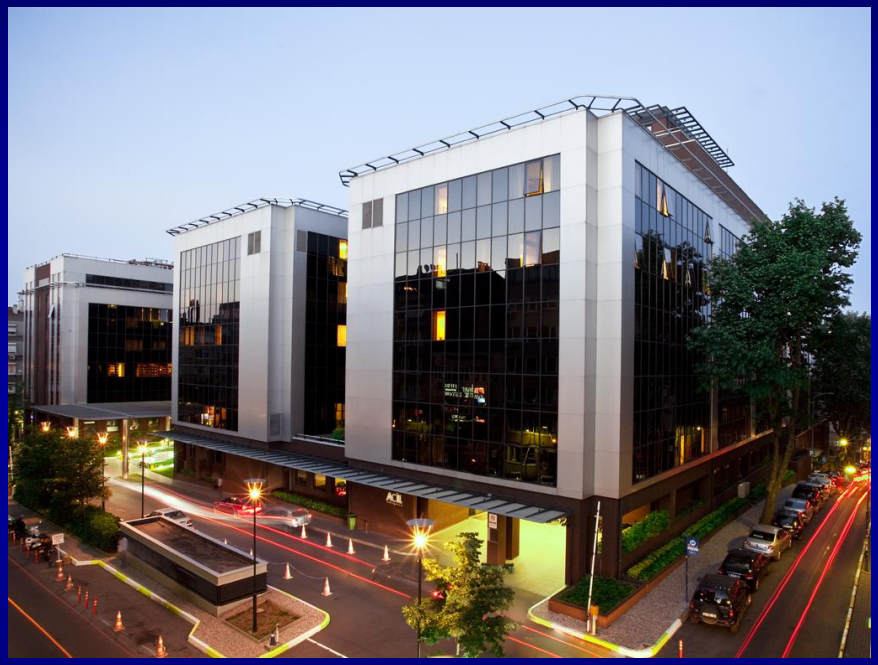
# EFC and European Standards for Colposcopic Evaluation

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# Is Colposcopy Gold Standard

- **Screening-Colposcopy showed poor sensitivity and specificity**

  ***Schneider A, IJC 2000***

- **HPV-Vaccine trials showed poor sensitivity of colposcopy impression for CIN3+**

  ***Stoler M, IJC 2011***

- **Sensitivity of colposcopy guided biopsies for CIN3 ranged from 29-93% in a US trial**

  ***Pretorius R, JLGTD 2011***

- **The failure rate of colposcopy (missed CIN3+) is significantly increased in women with positive HPV tests but normal cytology**

  ***Petry KU, GynOncol 2013***

# Standardized colposcopy is safe – colposcopy without standards may be harmful

| Standard | Detected CIN3+ at 1st colpo | Missed CIN3+ in 5 yrs FU | Failure rate (missed CIN3+ of all CIN3+) |
|---|---|---|---|
| Punch biopsies of major changes) in type 1 or 2 TZ | 66 | 34 | 34% |
| ECC in all type 3 TZ | 13 | 5 | 27.8% |
| Excisional treatment in HSIL+ and HPV+ | 19 | 0 | 0 |
| Excisional treatment in CIN2+ and type 3 TZ | 7 | 0 | 0 |
| Excisional treatment in major changes/HPV+/type 3 TZ | 4 | 0 | 0 |

**N= 667 women with abnormal screening results, 171 CIN3+**

*Petry KU et al. , Gyn Oncol 2013*

# EFC 2013 Quality Standards

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## European Federation of Colposcopy quality standards Delphi consultation

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- **Optimization of colposcopic practice**
- **Program of quality assurance**
- **Monitorization of performance indicators**
- **EFC: list of quality indicators**
  - **relevant**
  - **reproducible**
  - **practical**

# Methodology

- Median 33 countries (31-36)
- Two senior colposcopist  from each country
- Internet based survey
- Round 1: long list of potential standards
- Asked for additional standards
- Round 2: asked to score (1-5)
- Round 3-4-5

# EFC Standards & How Developed ?

- **30 full, 5 associate, 4 potential member countries**
- **37 proposed standards: 6 indicators selected**

**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 |

# EFC 2013 Countries including Turkey

EUROPEAN FEDERATION FOR COLPOSCOPY
AND PATHOLOGY OF THE LOWER GENITAL TRACT

## European Federation of Colposcopy Training Curriculum Core Compentencies: A Delphi consensus study


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### INTRODUCTION

In 2000 a list of 51 core competencies required for colposcopic practice was determined by experts from 21 countries through a Delphi study.

