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Title page

2017 update of the European Federation for Colposcopy (EFC) performance standards for the practice of colposcopy

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Condensation

Six quality indicators are described defining good colposcopic practice derived following a series of meetings led by the European Federation for Colposcopy.

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Abstract

A refinement of quality indicators (QIs) is described whereby the quality of care can be measured across colposcopy services in different countries and healthcare settings.

A five-round Delphi process was conducted at successive satellite meetings from 2011 to 2015 of leading European colposcopists to refine the most high-scoring QIs relevant to colposcopic practice. A review and refinement of the wording of the standards and their criteria was undertaken by national society representatives.

Six quality indicators were identified and refined. *"Documentation of whether the squamocolumnar junction (SCJ) has been visible or not"* was changed into *"for cervical colposcopy transformation zone (TZ) type (1, 2 or 3) should be documented". The standard "percentage of cases having a colposcopic examination prior to treatment for abnormal cytology"* was changed to *"percentage of cases having a*

colposcopic examination prior to treatment for abnormal cervical screening test". The standard *"percentage of all excisional treatments/ conizations containing CIN2+ (cervical intra-epithelial neoplasia grade two or worse)"* was changed into *"percentage of excisional treatments/ conizations having a definitive histology of CIN2+. Definitive histology is highest grade from any diagnostic or therapeutic biopsies*". The standard *"percentage of excised lesions/ conizations with clear margins"* was unchanged. The remaining two QIs define the minimum caseloads required for colposcopists. However, *"cytology"* was replaced by *"screening results"* to acknowledge the introduction of human papillomavirus testing to European screening programmes.

Six QIs were identified to define good practice in colposcopy.

239 words

Keywords colposcopy, healthcare quality assurance, early detection of cancer

Introduction

European countries offer a variety of different screening concepts from opportunistic to organized call and recall screening with an ongoing shift to human papillomavirus (HPV)-based screening in many countries and regions. Accordingly, the management of abnormal screening results and the practice of colposcopy shows a high heterogeneity throughout the continent. The European Federation for Colposcopy (EFC) is the umbrella organization for 34 national colposcopy societies in Europe and neighbouring regions (see figure 1). During the EFC congress 2010 in Berlin there was a broad consensus that on one hand colposcopy is the gold standard to diagnose and guide treatment of high-grade cervical neoplasia but on the other hand it performs badly without standards in education, training and practice of colposcopy. For instance, before 2015 the majority of treatments for cervical intraepithelial neoplasia (CIN) performed in France were not performed under colposcopic vision or had a prior colposcopy[1]. In Germany patient management including most treatments were performed without a pre-treatment biopsy[2]. It was decided to establish EFC annual satellite meetings between the three yearly scientific congresses. These aimed to evaluate the differences in screening policy and practice of colposcopy among EFC member countries and to develop a common European standard of education, training and practice of colposcopy. National member societies were invited to send their society presidents or nominated deputies who were considered representative of and responsible for their society's views.

During the first satellite meeting 2011, it became apparent that well defined quality indicators were needed for the monitoring of the quality of colposcopy in daily practice. The delegates independently selected a number of possible indicators to measure the quality of performing colposcopy, select patients for excisional treatment, perform minimal invasive treatment and gain proof of cure. These proposed quality indicators went through a five-round Delphi consultation[3] which led to the original six EFC quality indicators (QIs) listed in table 1.

As quality assessment is a learning system, the EFC encouraged the use and evaluation of the identified QIs in daily practice. A body of unpublished work as well as the review of the German colposcopy network (G-CONE) showed the principal utility of the QIs as well as a need for revisions[4].

