QA and Quality Indicators for Cervical Cancer Screening Programs

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Disclosures

- No financial relationships or conflict of interest to disclose

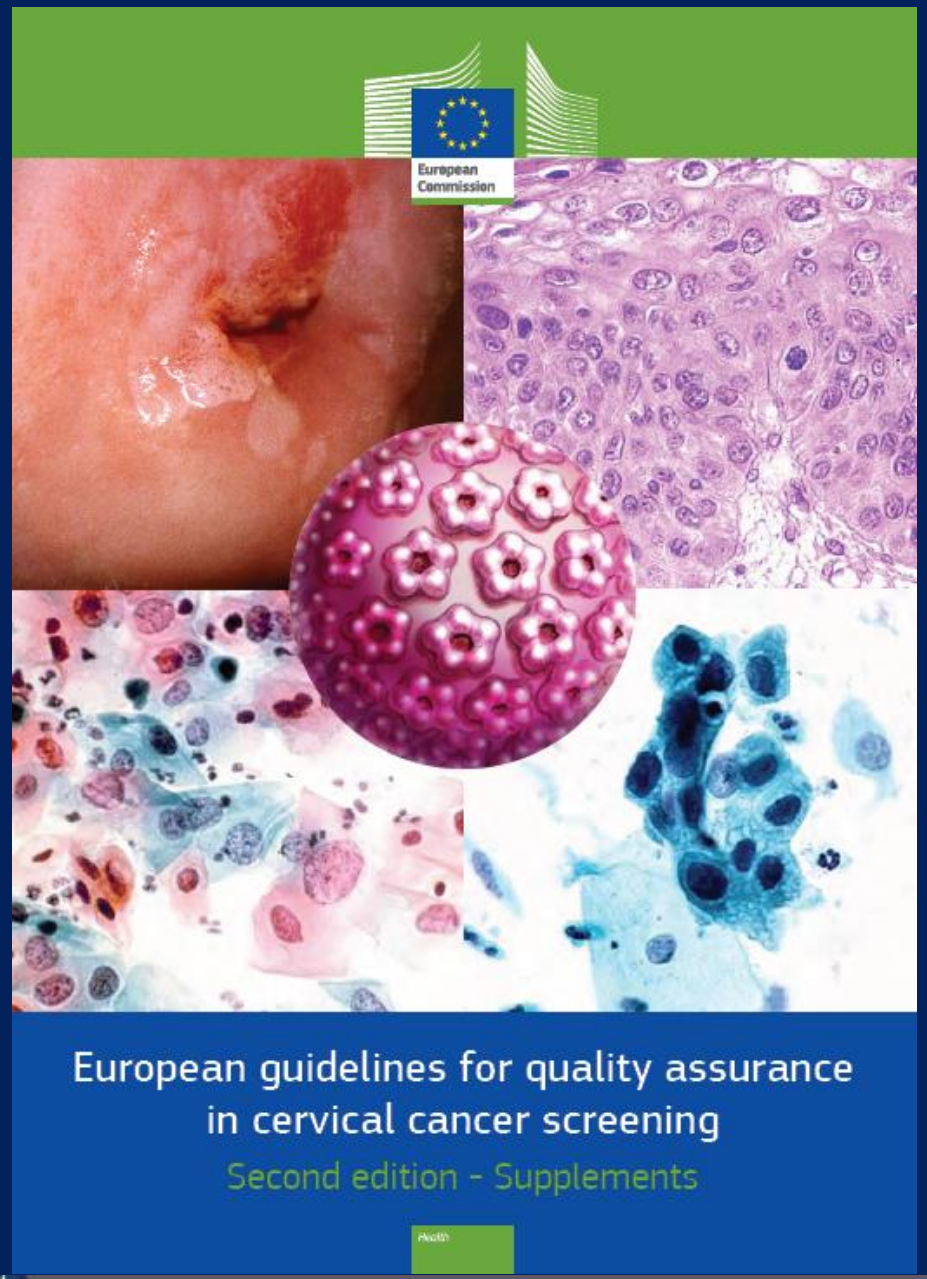
Organised screening programs

- Active invitation (all or “integrated”)
- Defined (evidence-based) protocols for all phases
- Fail safe system for women with non normal primary test (guarantee diagnostic work-up)
- Fail safe system for women needing treatment
- Registration of all screening events (linkage with cancer registry)
- QA and monitoring.

