

# GISCi

Le nuove linee guida europee

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Torino

Viterbo 16 giugno 2011

# European guidelines for quality assurance in cervical cancer screening

European guidelines for quality assurance in cervical cancer screening



European guidelines for quality assurance  
in cervical cancer screening *Second Edition*



European Commission



Health & Consumer Protection  
Directorate-General



## European guidelines for quality assurance in cervical cancer screening

*Second Edition*

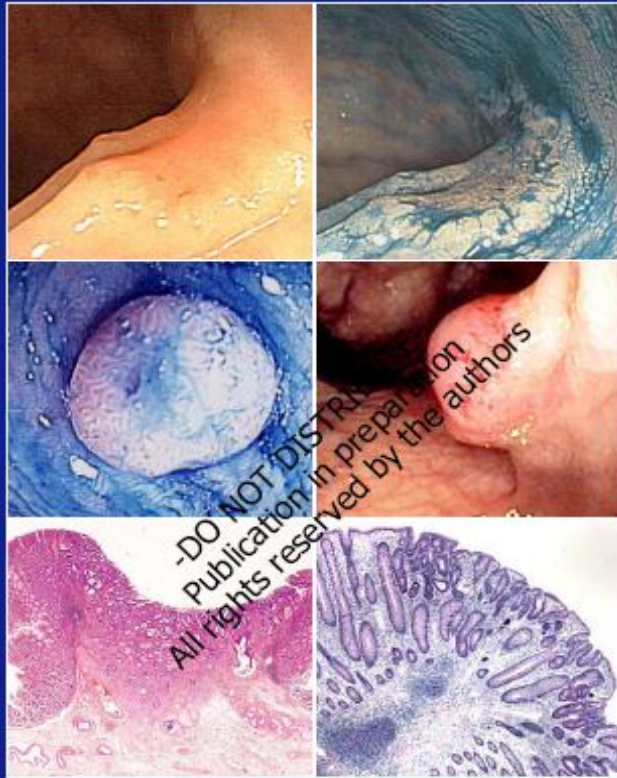
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International Agency for Research on Cancer  
Centre International de Recherche sur le Cancer

# European guidelines for quality assurance in colorectal cancer screening



## European Guidelines for Quality Assurance in Colorectal Cancer Screening



European Commission



Directorate-General for  
Health & Consumers



## European guidelines for quality assurance in colorectal cancer screening and diagnosis

*First Edition*

### Editors

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International Agency for Research on Cancer



# European Guidelines for Quality Assurance in Colorectal Cancer Screening – first edition \*

## Volume 1 – 10 Chapters, 386 pages

- Introduction
- Organisation
- Evaluation
- FOBT
- Endoscopy
- Training
- Pathology
- Clinical Management
- Surveillance
- Communication

,

## Volume 2 – Evidence 1.000 pages, 500 tables of evidence

102 Authors, Contributors,  
Editors, Reviewers

from Europe ,Israel, US ,  
Canada, India, Japan, China,  
Korea, Australia

# Evidence based guidelines

# PROCESSO

1. Definizione di quesito clinico e di PICOS da parte degli autori
2. Ricerca bibliografica, tabelle di evidenza e documenti riassuntivi da parte del gruppo bibliografico
3. Bozza del capitolo sulla base dei risultati bibliografici
4. Distribuzione della bozza ed incontri con gli autori dei capitoli, il comitato editoriale ed il gruppo bibliografico per verificarne e condividerne i contenuti
5. Revisione esterna e consultazione web
6. Revisione finale ed editing da parte degli autori e del comitato editoriale

# FORMULAZIONE DEI QUESITI

Tutti gli autori dei capitoli sono stati invitati a definire per ogni titolo ed ogni sottotitolo, **uno o più quesiti clinici rilevanti** cui dare risposta attraverso una ricerca bibliografica.

Sono inoltre stati invitati a compilare i **PICOS**:

**P:** characteristics of patients

caratteristiche dei pazienti

**I:** intervention to be assessed

intervento da valutare

**C:** comparison

comparazione

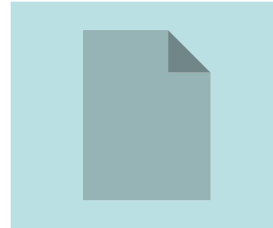
**O:** relevant outcomes

outcome rilevanti

**S:** study designs to be considered

disegno dello studio da considerare

## Un esempio di PICOS....



# Esempio di PICOS

Evidenza dell'accuratezza del FOBt di screening

**Il FOBT immunochimico (I-FOBT) è superiore al FOBT al guaiaco (G-FOBT) nelle proprie caratteristiche di performance (sensibilità e specificità)?**