Materials and Methods

During the subsequent 2013 and 2015 satellite meetings criticism was raised by the review of Luyten et al (2015)[4] regarding a margin status standard which may encourage inappropriately oversized excisions to achieve margins of excision clear of CIN and so increase risk of subsequent preterm delivery in young women[5]. There was further critique from unpublished reviews and national societies which were collected, discussed with delegates at each meeting and evaluated. These critical points were clustered as:

1. The need to check for better arrangement of QIs so that the order of presentation of these follows the pathway of care for colposcopy patients from colposcopic examination to evaluation of the excision specimens.
2. The need to check for more precise wording of QIs.
3. The need to check for more practicable criteria or targets for achieving standards by reviewing the quality data available from various practices across Europe.
4. The need to check for replacement of the QI "margin status".

Modifications were proposed by national society representatives or their societies, intensively discussed and either rejected, again modified and/ or accepted. During the satellite meetings more than 80% of the member societies were represented by delegates. All satellite meetings were moderated by members of the EFC executive and detailed in meeting records, of which a summary is available on the EFC website (https://efcolposcopy.eu/efc-symposium-paris-11th-january-2017/). Each society had one vote and votes were collected and counted during the meetings. Changes to any QI needed a strong consensus although a minimum percentage to define a strong consensus was not defined. In fact, all of the subsequently listed modifications had the unanimous support of delegates and were finally accepted at the EFC General Assembly 2017, in Paris which was attended by 28 of the 34 member societies. Only Malta as an EFC member society failed to attend any of the satellite meetings. Table 2 shows the timetable of progress in agreeing QIs.

Results

1. It was decided to rearrange the QIs according to the pathway of care during and after colposcopy. Therefore, the list of the QIs starts with identification of the transformation zone and leads through the process of colposcopy.
2. There was a broad consensus that rewording was necessary for almost all QIs:

a. *"Documentation of whether the squamocolumnar junction (SCJ) has been visible or not"* was changed into *"for cervical colposcopy transformation zone (TZ) type (1, 2 or 3) should be documented".* The new wording is clearly specific for cervical colposcopy and excluded cases after hysterectomy. The second part of the QI was changed to documentation of the TZ type to harmonize with the International Federation of Cervical Pathology and Colposcopy (IFCPC) nomenclature[6]. This was because delegates believed that the classification of three TZ types

demands higher alertness than the yes/ no statement of visibility of the SCJ regardless of whether or not such a classification was reproducible amongst colposcopists[7]. This is also relevant as the English colposcopy guidelines has recommended adjusting loop length to correspond to TZ type[8]. Overall this first QI was rated as most important for all cases of cervical colposcopy in view of the relevance of the TZ in the development of cervical pre-cancer and cancer for all aspects of etiology, diagnosis and management of lesions.

b. *"Percentage of cases having a colposcopic examination prior to treatment for abnormal cytology (100%)"* was changed to *"percentage of cases having a colposcopic examination prior to treatment for abnormal cervical screening test (100%)"* because of the shift towards screening based on HPV-testing in some countries and regions in Europe. This QI is intended to protect women from unnecessary treatment of abnormal screening results without colposcopic evaluation.

c. *"Percentage of all excisional treatments/ conizations containing CIN2+ (cervical intra-epithelial neoplasia grade two or worse) (85%)"* was changed into *"percentage of excisional treatments/ conizations having a definitive histology of CIN2+ (85%). Definitive histology is highest grade from any diagnostic or therapeutic biopsies*". The G-CONE review and reports from national societies found a reasonable proportion of cases with biopsy proven CIN2+ but no high-grade lesion in the definitive excisional specimen. The lack of correlation between pre-treatment biopsy and subsequent excisional treatment was noted by Hopman et al (1998)[9]. However, these cases were considered as correct treatment by all delegates of the satellite meetings and general assembly. Therefore, the above rewording became necessary (see table 3).

d. *"Percentage of excised lesions/ conizations with clear margins (80%)"* was the most discussed QI and the single QI without full consensus. Although criticized as a potentially counterproductive indicator that may favour unnecessary large volume excisions of the uterine cervix, it was the final majority decision to leave the QI without any changes in wording.

e. The remaining two QIs define the minimum caseloads required for colposcopists. They remained basically unchanged but because of the shift in screening programmes towards HPV testing *"cytology"* was replaced by *"screening results"*.

