EFC concept of achieving European quality assessment in colposcopy

K. Ulrich Petry, Germany

DISCLOSURES

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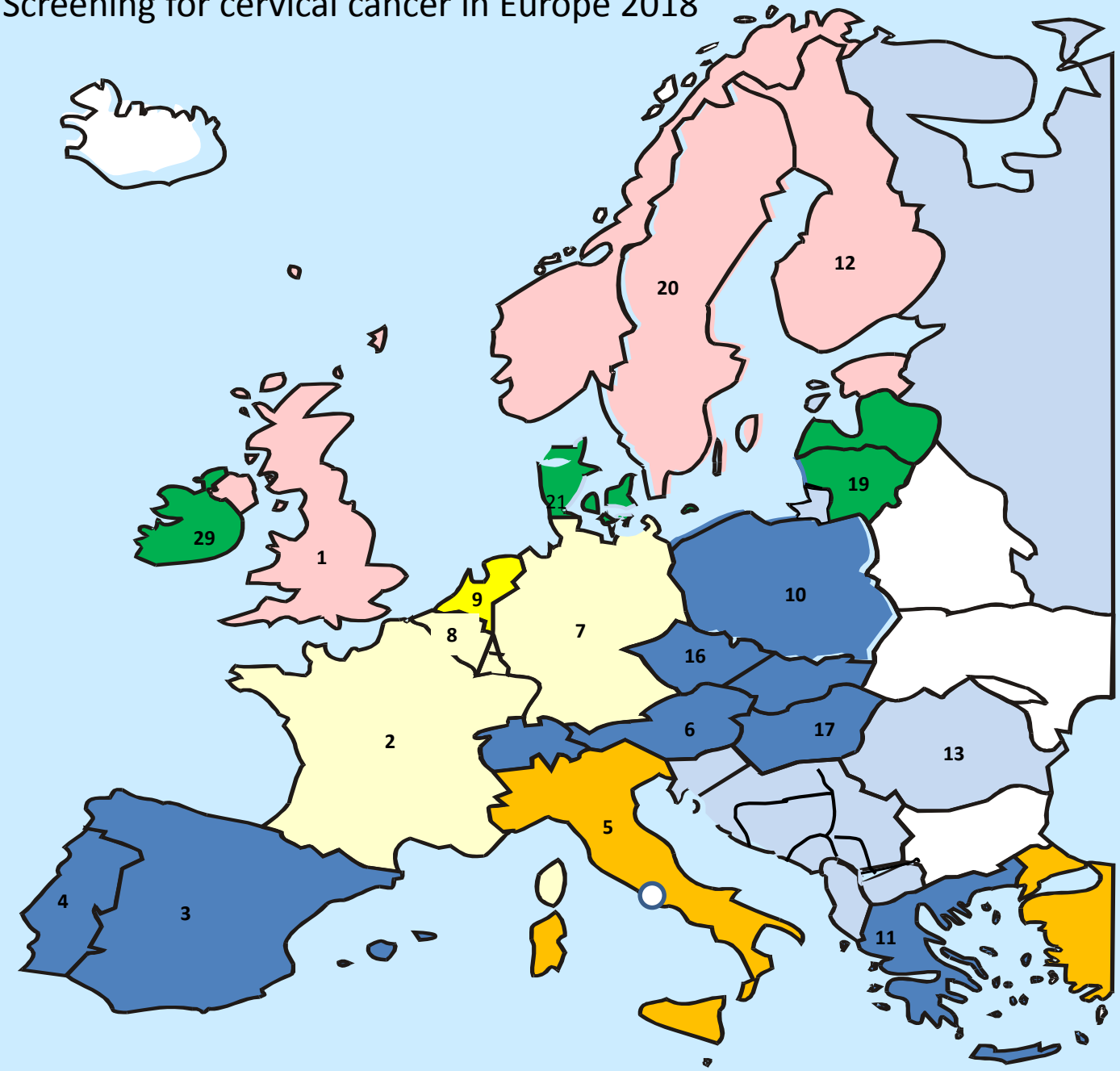
No conflict of interest related to my presentation

Occasional advisor / speaker:

- Roche Diagnostics
- MSD & Merck
- Vaccibody
- GSK

Screening for cervical cancer in Europe 2018



Nationwide HPV screening

Regional HPV screening

Organised HPV screening in progress

Political decision for organised HPV Screening

Organised recall Pap Screening

Pap screening programs

Wild Pap screening

K.U. Petry 2017

Summary on screening

Conclusions

- 1.1 Primary HPV-Screening for women (30) 35+ years (I-A)
- 1.2 Avoidance of co-testing (HPV plus cytology) (II–A)
- 1.4 No HPV-Screening below age 30 years (I–E)
- 1.8 The screening interval after a negative HPV-test should be at least 5 years (I-A)
- 1.15 Direct referral to colposcopy of all HPV positive women is not recommended (I-D)

WHO / IARC / EC 2015

- What is the status of education and training in colposcopy in Europe?
- How is colposcopy practised in Europe?
- Is there an interest in developing European colposcopy standards?
- Are member societies interested in developing a European Colposcopy Diploma?