In view of changes in colposcopic practice that have occurred over the past decade and the expansion of the European Federation of Colposcopy (EFC), the decision was made for a review of the contents of the training curriculum and to repeat the Delphi study in order to gain approval for any changes from the EFC membership.

### METHODS


In 2000 a list of 51 core competencies required for colposcopic practice was determined by experts from 21 countries through a Delphi study.

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# First Questionair

## RESULTS

•Responses were received from 28 (93%) EFC members, 4 (80%) EFC associate members and 2 (50%) potential member countries.

| General | Members | Members and Associate members | All |
|---|---|---|---|
| Understand the development of cervical neoplasia | 5 | 5 | 5 |
| Ensure that practice complies with health and safety recommendations | 5 | 5 | 5 |
| Manage patients within EFC guidelines | 5 | 5 | 5 |
| Provide adequate information prior to colposcopy | 5 | 5 | 5 |
| Answer questions about management | 5 | 5 | 5 |
| Communicate with other health professionals | 5 | 5 | 5 |
| Understand national cervical screening guidelines | 5 | 5 | 5 |
| Be able to communicate results in a sensitive manner | 5 | 5 | 5 |
| Provide data to national body | 4 | 4.5 | 4.33 |

| Basic examination | Members | Members and Associate members | All |
|---|---|---|---|
| Be able to take a history | 5 | 5 | 5 |
| Examine the vagina | 5 | 5 | 5 |
| Examine the vulva | 5 | 5 | 5 |
| Position and adjust the colposcope | 5 | 5 | 5 |
| Be able to position a patient for colposcopy | 5 | 5 | 5 |
| Be able to insert a vaginal speculum | 5 | 5 | 5 |
| Use endocervical speculum | 5 | 5 | 5 |
| Document colposcopic findings | 5 | 5 | 5 |
| Provide adequate information after colposcopy | 5 | 5 | 5 |

| Colposcopic procedure | Members | Members and Associate members | All |
|---|---|---|---|
| Perform cervical sampling (including cytobrush) | 5 | 5 | 5 |
| Perform bacteriological swabs | 4.1 | 4.75 | 4.35 |
| Examine the transformation zone with acetic acid | 5 | 5 | 5 |
| Perform Schiller's and iodine test | 5 | 5 | 5 |
| Examine the transformation zone with saline and green filter | 5 | 5 | 5 |
| Quantify and describe acetic acid changes | 5 | 5 | 5 |

| Colposcopic findings | Members | Members and Associate members | All |
|---|---|---|---|
| Determine whether colposcopy is satisfactory or not | 5 | 5 | 5 |
| Determine the type of transformation zone (1,2,3) | 5 | 5 | 5 |
| Recognise the extent of abnormal epithelium | 5 | 5 | 5 |
| Recognise original squamous epithelium | 5 | 5 | 5 |
| Recognise columnar epithelium | 5 | 5 | 5 |
| Recognise metaplastic epithelium | 5 | 5 | 5 |
| Recognise congential transformation zone | 5 | 5 | 5 |
| Recognise minor colposcopic changes | 5 | 5 | 5 |
| Recognise major colposcopic changes | 5 | 5 | 5 |
| Recognise features suggestive of invasion | 5 | 5 | 5 |
| Recognise abnormal vascular patterns | 5 | 5 | 5 |
| Recognise changes associated with previous treatment | 5 | 5 | 5 |
| Recognise the effects of pregnancy on the cervix | 5 | 5 | 5 |
| Recognise features of a postmenopausal cervix | 5 | 5 | 5 |
| Recognise acute inflammatory changes | 5 | 5 | 5 |
| Recognise VaIN | 5 | 5 | 5 |
| Recognise VIN | 5 | 5 | 5 |
| Recognise benign cervical polyps | 5 | 5 | 5 |
| Recognise condyloma plana | 5 | 5 | 5 |
| Recognise condyloma accuminata | 5 | 5 | 5 |

| Biopsies and treatment | Members | Members and Associate members | All |
|---|---|---|---|
| Obtain informed consent for performing a procedure | 5 | 5 | 5 |
| Be able to administer local analgesia | 5 | 5 | 5 |
| Determine where to take directed biopsies | 5 | 5 | 5 |
| Perform directed cervical biopsies | 5 | 5 | 5 |
| Perform directed vaginal biopsies | 5 | 5 | 5 |
| Perform directed vulval biopsies | 5 | 5 | 5 |
| Control bleeding from biopsy sites | 5 | 5 | 5 |

• Of the 51 competencies previously identified only 2 did not receive support to be included in the revised curriculum: 'perform bacterial swabs' 'provide data to national body'.