- **P:** popolazione generale a rischio medio di cancro colorettole, dai 50 anni in poi
- **I:** I-FOBT;
- **C:** G-FOBT
- **O:** sensibilità, specificità, rapporto dei verosimiglianza, VPP
- **S:** (revisione sistematica di) studi di accuratezza diagnostica(RCT, prospettici, retrospettivi or caso-controllo)

## Numero di PICOS per ogni capitolo

Capitolo	1	2	3	4	5	6	7	8	9	10
N. di PICOS	22	13	12	8	15	9	20	9	8	3

# BIBLIOGRAPHIC SEARCH

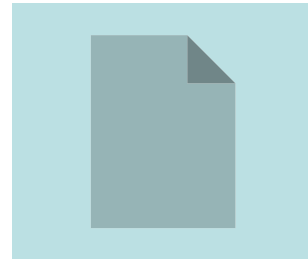
- The literature group performed a **comprehensive bibliographic search** for each PICOS on Medline, Embase, Cochrane library, since 2000 or earlier
- The literature **suggested by the authors** have also been used
- As first resort **systematic reviews** have been considered. If not found, primary studies have been searched
- For some questions, also **published guidelines** have been considered

# DOCUMENTO RIASSUNTIVO

Per ogni quesito clinico è stato preparato un documento riassuntivo contenente:

- quesito **PICOS**
- **Metodi:** strategia di ricerca utilizzata
- **Risultati:** n. and e tipo di studi trovati, sommario delle loro caratteristiche e dei loro risultati, qualità metodologica
- **Conclusioni e livello complessivo di evidenza**

## HPV - biomarkers



# LIVELLO DI EVIDENZA

In ogni tabella di evidenza e documento riassuntivo è stata utilizzata e riportata una classificazione del livello di evidenza

**I:** molti trial controllati e randomizzati (RCT) o revisioni sistematiche (SR) di trial controllati e randomizzati

**II:** un RCT

**III:** studi prospettici di coorte o SR di studi di coorte

**IV:** studi caso-controllo retrospettivi o SR di studi caso-controllo retrospettivi, analisi di serie temporali

**V:** serie di casi; studi “before after” senza gruppo di controllo, studi trasversali,

**VI:** opinione degli esperti

# FORZA DELLE RACCOMANDAZIONI

- A** intervento fortemente raccomandato per tutti i pazienti
- B** intervento raccomandato
- C** intervento da considerarsi ma con incertezza sull'impatto
- D** intervento non raccomandato
- E** intervento fortemente non raccomandato

# Corrispondenza LE – Racc

**C**: coerenza tra il livello di evidenza e la forza delle raccomandazioni

**nc**: non tra il livello di evidenza e la forza delle raccomandazioni

Se gli autori formulano raccomandazioni senza coerenza con il livello di evidenza, devono giustificare tale decisione

	<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
<b>I</b>	<b>C</b>	<b>C</b>		<b>C</b>	<b>C</b>
<b>II</b>	nc	<b>C</b>		<b>C</b>	<b>C</b>
<b>III</b>	nc	<b>C</b>	<b>C</b>	<b>C</b>	nc
<b>IV</b>	nc	nc	<b>C</b>	nc	nc
<b>V</b>	nc	nc	<b>C</b>	nc	nc
<b>VI</b>	nc	nc	<b>C</b>	nc	nc

