopsy	3	3	3

Table 2
The six quality indicators identified through the five-round Delphi consultation.

Proposed standards	ECF members	Full and associate members	Full, associate and potential members
Percentage of excisional treatments/conizations containing CIN2+	85%	85%	88%
Percentage of cases having a colposcopic examination prior to treatment for abnormal cervical cytology	100%	100%	100%
Percentage of excised lesions/conizations with clear margins	80%	80%	80%
Documentation of whether the squamocolumnar junction has been seen or not	100%	100%	100%
Number of colposcopies personally performed each year for a low-grade/minor abnormality on cervical cytology	>50	>50	>50
Number of colposcopies personally performed each year for high-grade/major abnormality on cervical cytology	>50	>50	>50

asked to score each of the standards using a five-point Likert scale (1 – strongly disagree, 5 – strongly agree) [8] according to their opinions as to how useful the standard would be. In round 3, the scores given by the participants were revealed and there was the opportunity to re-score each of the indicators in light of the collective scores given in round 2. The highest scoring standards identified in round 3 were taken onto round 4 where a numerical figure was attributed to each by the participants from a wide range of values (0, 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 98, 100%). The opportunity was given to revise the value attributed to the standards in round 5 in light of the collective score given in round 4.

3. Results

In total, 30/30 member, 5/5 associate member and 2/4 (Montenegro, Norway) potential member countries participated in the Delphi consultation. The median number of countries participating in each round of the study was 33 (84.6%), range 31 (79.5%) to 36 (92.3%) countries.

Round 1 resulted in a list of 37 potential standards. In round 3, five standards scored a median of greater than 4.5 out of 5, 25 scored a median of 4 and 7 scored less than 4 (Table 1). There was no significant difference in the scores attributed to each of the potential indicators by member, associate member or potential member countries. The five standards with the highest scores were taken on to the final two rounds of the Delphi consultation. One additional standard (number of colposcopies personally performed each year for high-grade/major abnormality on cervical cytology) that had achieved a score of 4 but was deemed highly important by the committee conducting the Delphi was added, making a total of six standards. The final outcome was the identification of two indicators focused on the number and disease profile of cases seen by colposcopists, one related to documentation and two for standards expected from excisional treatments of cervical pre-cancer in order to minimize therapeutic failure and avoid over-treatment (Table 2). Again, there was no significant difference in the values attributed to each of the indicators by the full, associate and potential member countries.

4. Comments

The EFC Delphi consultation has utilized the expert opinion of senior colposcopists from 37 countries in order to determine a list of six quality indicators that can be used to monitor the standard of colposcopy across Europe. Calculating the mean score for each of the responses by country enabled equal weighting to each of the participating states so as not to bias countries with only one respondent. The final outcome can be concluded as being representative of the views of the member, associate member and potential member countries and is a constructive step towards optimizing colposcopy practice throughout Europe.

The indicators identified are based on expert opinion and will need validation and possible adaptation in the future. Two of the standards relate to basic colposcopic practice; 'percentage of cases having a colposcopic examination prior to treatment for abnormal cervical cytology' and 'documentation of whether the squamocolumnar junction has been seen or not'. Their fundamental importance was reinforced by the study population assigning a target of 100% for both of these standards.

The standards related to the number of cases of low-grade/minor abnormalities and high-grade/major abnormalities both determined a minimum of 50 cases to be performed personally per year. While 100 cases a year is not an unrealistic target it may be more achievable in particular health care settings, for example densely populated countries with state-provided healthcare. The number of women in a population participating in cervical screening will also determine the number referred on for a colposcopic examination with abnormal cervical cytology.

The standard 'percentage of excisional treatments/conizations containing cervical intra-epithelial neoplasia grade two or worse (CIN2+)' was assigned the value of 85% and is aimed at avoiding the overtreatment of low-grade/minor abnormalities. The EFC [3], American Society for Colposcopy and Cervical Pathology (ASCCP) [9,10] and British Society for Colposcopy and Cervical Pathology (BSCCP) [11] all advocate the cytological surveillance of such lesions, with treatment being reserved for persistent abnormalities and when questioned colposcopists do report following this guidance [12]. Implementation of this standard would allow monitoring of an individual colposcopist's practice to ensure the guidance is being followed and not exposing women to unnecessary procedures and their iatrogenic consequences.

The standard 'percentage of excised lesions/conizations with clear margins' was given a target of 80% by the participants. The association between positive margins and disease recurrence is well reported [13] and therefore the aim of achieving clear margins in the majority of patients can be understood in order to reduce the risk of future CIN. This standard may need to be expanded, however, to determine a definition of 'clear margins'. Is the primary margin of interest the endocervical margin [14,15], the ectocervical margin, or both? Should the margins be clear of CIN2+ or all grades of CIN? What about the effect of diathermy artefact on the assessment of margins? The quality of pathology reporting also needs to be considered when clearly defining this standard. Should the number and size of blocks be specified? There may be a temptation with the introduction of this standard for the size of excisional treatments to increase in order to achieve clear margins and consequentially this may result in an increase in the depth of conizations. The increasing evidence of an association between the depth of an excision and subsequent pregnancy-related morbidity [16,17] would be at variance with this and therefore a close

monitoring of the depth of treatments would indicate whether this consequence is theoretical or is altering clinical practice. The EFC is currently exploring whether the distribution of cone dimensions in relation to size and severity of CIN could be considered as an additional quality indicator.

In providing a list of core quality indicators the EFC is hopeful that each of the participating countries will utilize their national colposcopy societies and develop QA programs with the identified standards as a foundation. Data will need to be collected from colposcopy settings across Europe to determine whether the indicators are achievable practice-based benchmarks suitable for the varied healthcare systems encompassed by the EFC. Audit will also help in improving and fine-tuning the list of performance indicators and targets.

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