• There was no significant difference in the responses given by member, associate member or potential member countries.

# Six EFC Standards

- **SCJ: has been seen or not**

**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 |

- **Two indication of number of colposcopies per year**
  - **> 50 low grade /minor cytological abnormalities**
  - **> 50 high grade / major cytological abnormalities**

# Luyten 2015 & G-Cone & Testing EFC 2013

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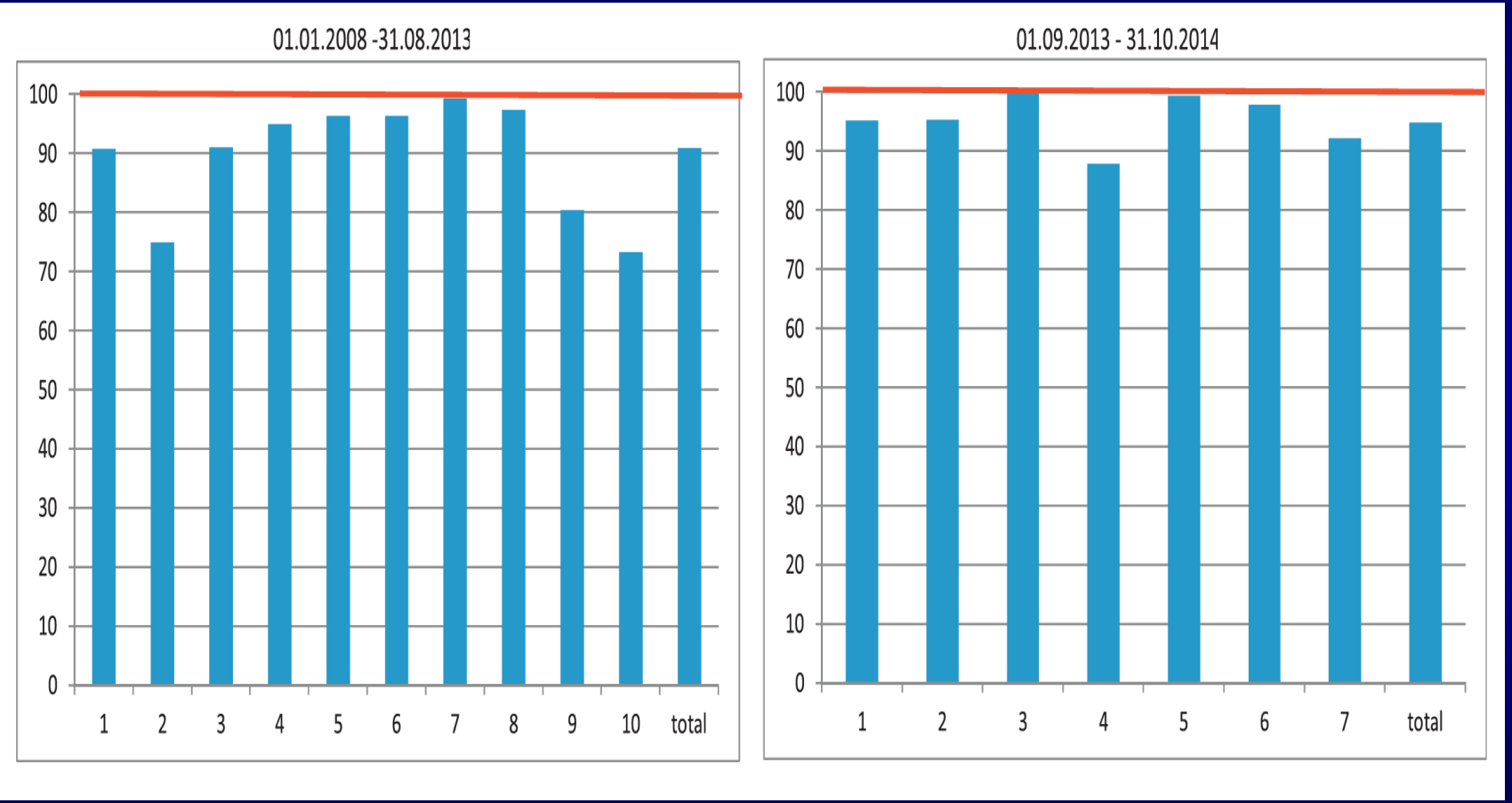
## Utility of EFC quality indicators for colposcopy in daily practice: results from an independent, prospective multicenter trial