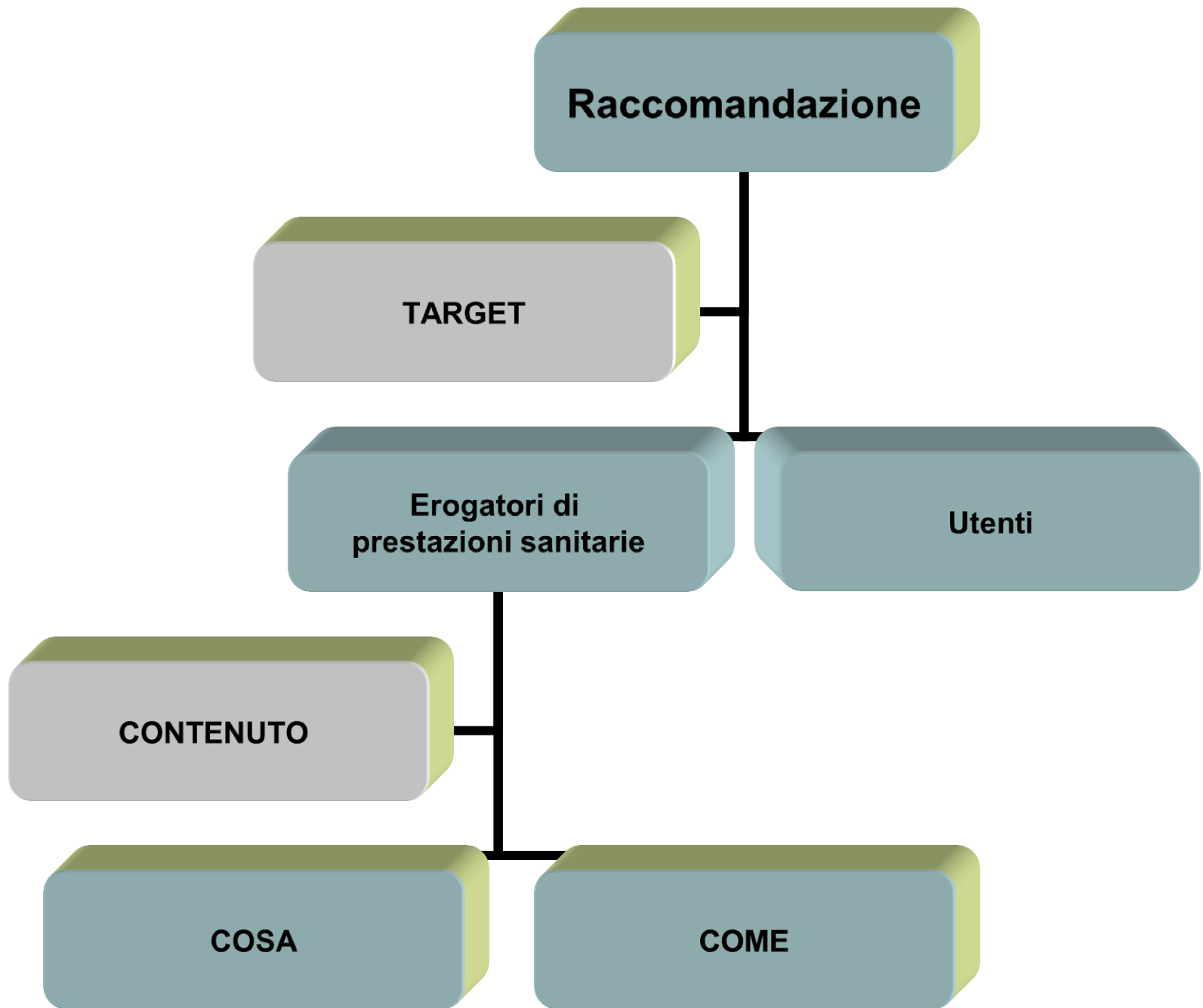
## Recommendations by levels of evidence and strength