EFC Satellite meetings:

- Each national society may send one (max two) delegate(s)
- Delegates are authorized by their society to vote / speak in the name of the country about standards in colposcopy
- One country, one vote
- Satellite meetings are mini general assemblies that enable EFC to develop colposcopy standards and quality assessment much faster and to guide research on colposcopy

5th European Congress of the European Federation for Colposcopy and Cervical Pathology

27–29 May 2010

Hotel InterContinental Berlin | Germany

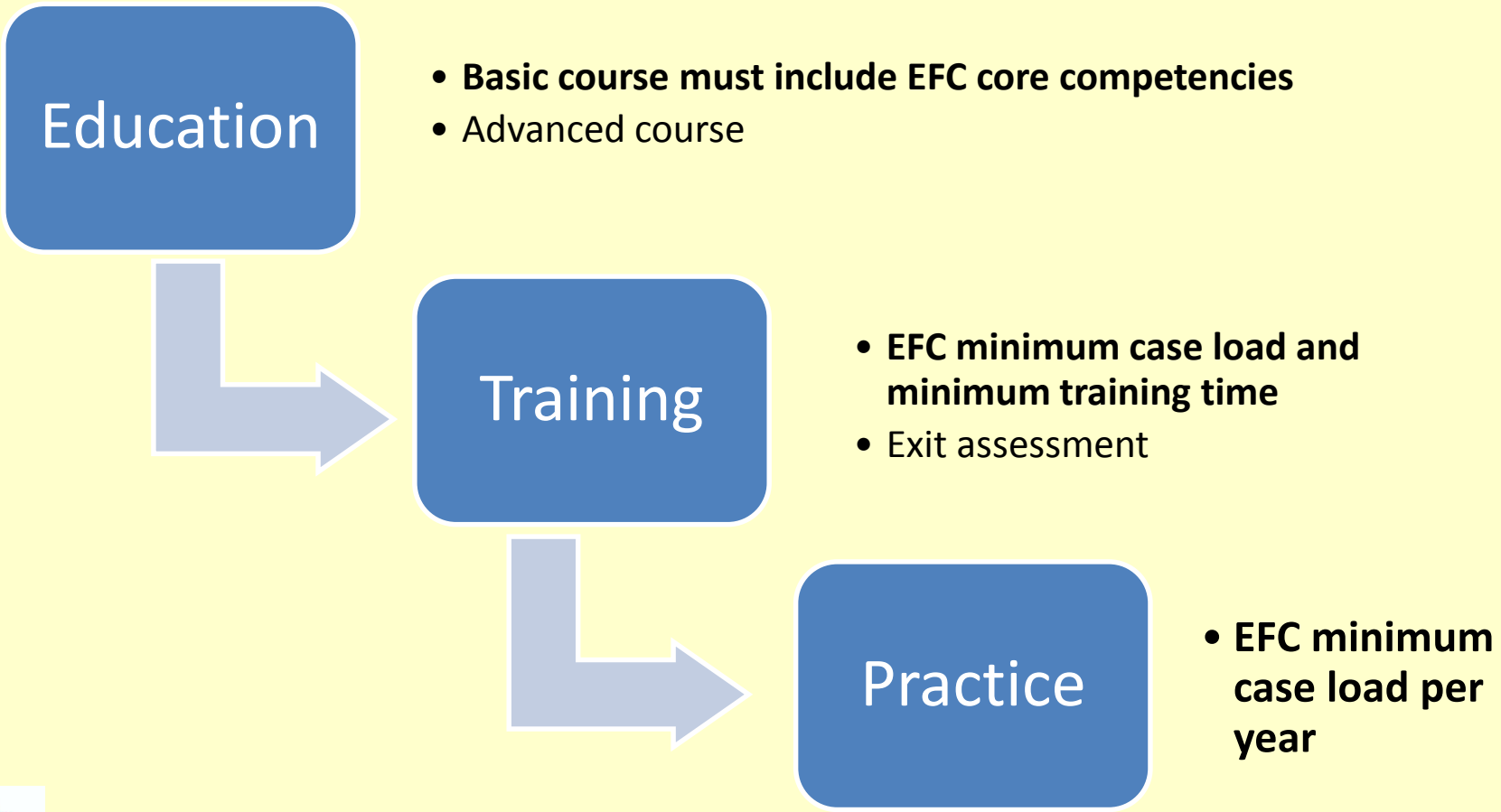
- 2011 1st Satellite meeting Berlin
- 2012 2nd Satellite meeting Berlin