Alexander Luyten [a], Ingke Hagemann [b], Sarah Scherbring [c], Gerd Boehmer [d], Friederike Gieseking [e], Linn Woelber [e], Frank Glasenapp [f], Monika Hampl [g], Christina Kuehler-Obbarius [h], Marcus van den Bergh [i], Simon Leeson [j], Charles Redman [k], Karl Ulrich Petry [a,*] for "Studiengruppe Kolposkopie eV (SGK)" and "G-CONE (German Colposcopy Network)"

- **2008-2014, 8 clinics**
- **10.869 patients**
- **Excisional treatment/conizations CIN2+ 83%**
- **Colposcopy prior to treatment of abnormal cytology 94%**
- **Visiability of SCJ 91% to 95 %**
- **> 80% clear margin not documented well**

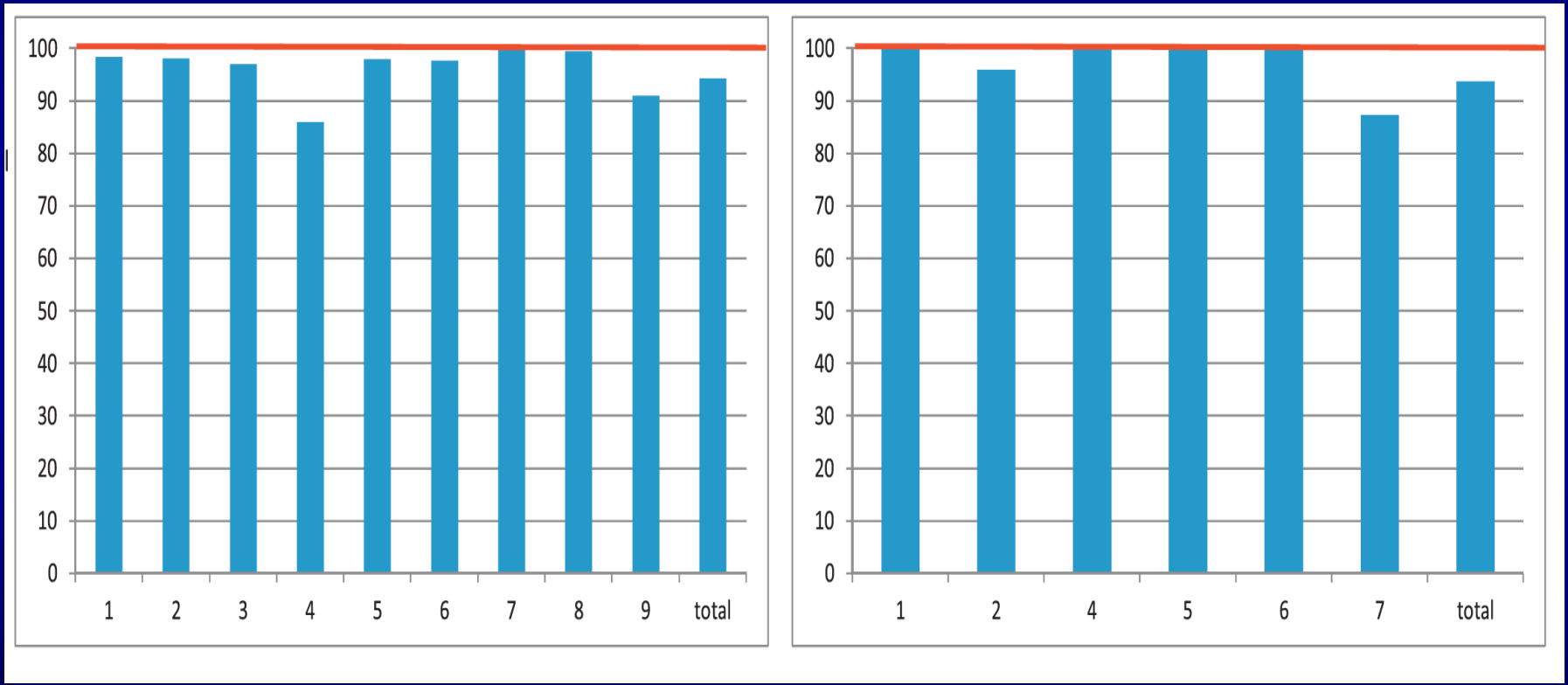
*Luyten A, EJOGRB, 2015*

# SCJ Visibility & Near 100% After 2013



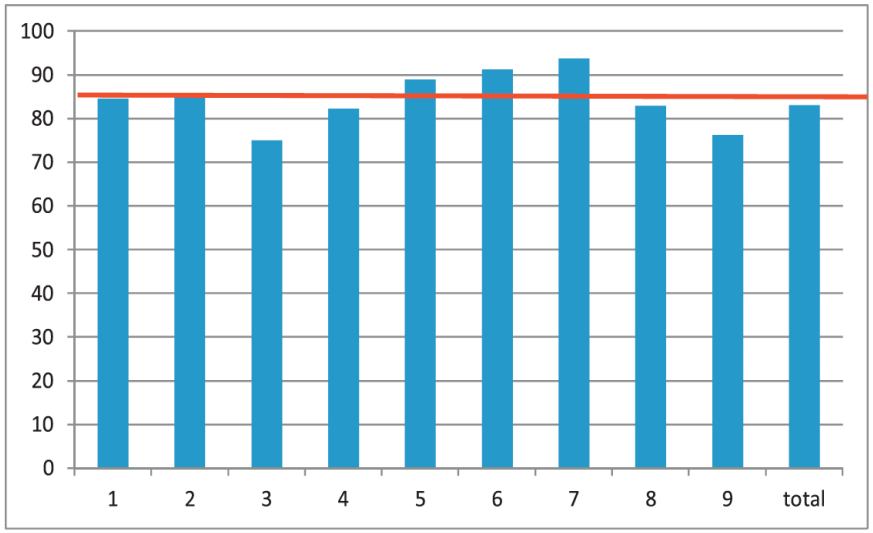

Luyten A, EJOGRB 2015

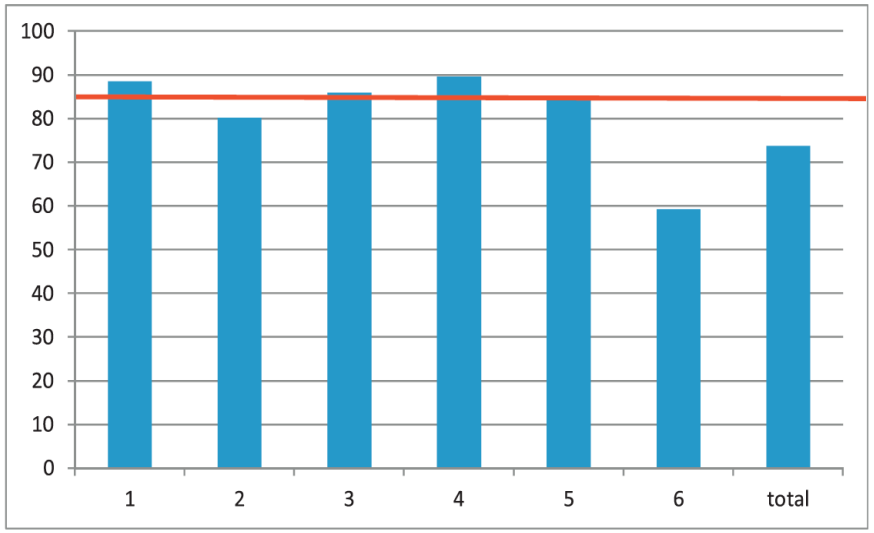
# Percentage of cases having a colposcopic examination prior to treatment for abnormal cervical cytology