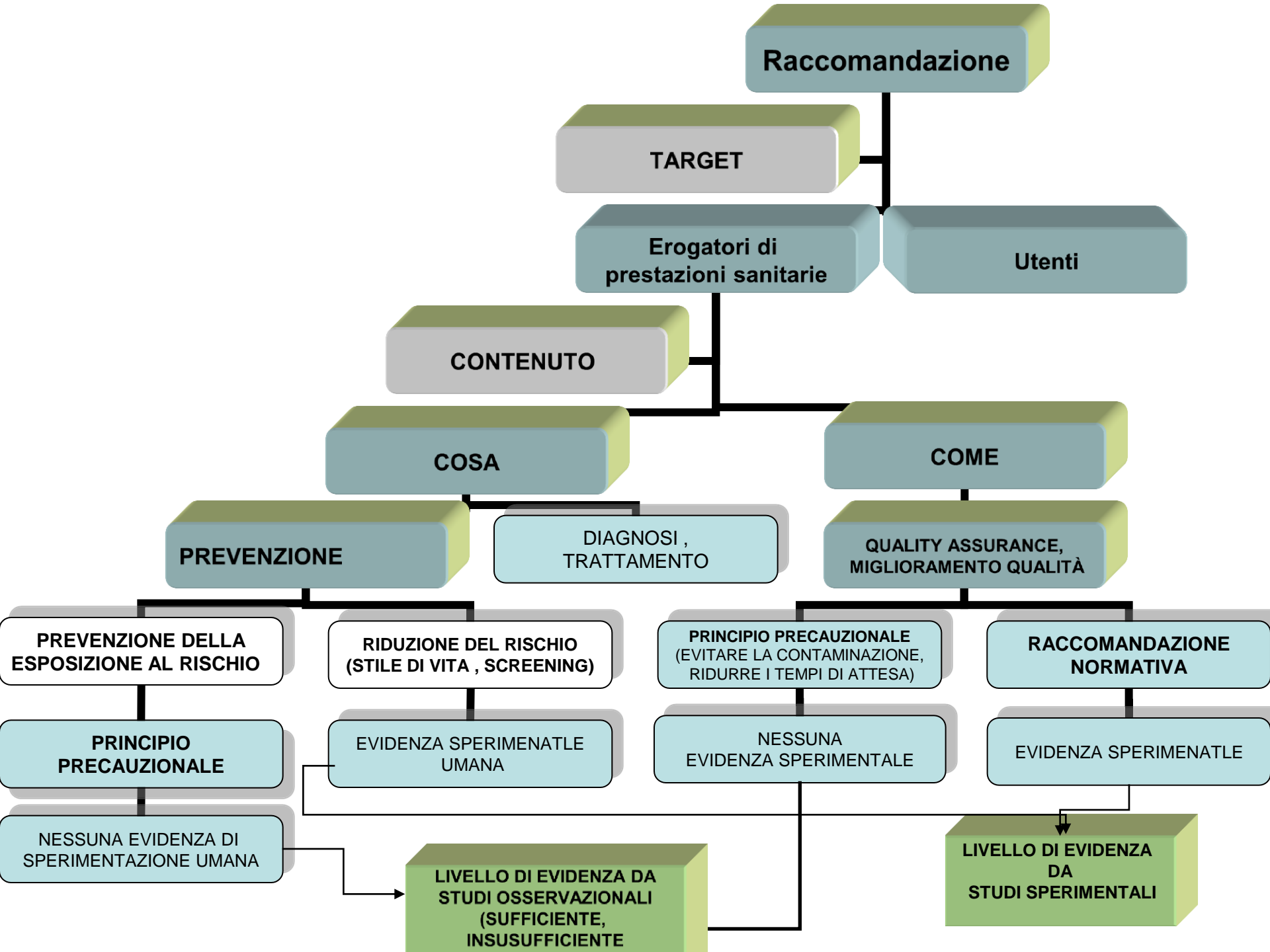
	<b>Levels of evidence</b>						
<b>Strength of recommendation</b>		<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>	<b>V</b>	<b>VI</b>
<b>A</b>		<b>12</b>	<b>13</b>	<b>23</b>		<b>4</b>	<b>69</b>
<b>B</b>		<b>13</b>	<b>11</b>	<b>17</b>	<b>2</b>	<b>9</b>	<b>62</b>
<b>C</b>			<b>3</b>	<b>6</b>	<b>4</b>	<b>4</b>	<b>18</b>
<b>D</b>			<b>1</b>	<b>5</b>		<b>2</b>	<b>1</b>
<b>E</b>							
<b>Total</b>		<b>25</b>	<b>28</b>	<b>51</b>	<b>6</b>	<b>19</b>	<b>150</b>

\*including recommendations reported just once

# **E' necessario considerare le dimensioni della raccomandazione**

- Target (individui ,popolazione e/o utenti and somministratori di cure)**
- contenuti (che cosa fare e come farlo)**
- processo di cura (prevenzione, trattamento)**
- implementazione**
- .....**