- **2013 6th EFC Congress Prague**

- 2014 3rd Satellite meeting Berlin
- 2015 4th Satellite meeting Brussels

- **2017 EFC Symposium and GA Paris**

3 steps that will determine the quality of colposcopy services – EFC phase 1



Berlin Consensus 2011

QA of each part of the colposcopy service

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

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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/

EFC Quality indicators for colposcopy

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

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

E. Moss et al.: European Federation for Colposcopy quality standards Delphi consultation. Eur.J.Obstet.Gynecol.Reprod.Biol. 2013: 170:255

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

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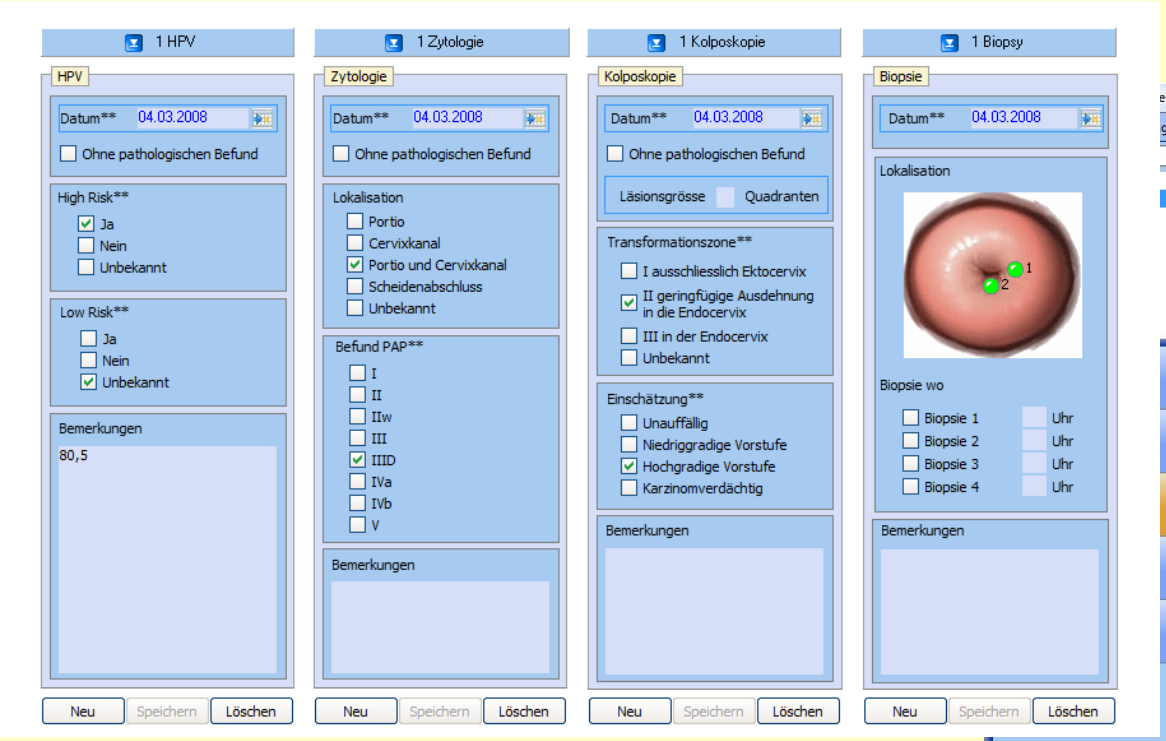
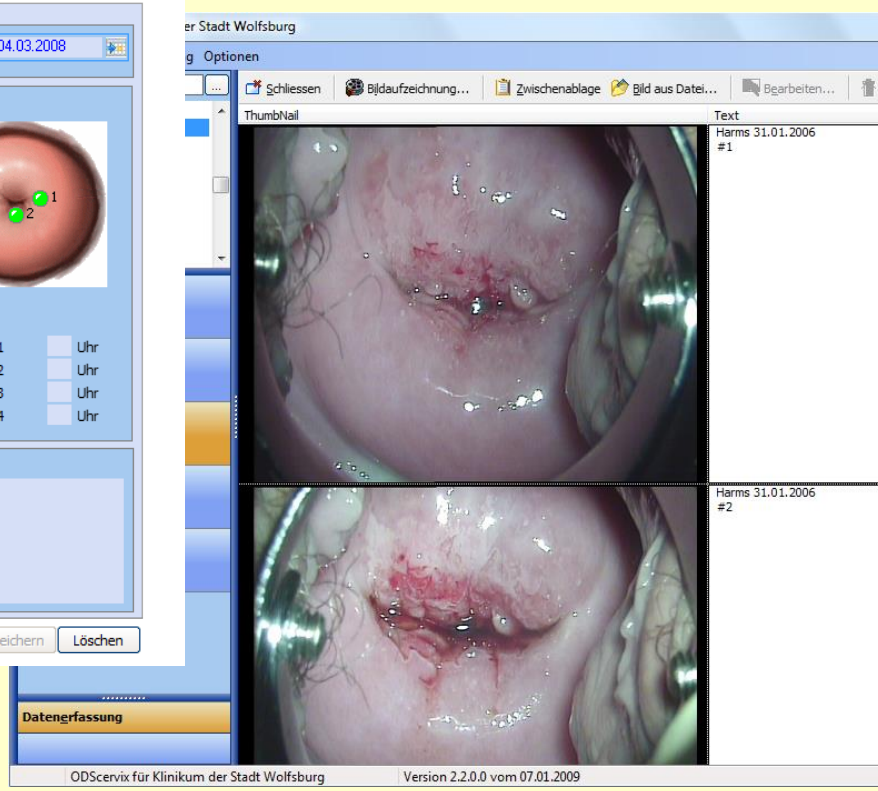
Independent electronic bench-marking