*Luyten A, EJOGRB,2015*

# Percentage of excisional treatments/conizations containing CIN2+

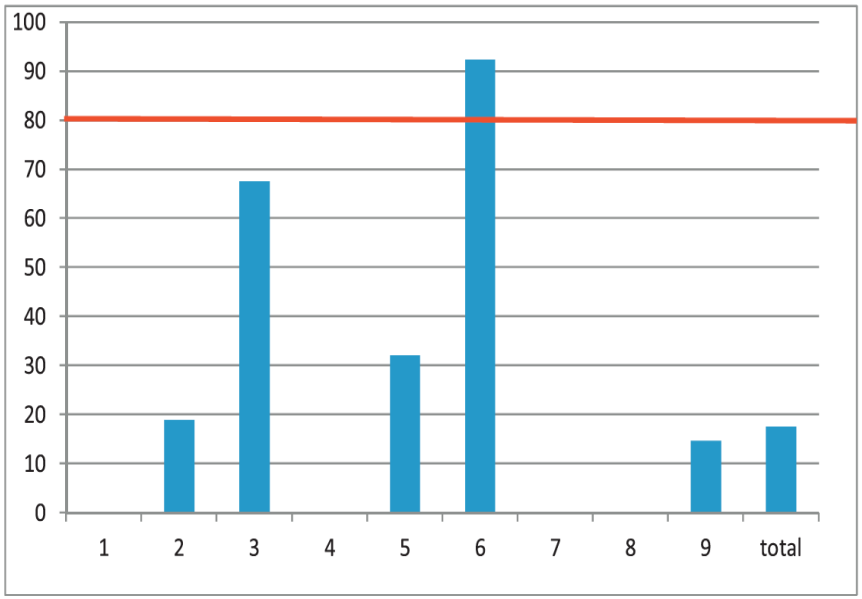


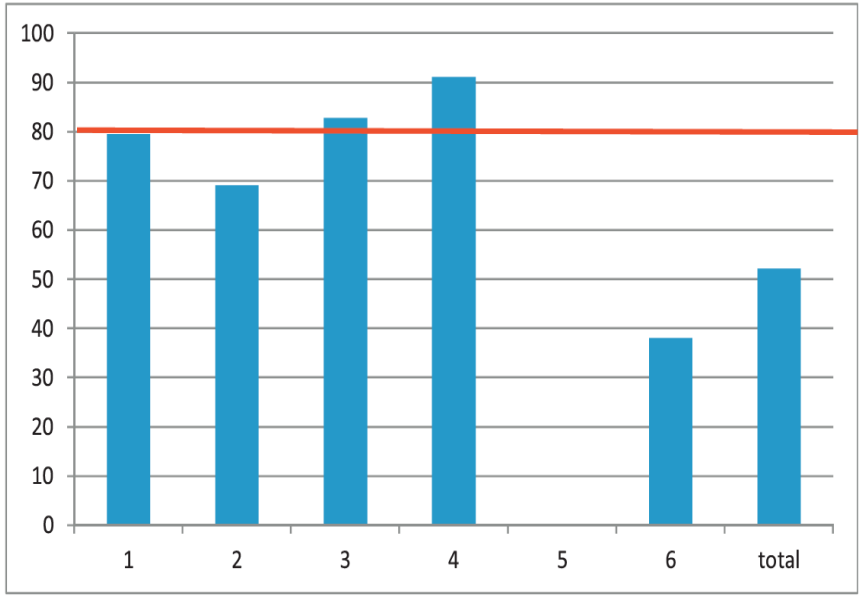




- One clinic 60%
- Higher number of biopsies CIN2+, no lesion at LEEP
- Corrected rate 86%

*Luyten A, EJOGRB, 2015*

# Percentage of excised lesions/conizations with clear margins




- Most of clinics use HPV and cytology based follow-up
- 5 years recurrence rate < 5%
- Harmful ?? More extensive excision

*Luyten A, EJOGRB,2015*

# Margin Dilemma

- Endocervical or ectocervical margin, or both?
- Should the margins be clear of CIN2+ or all grades of CIN?
- Diathermy artefact on the assessment of margins?
- The quality of pathology
- Number and size of blocks ?
- Danger: This may result in an increase in the depth of conizations.

# Risk of treatment failure associated with positive section margins of excisional treatment for high-grade CIN: a systematic review and meta-analysis

"The margin status has poor sensitivity to predict treatment outcome. hrHPV is approximately 50% more sensitive and not less specific compared to the margin status."

The importance of margin involvement to assess the risk of post-treatment disease is controversial, especially since a direct link between the size of the excisional specimen and obstetrical outcomes has been shown

The majority of colposcopists do not reach the EFC benchmark of >80% clear margins. A revision of this benchmark (>70%) should be considered.

***Marc Arbyn 2014 review for EFC***

# Notes from EFC 3rd Satellite Meeting, Berlin 28th Feb/ 1st March 2014

- 36 delegates from 27 member societies.
- The aim is to standardize and harmonize education, training and practice in colposcopy throughout Europe and neighbouring regions.
- The satellite meeting delegates to develop a frame programme for basic and advanced colposcopy courses with defined time slots
- template for training programmes in colposcopy including minimum / maximum time limits and minimum caseloads.