Objective QA and Monitoring Approaches

- Increasing effectiveness
  - Reducing cancer incidence and mortality in population
- Controlling undesired effects and costs

- Define “rules” (standard behaviour) – measure if followed
  - Does following the rules improve the desired final result?
- Monitor to measure intermediate results and costs – correct situation if needed



Organization of cytology-based and HPV-based cervical cancer screening

A. Anttila, G. Ronco, F. Nicula, P. Nieminen, M. Primic Žakelj

EU guidelines
Screening intensity

- Programme extension
- Coverage of the target population by invitation
- Coverage of the target population by smear/HPV test
- Compliance to invitation
- Smear/HPV primary test consumption
- Incidence of invasive cancer in unscreened and underscreened women in a given interval (3.5 and 5.5 years for cytology ; 5.5 and 7.5 for HPV)

EU guidelines
Screening test performance

- Proportion of women positive at the primary screening test
- Referral for triage test
- Referral for colposcopy
- Positive Predictive value for referral to colposcopy
- Detection of CIN (particularly CIN2 and CIN3)
- Cancer incidence after normal primary test result

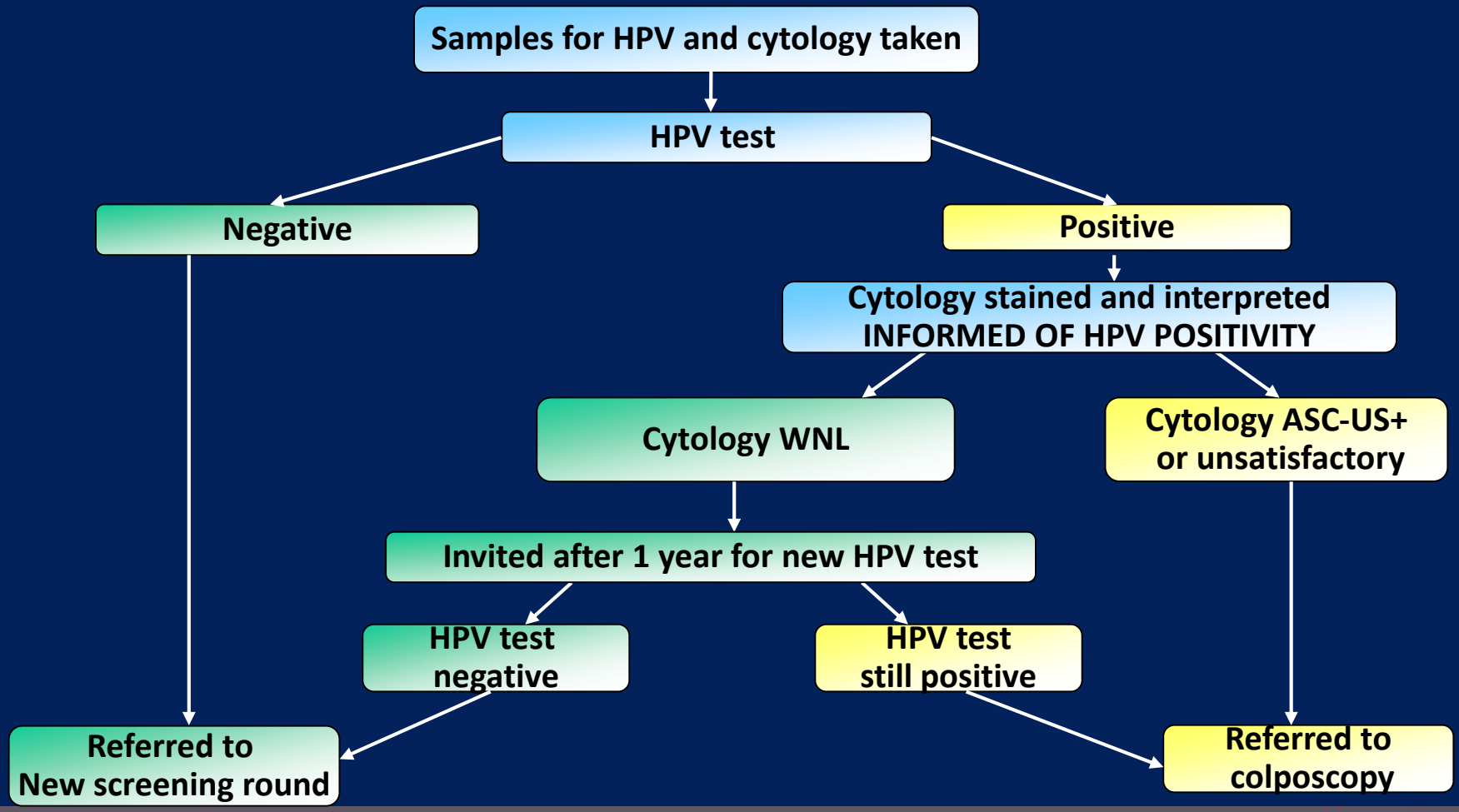
What cannot be measured in routine practice