Data collected were automatically anonymized, encrypted and stored in a secure relational database located within the clinics' network



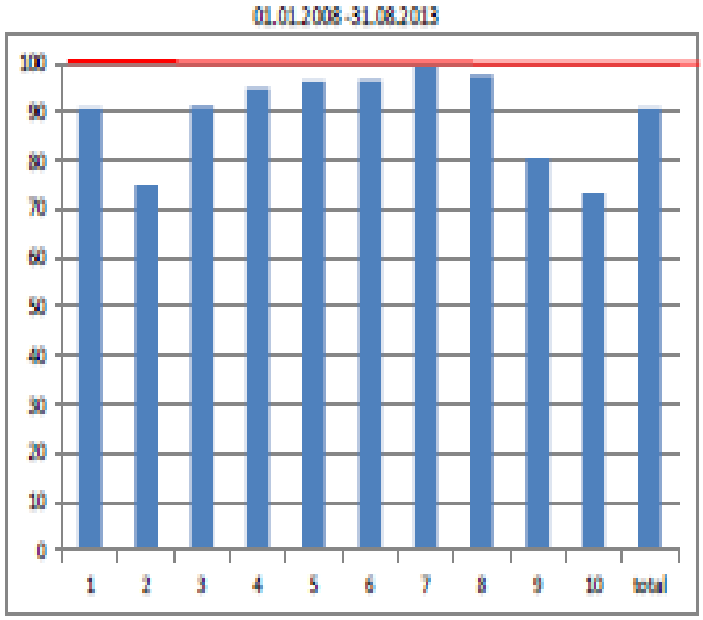


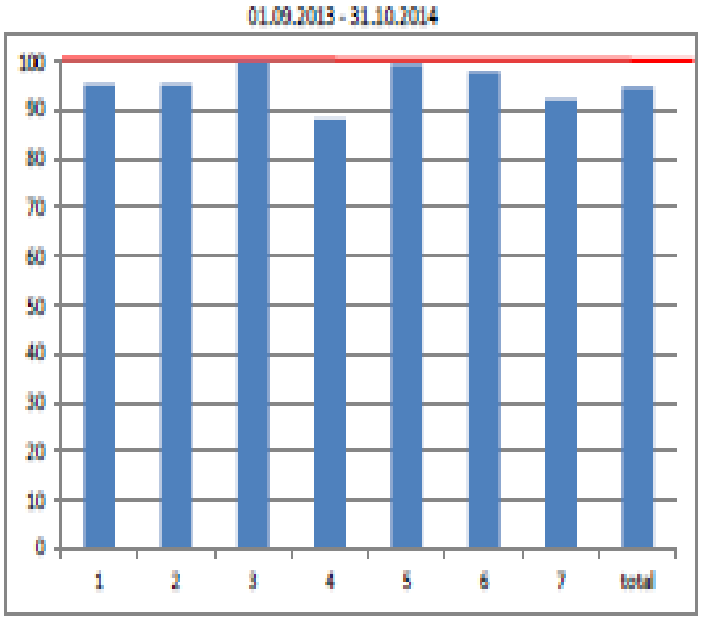
N= 10.869

Luyten A, EJOGRB 2015

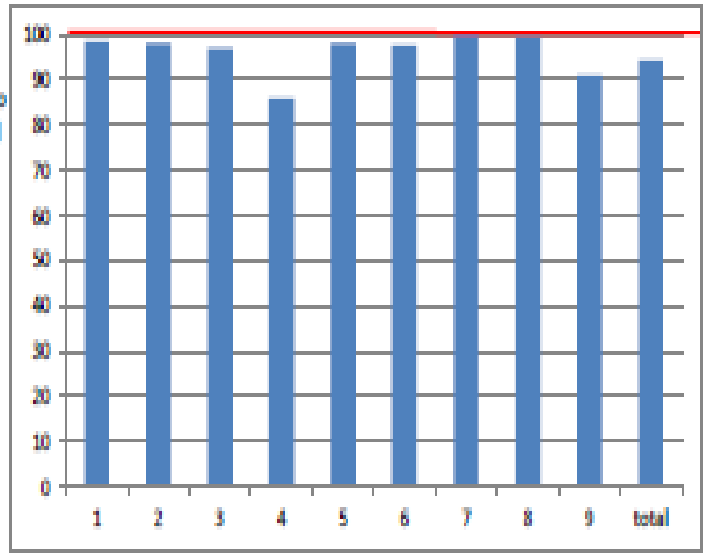
a. Documentation of whether the squamocolumnar junction has been

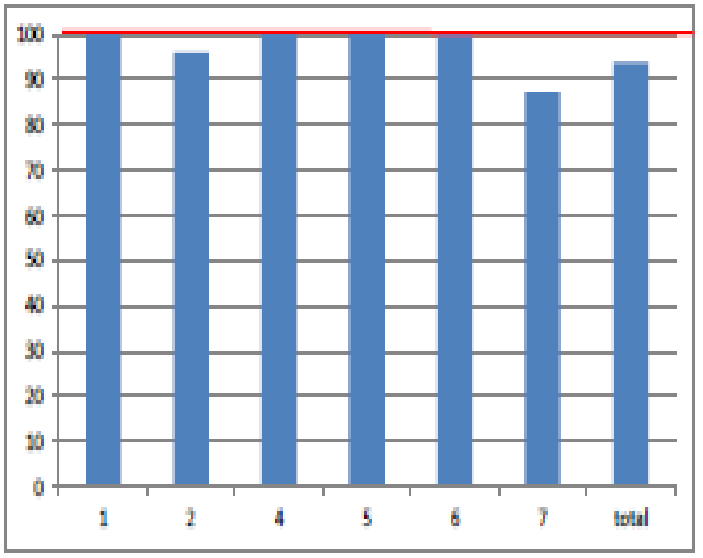
seen or not





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





- Use the quality parameters to assess quality in colposcopy.

- Use the quality assessment to evaluate the quality parameters

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

EFC Quality indicators

2015 EFC satellite meeting - Consensus revisions

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1. For cervical colposcopy TZ type (1,2 or 3) should be documented .	**100%**
2. Percentage of cases having a colposcopic examination prior to treatment for abnormal cervical screening test	**100%**
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4. Percentage 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
5. Number of colposcopies personally performed each year for high-grade/major abnormality on cervical *screening*	>50

Risk of treatment failure associated with positive section margins of excisional treatment for high-grade CIN: a systematic review and meta-analysis.
Marc Arbyn 2014 review for EFC

"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.

women treated for high-grade CIN observed in eligible studies. The red line (20%) represents the maximum positivity considered by EFC as the benchmark of good quality.

Standardized histological assessment improves the sensitivity of colposcopy

- Taking 3 biopsies increased sensitivity for CIN3+ to 95.6%
- Only 2% of HSIL were detected by random biopsies from colposcopically normal tissue

N. Wentzensen et al , JCO 2015

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 [redacted] 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 tranferred because of abnormal screening results, 171 CIN3+

Petry KU et al. , Gyn Oncol 2013

Better Quality indicators ahead?

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%**

A proposal for the EFC congress 2019 in Rome

Conclusions

- The basics of colposcopy should be part of any OBGYN training but this does not qualify to practise colposcopy in women with atypical screening results
- 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.