# EFC Quality indicators

## 2015 EFC satellite meeting - Consensus revisions

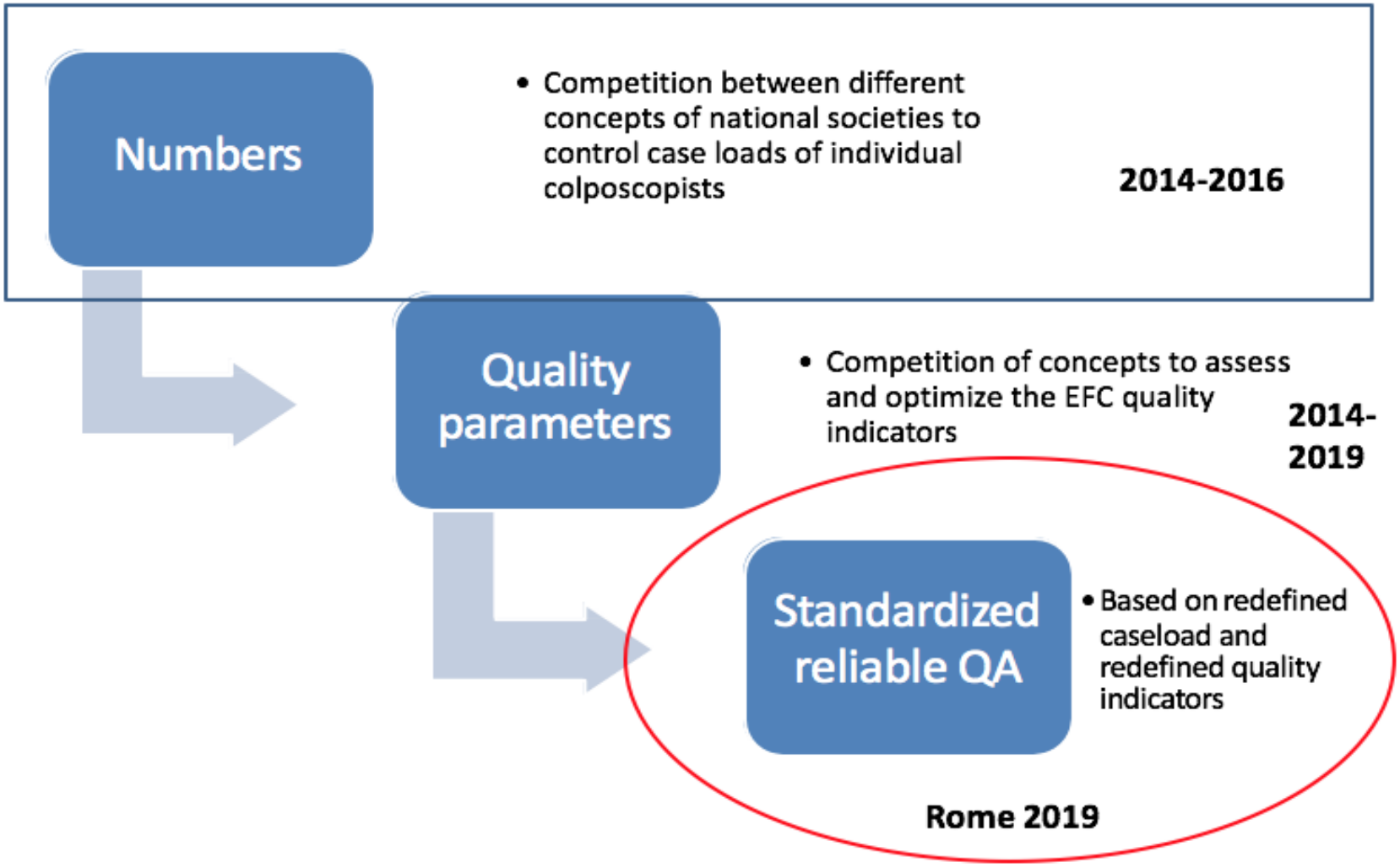
**The revised EFC Quality Indicators 2017**
**will be published as full paper but with comments to allow**
**national societies and/or governments**
**to define lower aims for national QA and/or to replace the „clear margin“ QI (No.4)**

# EFC Quality indicators

## 2015 EFC satellite meeting - Consensus revisions

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

# 3 steps to certify a reliable quality in colposcopy



# Better Quality Indicators ?? & Proposal for EFC 2019 Roma

| Quality indicator | Aim |
|---|---|
| For cervical colposcopy TZ type (1,2 or 3) should be documented | **>95%** |
| Percentage of cases having a colposcopic examination prior to treatment for abnormal cervical screening test | **>95%** |
| **Colposcopy with punch biopsies in </= LSIL and type 1 or 2 TZ with minor or major changes** | **>90%** |
| Excisional treatments/conizations have a definitive histology of CIN2+. Definitive histology is highest grade from any diagnostic or therapeutic biopsies **(exclude type 3TZ + age 40+)** | **>80%** |
| **Rate of HPV negative cases 6 months after excisional treatment** | **> 80%** |