- **Sensitivity**
  - Measuring them entails referring to second level all or a relevant number of subjects negative to primary test
  - If not, possibly relevant bias
- **Detection rate not surrogate measure of sensitivity except**
  - Risk can be assumed as uniform
    - in Italy high variability of %HPV+ in areas covered by same lab
  - Related to an external risk measure
    - Incidence in absence of screening (impossible to compute correcly)
    - Risk quite stable in HPV+ women given screening history (cfr. triage tests)

Detailed indicators depend on protocol.

- Italian guidelines give one precise protocol for management of HPV+ women. Process indicators very detailed.
- EU guidelines allow different approaches. Less detailed

HPV based screening - Italy



EU guidelines
Diagnostic assessment and treatment

- Compliance to referral for colposcopy
- Treatment of high-grade intraepithelial lesions
- Proportion of women hysterectomised on screen-detected CIN
- Proportion of women treated on CIN1
- Proportion of women with cytology negative for SIL 6 months after treatment

Italy, survey 2014

- Compliance to referral for colposcopy
  - Any reason 87.0% HSIL 91,2%
- Treatment of high-grade intraepithelial lesions
  - Recommended but not treated 3.8% (2.7%>3 mths.)
  - Unknown if treated 7.1%
- Proportion of women hysterectomised on screen-detected CIN
  - 0.0% of CIN1, 0.3% of CIN2, 1.4% OF CIN3
- Proportion of women treated on CIN1
  - 82% follow-up first recommended

Italy 2014 survey

Distribution of histology at excisional treatment by histology on biopsy

Histology on first excisional treatment

Biopsy	No CIN	CIN1	CIN2/3	AdenoCa IS	Inv Ca	Not available
CIN1	18.6% (64)	41.4% (143)	29.3% (101)	0.6% (2)	0.3% (1)	9.9% (34)
CIN2/3	3.4% (102)	8.7% (261)	81.1% (2432)	0.5% (15)	2.7% (83)	3.6% (107)
AdenoCa IS	6.4% (3)	2.1% (1)	6.4% (3)	59.6% (28)	17.0% (8)	8.5% (4)
Inv Ca	1.9% (1)	0% (0)	18.5% (10)	7.4% (4)	66.7% (36)	5.6% (3)
No Biopsy (see and treat)	6.7% (14)	21.0% (44)	54.3% (114)	3.8% (8)	1.4% (3)	12.9% (27)
Percents are on rows						

2014 Survey Italy
Free endocervical margins in excisional treatments

	Tot	Yes	%	No	%
Radio frequency device (LLETZ needle)	2352	1758	92,8%	136	7,2%
Cold knife conization	407	170	93,9%	11	6,1%
Laser conization	455	396	91,7%	36	8,3%
Total	3214	2324	92,7%	183	7,3%

Reference values

- What is best for effectiveness and cost
  - In some case relation with effect direct: the highest participation to screening the greatest effectiveness taking everything else stable. Logical relation. No extra evidence needed.
  - In some case relation can be complex, evidence needed – modelling.
- What is feasible.
  - Given the highest participation the best, which participation is it possible to reach?
  - What has been reached?
  - “External validity”
- Evaluate variability between programs
  - Explainable by different prevalence of searched condition?

- The most difficult is making changes when a problem is identified
- Sometimes simply showing variability reduces it

% Referral rate to colposcopy

Italy Surveys 2002 (blue) and 2014 (red)