3. Apart from the targets for the minimum caseloads all reviews showed that the defined targets for QIs 1 to 4 were not achievable in daily colposcopy practice (see table 3). In the G-CONE review, only single institutions reached some of the targets, unpublished data from Italy and UK showed similar findings. Proponents for reduced targets argued that only feasible QIs could guide quality in daily practice (see table 4). National data could not be collected but institutional data from Wolfsburg, Germany; Stoke, UK and Bari, Italy were obtained for more than 15,000 cases. These data were presented at the satellite meeting in 2015. However, there was a strong opposition of approximately half of the delegates who did not want to compromise what they considered to be aspirational targets. As a result, it was agreed that the EFC has no objections with lower targets defined by national societies or heath authorities who would like to use the EFC-agreed QIs for certification and quality assurance procedures.

4. It was proposed to replace the QI 4 defining the percentage of excisional specimens with clear margins. A systematic EFC review shows that the EFC target of 80% is met only by a minority of published trials and HPV testing is a better proof of cure test and could replace clear margins for that purpose without risk of overtreatment[10]. However, a majority of delegates was neither requesting to have a lower target nor a replacement of the complete QI.

Comment

Quality assessment is always an evolutionary process. While defined QIs are needed to guide and assess quality, the QIs themselves must be evaluated for appropriateness for routine colposcopic practice. There is a need for an ongoing review to adapt quality parameters whenever necessary. However, it seems that as a result of the Delphi consultations and the EFC validation process, five indicators of good colposcopy practice were found that were feasible in daily practice, had broad acceptance from Ireland to Georgia and Russia to Israel and seem to be universal rather than just relevant to European practice. The single exception was QI 4 (*the percentage of excised lesions/ conizations with clear margins*). An effort to obtain clear margins may misguide clinical practice towards unnecessarily large excision of the uterine cervix. Margin status of excision specimens has been a proxy for success of treatment[10]. However, radicality of treatment has varied over time with knowledge of known complications of treatment. Increasing excision length is associated with significant increase in risk of preterm delivery. Having had two or more loop conisations increases risk almost four times for subsequent preterm delivery compared with no loop conisation before delivery, and almost double the risk compared with one loop before delivery[11]. On the other hand, Strander and Adolfsson *(*2014) noted that an increased risk of cervical cancer after long term follow-up as treatment for CIN had become less radical over time[12]. Less hysterectomies, knife conisations and more limited loop conisations for treatment may be to blame following concern on poor obstetric outcome[13]. As a result of this debate, the EFC supported a systematic review which subsequently showed that HPV testing is a significantly better predictor of cure than margin involvement with similar specificity but better sensitivity[10]. It is very likely that this evidence will lead to a revision of QI 4. We consider this process to be a good example that the EFC´s strategy to achieve QIs via systematic expert and Delphi consultations is useful and may identify areas with broad consensus as well as areas in need of further exploration of evidence.

Another criticism is that QIs should be achievable. Health authorities and institutions who want to use the EFC QIs for certification processes should be aware that the aims were defined by expert colposcopists with an enthusiasm for the method and reputations for clinical excellence in their area of expertise. Therefore, apart from the minimum caseloads, the QIs with percentage targets should be seen as minimal standards. During the EFC general assembly 2017 in Paris, further alterations and two additional QI measures were suggested but it was decided to publish the consensus reached at previous satellite meetings. Nonetheless, part of the consensus was that the given aims are aspirational targets with regional or national services altering these as considered appropriate to be used for regional or national certification. The American Society for Colposcopy and Cervical Pathology (ASCCP) published recently 11 colposcopy standards that cover only the performance of colposcopy itself without subsequent therapy. The EFC´s QI 1 was included, four standards define maximum time

to inform patients with high-grade disease, while the remaining six standards regulate reporting of colposcopy findings[14]. As the EFC is the roof organization of more than 30 different countries with as many different health systems, we focused our search on universal core QIs and it is left to the national colposcopy societies to define other QIs to regulate more details. Effective consensus has been an evolution over six years. We have taken advice from senior practitioners in a variety of healthcare settings with different service demands. An assumption was that delegates were representative of the wishes of their national societies but this could not be validated. The next step is to make the QIs active to drive improvement in care.