# ASCCP 2017 Colposcopy Standards

ASCCP Colposcopy Recommendations

## ASCCP Colposcopy Standards: Colposcopy Quality Improvement Recommendations for the United States

*Edward J. Mayeaux, Jr, MD, DABFM, FAAFP, DABPM,[1] Akiva P. Novetsky, MD, MS,[2,3] David Chelmow, MD,[4] Francisco Garcia, MD, MPH,[5] Kim Choma, RN, DNP, APN,[6] Angela H. Liu, MD,[7] Theognosia Papasozomenos, MD, MPH,[8] Mark H. Einstein, MD, MS,[9] L. Stewart Massad, MD,[10] Nicolas Wentzensen, MD,[11] Alan G. Waxman, MD, MPH,[12] Christine Conageski, MD,[13] Michelle J. Khan, MD, MPH,[14] and Warner K. Huh, MD[15]*

- **The recommendations were developed by an expert group**
- **The working group appointed by ASCCP's Board of Directors**
- **The ASCCP Quality Improvement Group developed;**
  - **- evidence-based guidelines**
  - **- promote best practices**
  - **- reduce errors in colposcopy**
  - **- recommended indicators to measure colposcopy quality**

# ASCCP Guideline Development Methodology

- The working group performed a systemativ review of existing major society and national guidelines and quality indicators.
- An initial list of potential quality indicators was
  - developed and refine through successive iterative discussions
  - draft quality indicators were proposed
- The draft recommendations were then reviewed and commented on by the entire Colposcopy Standards Committee
- Posted online for public comment, and presented at the International Federation for Cervical Pathology and Colposcopy 2017 World Congress for further comment
- All comments were considered, additional adjustments made, and the final recommendations approved by the entire Task Force

# Results

- **Eleven quality indicators were selected spanning documentation, biopsy protocols, and time intervals between index screening tests and completion of diagnostic evaluation.**

# Proposed Minimum and Comprehensive Quality Measures for the Colposcopic Examination, ASCCP, 2017 & 11 Rules

| | Minimum target, % | Comprehensive target,% |
|---|---|---|
| Document that squamocolumnar junction is visualized (fully visualized/ not fully visualized | 90 | 100 |
| Documentation of whether any acetowhite lesion is present (yes/no) | 90 | 100 |
| Documentation of colposcopic impression (normal/benign; low grade; high grade; cancer) | 80 | 100 |
| Documentation of cervix visibility (fully visualized, not fully visualized | 70 | 100 |
| Documentation of extent of lesion visualized (fully/partial) | 70 | 100 |
| Documentation of location of lesion(s) | 0 | 100 |

# Proposed Minimum and Comprehensive Quality Measures for the Colposcopic Examination, ASCCP, 2017 & 11 Rules

| | Minimum target, % | Comprehensive target, % |
|---|---|---|
| Provider should take multiple biopsies targeting all areas with acetowhitening, metaplasia or higher abnormalities (at least 2 and up to 4 biopsies) | 85 | 100 |
| An attempt should be made to contact a patient with suspected invasive diseasea within 2 week of receipt of report or referral. | 60 | 90 |
| Patients with suspected invasive diseasea should be seen within 2 week of contact. | 60 | 90 |
| An attempt should be made to contact a patient with high-grade cytology results within 4 week of receipt of report or referral. | 60 | 90 |
| Patients with high-grade cytology results should be seen within 4 week of contact. | 60 | 90 |

# Conclusions

- Colposcopists need to pass a well defined education and training programme with exit assessment
- A continous QA of colposcopy practice is needed
- External QA is better than self QA. External QA should be organised by national societies for colposcopy and harmonized by EFC.
- QA of education, training and practice in colposcopy can be delivered in private and public health sectors, remote and rural as well as urban areas.

# Berlin Consensus 2011

**QA of each part of the colposcopy service**

1. **Quality of colposcopic examination /**
2. **identification of SCJ**
3. **Colposcopical guidance of excisional CIN therapy**
4. **Quality of indication/selection for excisional therapy**
5. **Proof of cure following invasive treatment of CIN**
6. **Experience**