**Raccomandazione**

**TARGET**

**Erogatori di prestazioni sanitarie**

**Utenti**

**CONTENUTO**

**COSA**

**COME**

**PREVENZIONE**

**DIAGNOSI, TRATTAMENTO**

**QUALITY ASSURANCE, MIGLIORAMENTO QUALITÀ**

**PREVENZIONE DELLA ESPOSIZIONE AL RISCHIO**

**RIDUZIONE DEL RISCHIO (STILE DI VITA, SCREENING)**

**PRINCIPIO PRECAUZIONALE (EVITARE LA CONTAMINAZIONE, RIDURRE I TEMPI DI ATTESA)**

**RACCOMANDAZIONE NORMATIVA**

**PRINCIPIO PRECAUZIONALE**

**EVIDENZA SPERIMENTALE UMANA**

**NESSUNA EVIDENZA SPERIMENTALE**

**EVIDENZA SPERIMENTALE**

**NESSUNA EVIDENZA DI SPERIMENTAZIONE UMANA**

**LIVELLO DI EVIDENZA DA STUDI OSSERVAZIONALI (SUFFICIENTE, INSUFFICIENTE)**

**LIVELLO DI EVIDENZA DA STUDI SPERIMENTALI**

**Conseguenze:**

**raccomandazioni prescrittive/normative**

**LIVELLO DI EVIDENZA BASATO SU STUDI SPERIMENTALI  
(RCT)**

**raccomandazioni basate sul principio di precauzione**

**LIVELLO DI EVIDENZA BASATO SU STUDI  
OSSERVAZIONALI  
(SUFFICIENTE, INSUFFICIENTE  
INADEGUATO) :**

Chapter	Authors	Reviewers
<b>Part I - INTRODUCTION</b>		
<b>Ch 1 - Intro</b>		
<i>lead author</i>	Marc Arbyn	<b>Ahti Anttila</b>
<i>author</i>	Silvia Franceschi	<b>Xavier Bosch</b>
<i>author</i>	Larry von Karsa	
<b>Ch 2 - Principles of assessment of evidence</b>		
<i>lead author</i>	Silvia Minozzi	<b>Guglielmo Ronco</b>
<i>author</i>	Paola Armaroli	<b>Jack Cuzick</b>
<i>author</i>	Nereo Segnan	
<i>author</i>	Marc Arbyn	
<b>Ch 3 - Natural History of HPV infection</b>		
<i>lead author</i>	Xavier Bosch	<b>Hugo De Vuyst</b>
<i>author</i>	Silvia de Sanjose	<b>Marc Arbyn</b>
<i>author</i>	Gary Clifford	
<b>Ch 4 - Burden of HPV infection in Europe</b>		
<i>lead author</i>	Hugo De Vuyst	<b>Silvia de Sanjose</b>
<i>author</i>	Gary Clifford	<b>Guglielmo Ronco</b>
<i>author</i>	Silvia Franceschi	

<b>Part II - HPV TESTING</b>		
<b>Ch 5 - Description of HPV tests</b>		
<i>lead author</i>	Thomas Iftner	<b>Marc Arbyn</b>
<i>author</i>	Ruth Tachezy	<b>Joakim Dillner</b>
<i>author</i>	Peter Snijders	
<i>author</i>	Michael Pawlita	
<b>Ch 6 - Triage of minor cytological abnormalities</b>		
<i>lead author</i>	Marc Arbyn	<b>Marjeta Vrscaj</b>
<i>author</i>	Pierre Martin-Hirsch	<b>Pekka Nieminen</b>
<i>author</i>	Evangelos Paraskevaidis	
<i>author</i>	Walter Prendiville	
<i>author</i>	Marjolein van Ballegooijen	
<i>author</i>	H. Berkhof	
<b>Ch 7 - HPV-based primary screening</b>		
<i>lead author</i>	Guglielmo Ronco	<b>Ahti Anttila</b>
<i>author</i>	Jack Cuzick	<b>Piret Veerus</b>
<i>author</i>	Chris Meijer	<b>Christine Bergeron</b>
<i>author</i>	Peter Snijders	
<i>author</i>	Marc Arbyn	
<b>Ch 8 - Histological conf of cervical lesions</b>		
<i>lead author</i>	Pierre Martin-Hirsch	<b>Walter Prendiville</b>
<i>author</i>	Marc Arbyn	<b>H. Berkhof</b>
<i>author</i>	Evangelos Paraskevaidis	
<i>author</i>	Marjeta Vrscaj	
<i>author</i>	Pekka Nieminen	
<i>author</i>	Christine Bergeron	
<i>author</i>	David Luesley	
<b>Ch 9 - Quality control in laboratories using HPV tests</b>		
<i>lead author</i>	Joakim Dillner	<b>Thomas Iftner</b>
<i>author</i>	Lena Dillner	
<b>Ch 10 - Organisation of HPV-based cervical cancer screening</b>		
<i>lead author</i>	Ahti Anttila	<b>Julietta Patnick</b>
<i>author</i>	Guglielmo Ronco	<b>Sven Törnberg</b>
<i>author</i>	Florian Nicula	
<i>author</i>	Pekka Nieminen	
<i>author</i>	Maja Zakelj	

<b>Part III - HPV VACCINATION</b>		
<b>Ch 11 - Review of prophylactic HPV vaccines</b>		
<i>lead author</i>	Marc Arbyn	<b>Silvia Franceschi</b>
<i>lead author</i>	Joakim Dillner	<b>Isabelle Heard</b>
<b>Ch 12 - Population trials &amp; demonstration projects</b>		
<i>lead author</i>	Joakim Dillner	<b>Hugo De Vuyst</b>
<i>author</i>	M. Lehtinen	<b>Daniel Levy-Bruhl</b>
<b>Ch 13 - Implementation of HPV vaccination in Europe</b>		
<i>lead author</i>	Hugo De Vuyst	<b>Marc Arbyn</b>
<i>author</i>	Daniel Levy-Bruhl	<b>Julietta Patnick</b>
<i>author</i>	Teri Kilpi	
<i>author</i>	Rebecca Howell-Jones	
<i>author</i>	P.G. Rossi	
<i>author</i>	Silvia Franceschi	

# Conclusioni

- **Migliorare e rifinire la metodologia delle LG**
- **Migliorare il processo di consultazione e definire l'indice dei contenuti delle LG con utenti e somministratori di cure**
- **Aggiornare regolarmente l'evidenza delle LG per il controllo e il miglioramento della qualità nello screening oncologico (mammografico, cervicale e coloretale, altro?)**
- **Aggiornamento dei capitoli e pubblicazione sul WEB, anziché la pubblicazione di una nuova edizione completa**
- **Progettare la diffusione e l'implementazione di LG**
- **Progettare la valutazione dell'impatto delle LG sullo screening**
- **Fornire le risorse e definire il contesto per l'aggiornamento continuo delle LG**

# EU CRC GL download

[http://bookshop.europa.eu/is-bin/INTERSHOP.enfinity/WFS/EU-Bookshop-Site/en\\_GB/-/EUR/ViewPublication](http://bookshop.europa.eu/is-bin/INTERSHOP.enfinity/WFS/EU-Bookshop-Site/en_GB/-/EUR/ViewPublication)

# Development of European Guidelines for Quality Assurance in Colorectal Cancer Screening\* – Project Partners Project 2005317 – EU Health Programme

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Quali sono le dimensioni  
dell'evidenza?

## Evidence dimensions — definitions

Type of evidence (dimension)	Definition
<b>Strength of evidence</b>	
Level	The study design used, as an indicator of the degree to which bias has been eliminated by design (see Table 1.3).
Quality	The methods used by investigators to minimise bias within a study design.
Statistical precision	The <i>P</i> -value or, alternatively, the precision of the estimate of the effect (as indicated by the confidence interval). It reflects the degree of certainty about the existence of a true effect.
<b>Size of effect</b>	The distance of the study estimate from the 'null' value and the inclusion of only clinically important effects in the confidence interval.
<b>Relevance of evidence</b>	The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used.

## Criteria for deciding the update status of a clinical guideline

14 Updating clinical guidelines and correcting errors © National Institute for Health and Clinical Excellence ( 2009)

Update decision	Criteria	Actions
Full update	<ul style="list-style-type: none"> <li>• Major sections of the guideline need updating</li> <li>• Many of the recommendations are no longer necessary</li> <li>• New key areas have been identified</li> </ul>	<ul style="list-style-type: none"> <li>• Prepare a new scope</li> <li>• Consult on the scope</li> </ul>
Partial update	<ul style="list-style-type: none"> <li>• Some recommendations need updating in the light of new evidence, or because they are unclear</li> <li>• No new key areas have been identified that need to be covered in the guideline</li> </ul>	<ul style="list-style-type: none"> <li>• Use the original scope</li> <li>• Do not consult on the scope</li> <li>• Inform stakeholders</li> </ul>
	<ul style="list-style-type: none"> <li>• New key areas have been identified that need to be covered in the guideline</li> </ul>	<ul style="list-style-type: none"> <li>• Prepare a new scope</li> <li>• Consult on the scope</li> </ul>
No update	<ul style="list-style-type: none"> <li>• No new evidence has been identified that would overturn any of the recommendations</li> <li>• There is no evidence from clinical practice to indicate that any of the recommendations need changing</li> <li>• There is no evidence from clinical practice that the original scope need changing</li> </ul>	<ul style="list-style-type: none"> <li>• The guideline is not updated</li> <li>• The guideline is reviewed after a further 3 years to determine its update status</li> </ul>
Transfer to the 'static list'	<ul style="list-style-type: none"> <li>• The recommendations are unlikely to change in the foreseeable future</li> </ul>	<ul style="list-style-type: none"> <li>• No further update planned</li> <li>• May be reviewed if new evidence emerges</li> </ul>
Withdraw the guideline	<ul style="list-style-type: none"> <li>• The guideline no longer applies</li> </ul>	<ul style="list-style-type: none"> <li>• Consult with stakeholders</li> </ul>

## Types of clinical and public health questions, ideal study types and major appraisal issues

Question	Study types	Major appraisal issues
1. Intervention	Systematic review RCTs Cohort study Case-control study	Randomisation Follow-up complete Blinding of patients and clinicians
2. Frequency/ rate (burden of illness)	Systematic review Cohort study Cross-sectional study	Sample frame Case ascertainment Adequate response/ follow-up achieved
3. Diagnostic test performance	Systematic review Cross-sectional study (random or consecutive sample)	Independent, blind comparison with 'gold standard' Appropriate selection of patients
4. Aetiology and risk factors	Systematic review Cohort study Case-control study	Groups only differ in exposure Outcomes measurement Reasonable evidence for causation
5. Prediction and prognosis	Systematic review Cohort/survival study	Inception cohort Sufficient follow-up

RCT = randomised controlled trial

## Absolute reductions in risk associated with relative risk reductions of 50% and 25%

Baseline risk	50% Relative risk reduction (RR=0.50)		25% Relative risk reduction (RR=0.75)	
	Risk difference	NNT	Risk difference	NNT
10%	5%	20	2.5%	40
1%	0.5%	200	0.25%	400
1 in 1000	0.05%	2000	0.025%	4000
1 in 10,000	1 in 20,000	20,000	1 in 40,000	40,000

RR=relative risk; NNT=number needed to treat

## Definitions of terms relating to generalisability

Term	Definition
Generalisability (or external validity)	<p>The extent to which a study's results provide a correct basis for generalisation beyond the setting of the study and the particular people studied.</p> <p>The application of the results to a group or population.</p>
Extrapolation	<p>The application of results to a wider population than that studied (ie to infer, predict, extend, or project beyond what was recorded, observed or experienced).</p> <p>For example, the results of a clinical trial in which patients aged 40–55 were studied, may be extrapolated to patients aged 55–65.</p>
Applicability	<p>The application of results to both individual patients and groups of patients.</p> <p>This addresses whether a particular treatment that showed an overall benefit in a study can be expected to convey the same benefit to an individual patient.</p> <p>In the clinical setting, applicability is preferred to the above terms as it includes the idea of particularising or individualising treatment and is closest to the general aim of clinical practice.</p>

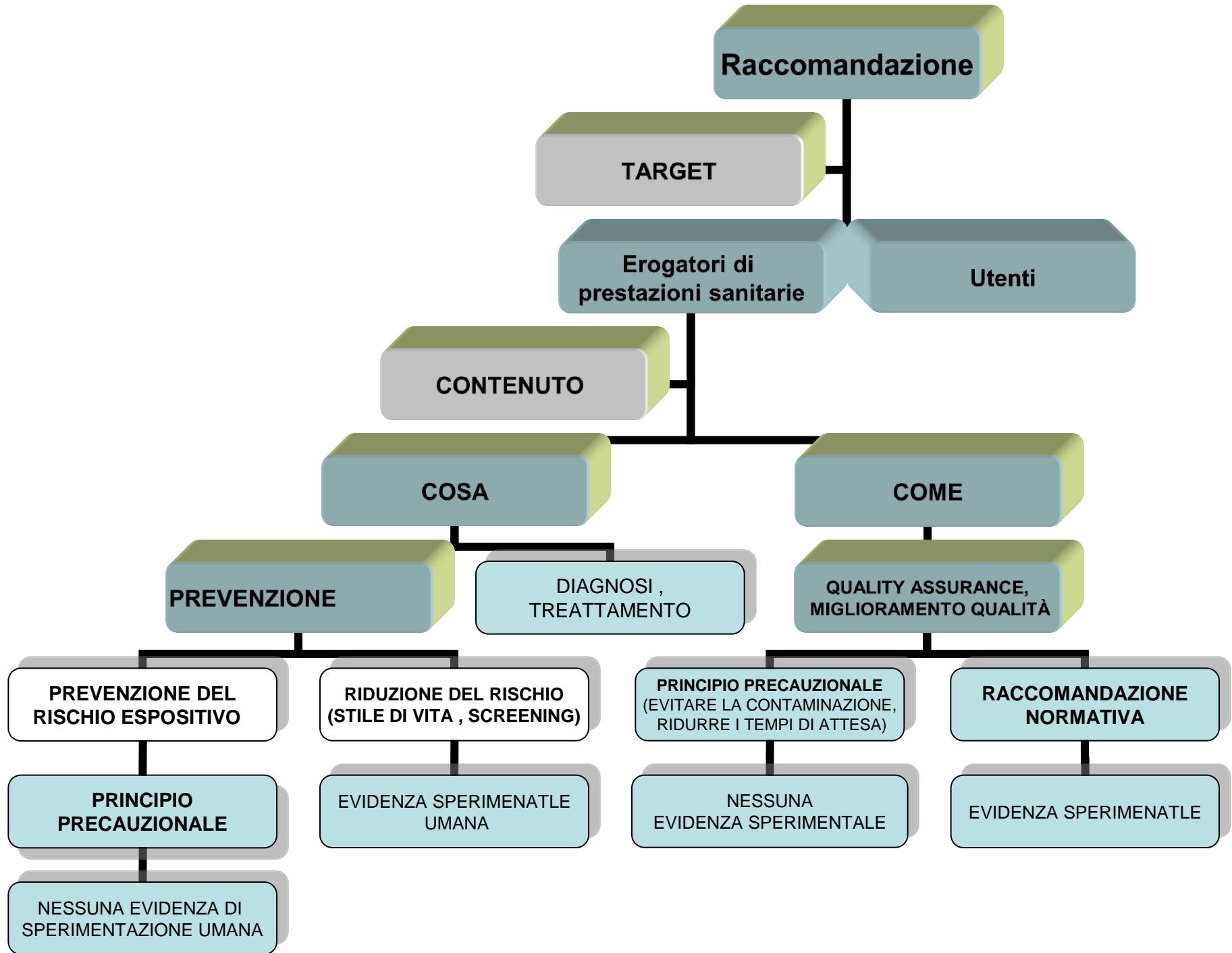
# Example of recommendations' list- chapter 5

## Endoscopic technique

- There should be local policies and processes in place to optimise sedation and patient support in order to maximise tolerance and minimise risk of complications (**I - B**).<sup>5.4.4</sup>
- Policies on the use of sedation must take into account historical context, the impact on the patient experience and costs (**I - B**).<sup>5.1.3</sup>
- Carbon dioxide insufflation is recommended for colonic endoscopic procedures (**I - A**).<sup>5.4.4</sup>
- Carbon dioxide insufflation should be avoided in patients with COPD, known CO<sub>2</sub> retention or reduced pulmonary function (**VI - A**).<sup>5.4.4</sup>

# Example of EVIDENCE TABLE, chapter 5

Author, publication year	Study objective Study Design	Study Participants	Intervention	outcomes	Results	Level of evidence Conclusions
Church 2003 (17)	To assess whether carbon dioxide insufflation would reduce post colonoscopy discomfort  Randomised, controlled trial	247 patients presenting for colonoscopy Body mass index, completion rate, and pattern of sedation and analgesia were similar for the two groups . Although there were more females in the CO2 group, hysterectomy rates were the same.. There were no significant differences between the groups for indications for colonoscopy, findings, and procedures performed.	Experimental intervention: carbon dioxide insufflation:123 patients.  Control group: air insufflation: 124 patients	Pain measured on a ten-point analog scale (0 : no pain, 10 : worst imaginable pain) immediately after the examination had been completed and ten minutes later. .Patient satisfaction measured on a ten-point analog scale1: completely unsatisfied; 10: completely satisfied.	Amounts of sedation or analgesia used: no significant differences., % of examinations completed: Air: 98.4 %; carbon dioxide:95.2 %, Patient satisfaction: Air: 9.4; carbon dioxide, 9.5).  <u>Pain scores</u> immediately after the examination: air: 4.3 carbon dioxide 3.6 NS  10 minutes later air: 2.1 carbon dioxide 0.9 ( $P_$ 0.05,).	<b>Level of evidence: II</b>  This study has shown that patients having colonoscopy with CO2 as the insufflating gas had less abdominal pain ten minutes after the examination had ended than a group of similar patients whose insufflating gas was air. Use of carbon dioxide as an insufflating agent offers a more comfortable experience to patients undergoing colonoscopy.  The present study suggests that it may be a particular advantage in the training setting, whereas others have encouraged its use particularly in cases of ischemic colitis, diverticulitis, irritable bowel syndrome, and inflammatory bowel disease. It is cheap, safe, and logistically straightforward to arrange.



**Raccomandazione**

**TARGET**

**Erogatori di prestazioni sanitarie**

**Utenti**

**CONTENUTO**

**COSA**

**COME**

**PREVENZIONE**

**DIAGNOSI, TREATTAMENTO**

**QUALITY ASSURANCE, MIGLIORAMENTO QUALITÀ**

**PREVENZIONE DEL RISCHIO ESPOSITIVO**

**RIDUZIONE DEL RISCHIO (STILE DI VITA, SCREENING)**

**PRINCIPIO PRECAUZIONALE (EVITARE LA CONTAMINAZIONE, RIDURRE I TEMPI DI ATTESA)**

**RACCOMANDAZIONE NORMATIVA**

**PRINCIPIO PRECAUZIONALE**

**EVIDENZA SPERIMENTATLE UMANA**

**NESSUNA EVIDENZA SPERIMENTALE**

**EVIDENZA SPERIMENTATLE**

**NESSUNA EVIDENZA DI SPERIMENTAZIONE UMANA**