Data is needed for quality assurance and this must be collected prospectively to be accurately validated and be exchangeable between agencies. Freely interchangeable data will permit comparison or benchmarking with others and so standardisation of data collection is imperative.

It therefore follows that basic organisational issues are essential for quality assurance to occur including an agreed database, standardised data with nominated personnel to provide the organisation of data collection and exchange to develop data collation, data monitoring and analysis.

Conclusions

Although EFC QIs will undergo a continuing review and future modifications seem very likely, we feel that at least six universal indicators of good colposcopy practice have been identified as concise measures of care. They should be useful to standardize colposcopy management throughout and beyond Europe.

2174 words

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Table 1

2011 EFC agreed 6 initial quality measures by Delphi process

Quality indicator	Target
1. documentation of whether the squamocolumnar junction has been seen or not (100%).	100%
2. % cases having a colposcopic examination prior to treatment for abnormal cervical cytology (100%).	100%
3. % excisional treatments/ conisations containing CIN2+ (85%).	80%
4. % excised lesions/ conisations with clear margins (80%).	80%
5. number of colposcopies personally performed each year for a low-grade/ minor abnormality on cervical cytology (>50).	>50
6. number of colposcopies personally performed each year for a high-grade/ major abnormality on cervical cytology (>50).	>50

Table 2

Year	Event	Achievement	National societies involved
2011	1. Satellite meeting Berlin	Development of 37 possible quality indicators for subsequent Delphi consultation	39*
2012	2. Satellite meeting Berlin	Review of results	27
2013		Publication of original EFC QIs	NA
2015	4. Satellite meeting Brussels	Review of publications and critics. Consensus revisions of 5 of 6 QIs.	32
2017	5. General assembly Paris	Ratification of the revised QIs	28

*Includes 25 societies at 1. Satellite meeting and 30 societies participating in the consultation and 4 associated and 5 possible member societies.

Table 3

Revised quality indicators, ratified by the EFC General Assembly 2017

Indicators are listed according to the timing of colposcopy based procedures. 1= performance of colposcopy,

2= quality of indication before and 3= quality of treatment, 4= proof of cure. 5 and 6 are minimum numbers as

a surrogate marker of experience.

Quality indicator	Target
1. for cervical colposcopy transformation zone (TZ) type (1,2 or 3) should be documented.	100%
2. % of cases having a colposcopic examination prior to treatment for abnormal cervical screening test.	100%
3. % of excisional treatments/ conizations have a definitive histology of CIN2+. Definitive histology is highest grade from any diagnostic or therapeutic biopsies.	85%
4. % of excised lesions/ conizations with clear margins.	80%
5. number of colposcopies personally performed each year for a low-grade/ minor abnormality on cervical screening.	>50
6. number of colposcopies personally performed each year for high-grade/ major abnormality on cervical screening.	>50

	UK (%)	Germany (%)	Italy (%)
Documentation of whether the squamocolumnar junction has been seen or not (100%)	93	95	99
% cases having a colposcopic examination prior to treatment for abnormal cervical cytology (100%)	100	94	98
% excisional treatments/ conisations containing CIN2+ (85%)	91	83	68
% excised lesions/ conisations with clear margins (80%)	25		73

Table 4
Performance of quality indicators from three member states

Figure 1

EFC member states

Austria, Belgium, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Israel, Italy, Kosovo, Latvia, Lithuania, FYRO Macedonia, Malta, Moldova, Netherlands, Norway, Poland, Portugal, Republic of Ireland, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom