Le nuove raccomandazioni Europee

Marco Zappa

CRPT-PROGRAMMA REGIONALE DI SCREENING
COLORETTALE PREVENZIONE SERENA – WORKSHOP 2022

Torino 30 Novembre 2022

OSSERVATORIO
NAZIONALE
SCREENING

- Nessun conflitto di interessi da segnalare

EUROPEAN
COMMISSION

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ANNEX

ANNEX

to the

Proposal for a Council Recommendation

on strengthening prevention through early detection: A new EU approach on cancer screening
replacing Council Recommendation 2003/878/EC

HEREBY RECOMMENDS TO MEMBER STATES:

Implementation of cancer screening programmes

(1) To offer evidence-based and person-centered cancer screening, taking into account the basic principles of safety, ethics, public engagement and equity, through systematic population-based programmes and, when appropriate, offer 'risk-stratified cancer screenings'; the types of cancer and the respective target populations, which should be considered are listed in the Annex;

(2) To implement accessible screening programmes in accordance with European guidelines with quality assurance, where they exist, through a stepwise approach to take account of available human and financial resources.

(3) To facilitate the development of piloting 'risk-stratified cancer screenings' protocols, guidelines, and indicators for high quality and accessible cancer screening programmes on a national and, where appropriate, regional level with adequate territorial coverage including rural and remote areas;

(4) To ensure that benefits and risks are presented to the people participating in the screening in an understandable way, allowing individuals to express informed consent when deciding on participation in the screening programmes, and that the principles of health literacy and informed decision-making to increase participation and equity are taken into account;

(5) To ensure adequate, timely, and complementary diagnostic procedures, treatments, psychological support and after-care to those individuals with a positive screening test;

(6) To make available human and financial resources in order to assure appropriate organisation and quality control;

(7) To assess and take decisions on the national or regional implementation of a cancer screening programme depending on the disease burden and the healthcare resources available, the side effects and cost effects of cancer screening, and experience from scientific trials and pilot projects;

(8) To set up a systematic call/recall system and quality assurance at all appropriate levels, together with an effective and appropriate diagnostic and treatment and after-care service following evidence-based guidelines;

(9) To ensure that due regard is paid to data protection legislation.

Registration and management of screening data

(10) To make available centralised data systems needed to run organised cancer screening programmes;

(11) To ensure by appropriate means that all persons targeted by the cancer screening programme are invited, by means of a call/recall system, to take part in the programme;

(12) To collect, manage and evaluate data on all screening tests, assessment and final diagnoses, including the data related to the cancer stage when detected in the context of the cancer screening programmes;

(13) To collect, manage and evaluate the data, including making the data available for cancer research, including implementation research and development of improved technological possibilities for early cancer diagnosis and prevention, in full compliance with applicable data protection legislation.

Training

(16) To adequately train personnel at all levels to ensure that they are able to deliver high quality screening.

Compliance

(17) To seek a high level of compliance, based on fully informed consent, when organised cancer screening is offered;

(18) To take action to ensure equal access to screening taking due account of the possible need to target particular socioeconomic groups;

(19) To ensure by appropriate means that persons with disabilities, as well as people living in rural or remote areas can access cancer screening services, and that clinical facilities for cancer screening are suitable for persons with disabilities.

Introduction of novel screening tests taking into account international research results

(20) To implement new cancer screening tests in routine healthcare only after they have been evaluated in randomised controlled trials;

(21) To run trials, in addition to those on screening-specific parameters and mortality, on subsequent treatment procedures, clinical outcome, side effects, morbidity and quality of life;

(22) To assess the level of evidence concerning the effects of new methods by pooling trial results from representative settings;

(23) To consider the introduction into routine healthcare of potentially promising new screening tests, which are currently being evaluated in randomised controlled trials, once the evidence is conclusive and other relevant aspects, such as cost-effectiveness in the different healthcare systems, have been taken into account;

(24) To consider the introduction into routine healthcare of potentially promising new modifications of established screening tests once the effectiveness of the modification has been successfully evaluated, possibly using other epidemiologically validated surrogate endpoints.

Colorectal cancer:

Faecal immunochemical testing (FIT), quantitative with thresholds defined per sex and age and earlier test result is considered the preferred screening test for referring individuals to follow-up colonoscopy between 50 and 74 years old. Endoscopy may be adopted as a primary tool to implement combined strategies.

Proposal of amendment - rewording

Colorectal cancer:

Faecal immunochemical testing (FIT) is considered the preferred triage test for referring individuals to follow-up colonoscopy between 50 and 74 years old. Quantitative information from FIT results might be used to implement risk-tailored strategies, introducing thresholds defined per sex, age and earlier test results. Combined strategies adopting endoscopy as an alternative primary screening tool may also be used.

Due punti differenti

- Protocollo di screening differente a secondo del livello di rischio di sviluppare un CRC

(➔ più intenso per il gruppo a maggior rischio)

- Possibilità di offrire (e dunque di scegliere) un diverso test di screening a seconda delle preferenze individuali

Perché stratificare per rischio

Distinguere individui con un rischio più o meno alto dà l'opportunità di modulare l'intensità dell'intervento ottenendo un miglior rapporto

-costo/efficacia (efficienza)

-effetti desiderati/indesiderati

➔ Costo/efficacia = risultato facilmente misurabile

➔ Effetti desiderati/indesiderati dipende dai valori e dalle esperienze di ciascuno

Quanto è 'indesiderabile' sottoporsi a una colonscopia che che non individua lesioni?

Risk Scores for Predicting Advanced Colorectal Neoplasia in the Average-risk Population: A Systematic Review and Meta-analysis

Le Peng, MM, PhD[1,2], Korbinian Weigl, MPH, PhD[1,2,3], Daniel Boakye, MPH, PhD[1,2] and Hermann Brenner, MD, MPH[1,3,4]

- Metanalisi di 22 Studi con 17 risk scores
- I fattori di rischio più comunemente usati sono stati Età, Sesso, BMI, Familiarità e Fumo
- Outcome: Adenomi Avanzati e CRC
- AUC arriva a valori variabili fra 0.61 e 0.70
- «Sebbene la maggioranza dei modelli di rischio disponibili abbiano un debole potere discriminatorio , essi possono essere utili per la stratificazione del rischio nello screening colorettale»

Attenzione

- Quasi tutti i tumori hanno una maggior incidenza nell'età più avanzate e nei maschi
- Lo screening colorettale ha anche la finalità di prevenire l'insorgenza dei CRC
- Concentrare l'intensità sulle età avanzate riduce i benefici potenziali di prevenzione

Altri fattori predittivi sembrano offrire una importante capacità discriminatoria

Association Between Concentrations of Hemoglobin Determined by Fecal Immunochemical Tests and Long-term Development of Advanced Colorectal Neoplasia

Esmée J. Grobbee,[1] Eline H. Schreuders,[1] Bettina E. Hansen,[1] Marco J. Bruno,[1] Iris Lansdorp-Vogelaar,[2] Manon C. W. Spaander,[1] and Ernst J. Kuipers[1]

Original Research

Changes in FIT values below the threshold of positivity and short-term risk of advanced colorectal neoplasia: Results from a population-based cancer screening program

Andrea Buron [a,b,c,*], Marta Román [a,b,c], Josep M. Augé [d,e],

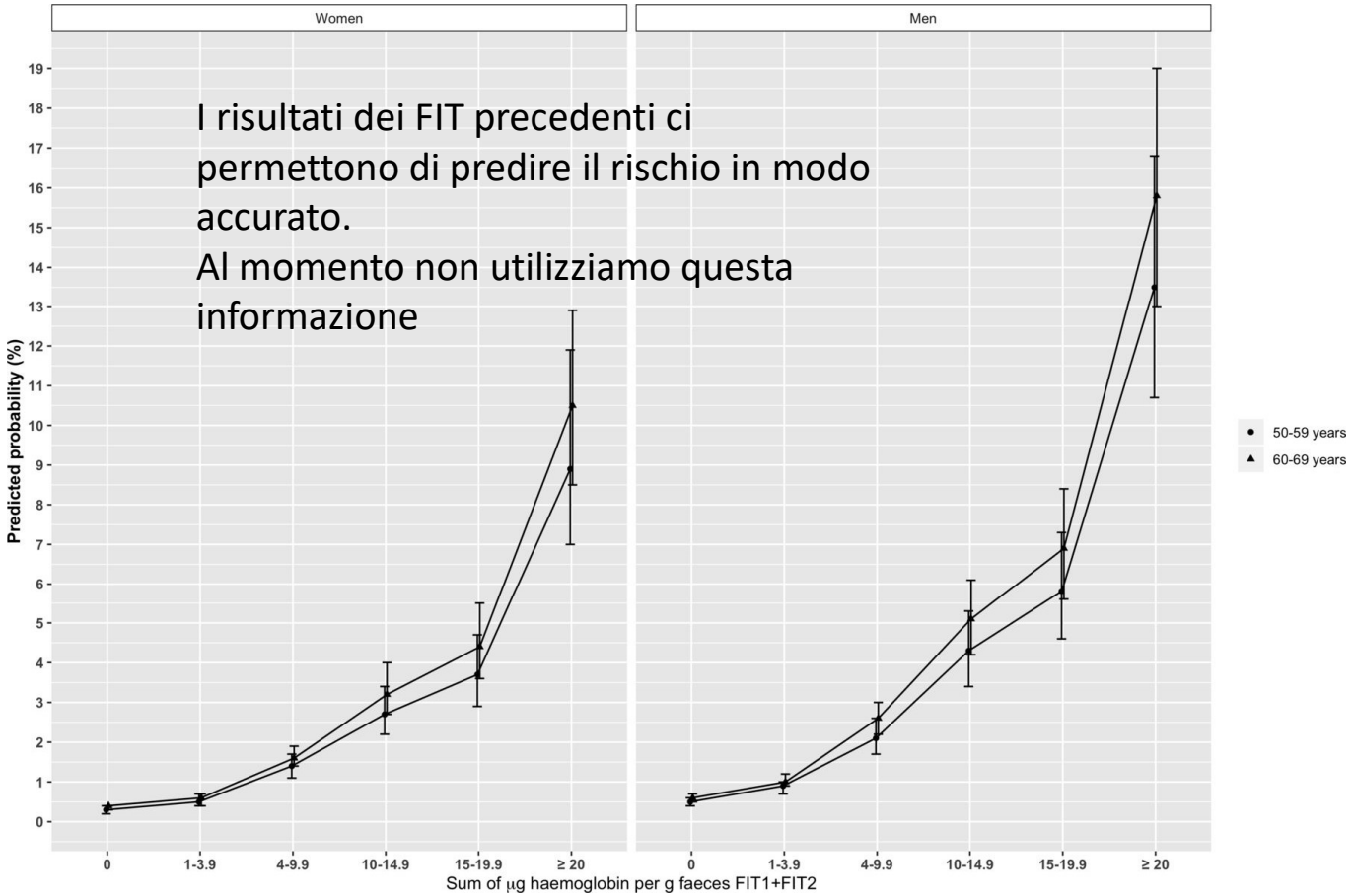
PostScript

Can the performance of a quantitative FIT-based colorectal cancer screening programme be enhanced by lowering the threshold and increasing the interval?

faecal occult blood test/FIT two-tier reflex algorithm used in Scotland,[3] the positivity in the first round was 2.5%: there were 30 screen-detected cancers (SDCs) and 31 interval cancers (ICs).[4] In the first round, 753 colonoscopies were performed. At the second round, there were 25 SDC, making a total of 55 SDC over two rounds.

Assuming that IC and colorectal cancer (CRC) detected at the subsequent screening

Predicted an DR by age and gender by cumulative f-Hb at the second FIT. DR, detection rate; f-Hb, faecal haemoglobin; FIT, faecal immunochemical test.



I risultati dei FIT precedenti ci permettono di predire il rischio in modo accurato.

Al momento non utilizziamo questa informazione

Carlo Senore et al. Gut 2020;69:523-530

GUT

Table 1 Association of cumulative f-Hb values over the initial two rounds and FIT PR, AN PPV, AA and CRC DR, NNScope to detect 1 AN at the third round - Men and women aged 50–69 years

Sum f-Hb µg/g FIT1 + FIT2	Examined N (%)*	FIT+		Colonoscopy		Advanced adenoma	CRC	PPV AN % (95% CI)	DR advanced adenoma % (95% CI)	DR CRC % (95% CI)	NNScope (95% CI)
		N	% (95% CI)	N	% (95% CI)						
0	80 579 (49.1)	2074	2.6 (2.5 to 2.7)	1793	86.5 (84.8 to 88.0)	257	35	16.3 (16.0 to 16.5)	0.3 (0.3 to 0.4)	0.04 (0.03 to 0.06)	6.1 (6.0 to 6.2)
0.1–3.9	54 352 (33.1)	1895	3.5 (3.3 to 3.6)	1621	85.5 (83.7 to 87.2)	294	56	21.6 (21.2 to 21.9)	0.5 (0.5 to 0.6)	0.10 (0.08 to 0.13)	4.6 (4.6 to 4.7)
4–9.9	19 715 (12.0)	1247	6.3 (6.0 to 6.7)	1098	88.1 (86.0 to 89.9)	301	36	30.7 (30.0 to 31.3)	1.5 (1.4 to 1.7)	0.18 (0.13 to 0.25)	3.3 (3.2 to 3.3)
10–14.9	5336 (3.3)	516	9.7 (8.9 to 10.5)	464	89.9 (86.7 to 92.5)	161	25	40.1 (38.8 to 41.4)	3.0 (2.6 to 3.5)	0.47 (0.31 to 0.70)	2.5 (2.4 to 2.6)
15–19.9	2912 (1.8)	367	12.6 (11.4 to 13.9)	315	85.8 (81.4 to 89.4)	123	16	44.1 (42.3 to 46.0)	4.2 (3.5 to 5.0)	0.55 (0.33 to 0.90)	2.3 (2.2 to 2.4)
≥20	1129 (0.7)	292	25.9 (23.4 to 28.5)	261	89.4 (84.8 to 92.8)	111	21	50.6 (47.6 to 53.5)	9.8 (8.2 to 11.7)	1.86 (1.18 to 2.86)	2.0 (1.9 to 2.1)
Total	164 023	6391	3.9 (3.8 to 4.0)	5552	86.9 (85.9 to 87.7)	1247	189	25.9 (25.7 to 26.1)	0.8 (0.7 to 0.8)	0.12 (0.10 to 0.13)	3.9 (3.8 to 3.9)

*% calculated over the total number of subjects examined.
AA, advanced adenoma; AN, advanced neoplasia; CRC, colorectal cancer; DR, detection rate; f-Hb, faecal haemoglobin; FIT, faecal immunochemical test; NNScope, number needed to scope; PPV, positive predictive value; PPV, positive predictive value; PR, positivity rate.

Lo screening stratificato sul rischio comporta

- Grande complessità informativa/comunicativa
- Grande complessità organizzativa

Possibilità di scegliere un diverso test di screening a seconda delle preferenze individuali

- Una preferenza la conosciamo : quella di genere

Annals of Internal Medicine®

Original Research | January 2022

Long-Term Follow-up of the Italian Flexible Sigmoidoscopy Screening Trial

Carlo Senore, MD, MSc, Emilia Riggi, PhD, Paola Armaroli, MD, MSc, ... View all authors +

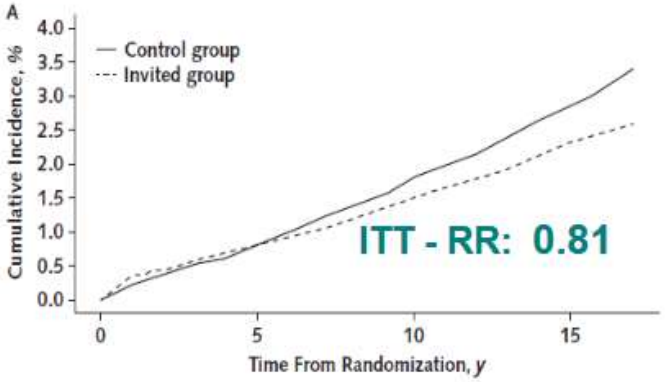
Author, Article, and Disclosure Information

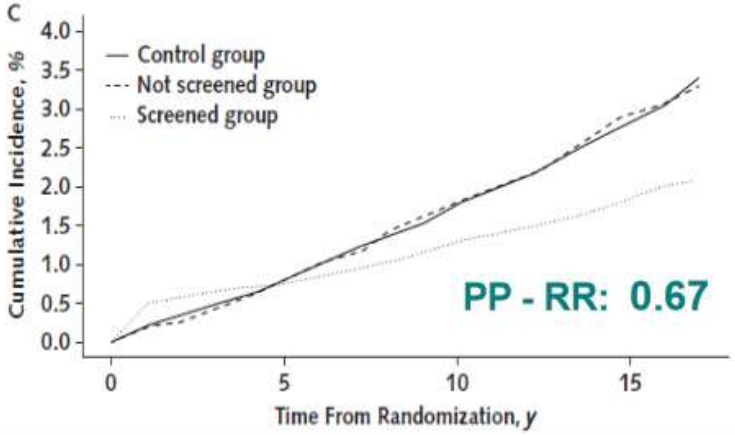
XV CONGRE NAZIONALE

L'impatto dello screening sull'incidenza

GISCoR po italiano screening colorettale

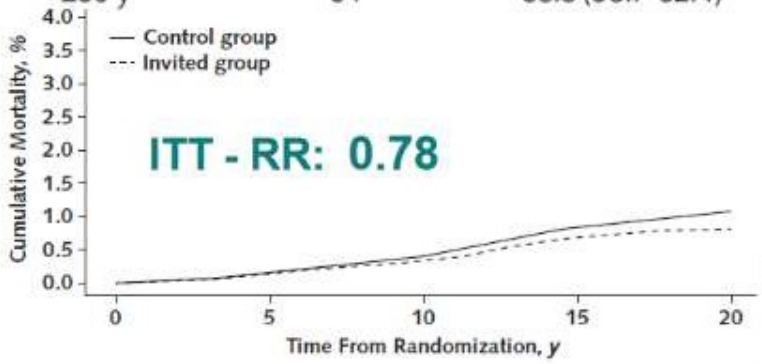
	Cases, *n*	Rate per 100 000 Person-Years (95% CI)	Cases, *n*	Rate per 100 000 Person-Years (95% CI)	Rate Ratio (95% CI)†
Incidence					
All sites	468	189.4 (173.0 to 207.4)	382	153.6 (1389.0 to 169.9)	0.81 (0.71 to 0.93)
Distal	297	120.2 (107.3 to 134.7)	209	84.1 (73.4 to 96.3)	0.70 (0.59 to 0.84)
Proximal	159	64.3 (55.1 to 75.2)	165	66.4 (57.0 to 77.3)	1.03 (0.83 to 1.28)
Sex					
Male	291	237.8 (212.0-266.8)	240	197.5 (174.0-224.1)	0.83 (0.70-0.98)
Female	177	141.9 (122.5-164.4)	142	111.7 (94.8-131.7)	0.79 (0.63-0.98)
Age§					
55-59 y	235	166.6 (146.6-189.3)	198	141.3 (122.9-162.4)	0.85 (0.70-1.02)
≥60 y	233	219.7 (193.3-249.8)	184	169.6 (146.8-196.0)	0.77 (0.64-0.94)





L'impatto dello screening sulla mortalità

	Deaths, *n*	Rate per 100 000 Person-Years (95% CI)	Deaths, *n*	Rate per 100 000 Person-Years (95% CI)	Rate Ratio (95% CI)†
All sites	157	53.2 (45.5 to 62.2)	122	41.1 (34.4 to 49.1)	0.78 (0.61 to 0.98)
Distal	90	30.5 (24.8 to 37.5)	62	20.9 (16.3 to 26.8)	0.69 (0.50 to 0.95)
Proximal	64	21.7 (17.0 to 27.7)	53	17.9 (13.6 to 23.4)	0.82 (0.57 to 1.19)
Sex					
Male	111	76.4 (63.4-92.0)	80	55.4 (44.5-69.0)	0.73 (0.54-0.97)
Female	46	30.7 (23.0-41.0)	42	27.6 (20.4-37.3)	0.90 (0.59-1.37)
Age§					
55-59 y	73	43.3 (34.4-54.4)	63	37.6 (29.3-48.1)	0.87 (0.62-1.22)
≥60 y	84	66.5 (53.7-82.4)	59	45.7 (35.4-59.0)	0.69 (0.49-0.96)



ITT - RR: 0.78

PP - RR: 0.61

Partecipazione (%) screening colorettale con FIT per genere e per macro area geografica – Anno 2021

fonte survey ONS

	ITALIA	NORD	CENTRO	SUD
Femmine	40,3	49,5	34,0	23,6
Maschi	36,0	44,5	28,5	21,2

Partecipazione (%) screening colorettale Regione Piemonte – Anno 2021- *fonte survey ONS*

		Maschi	Femmine
Popolazione Target	38668		
Invitati	37418		
Aderenti FS	8053		
Aderenti FIT	3377		
Adesione FS	21,6	23,7	20,1
Adesione FS+FIT		30,6	30,7

➔Tendenza confermata negli studi con offerta sequenziale

ORIGINAL ARTICLE

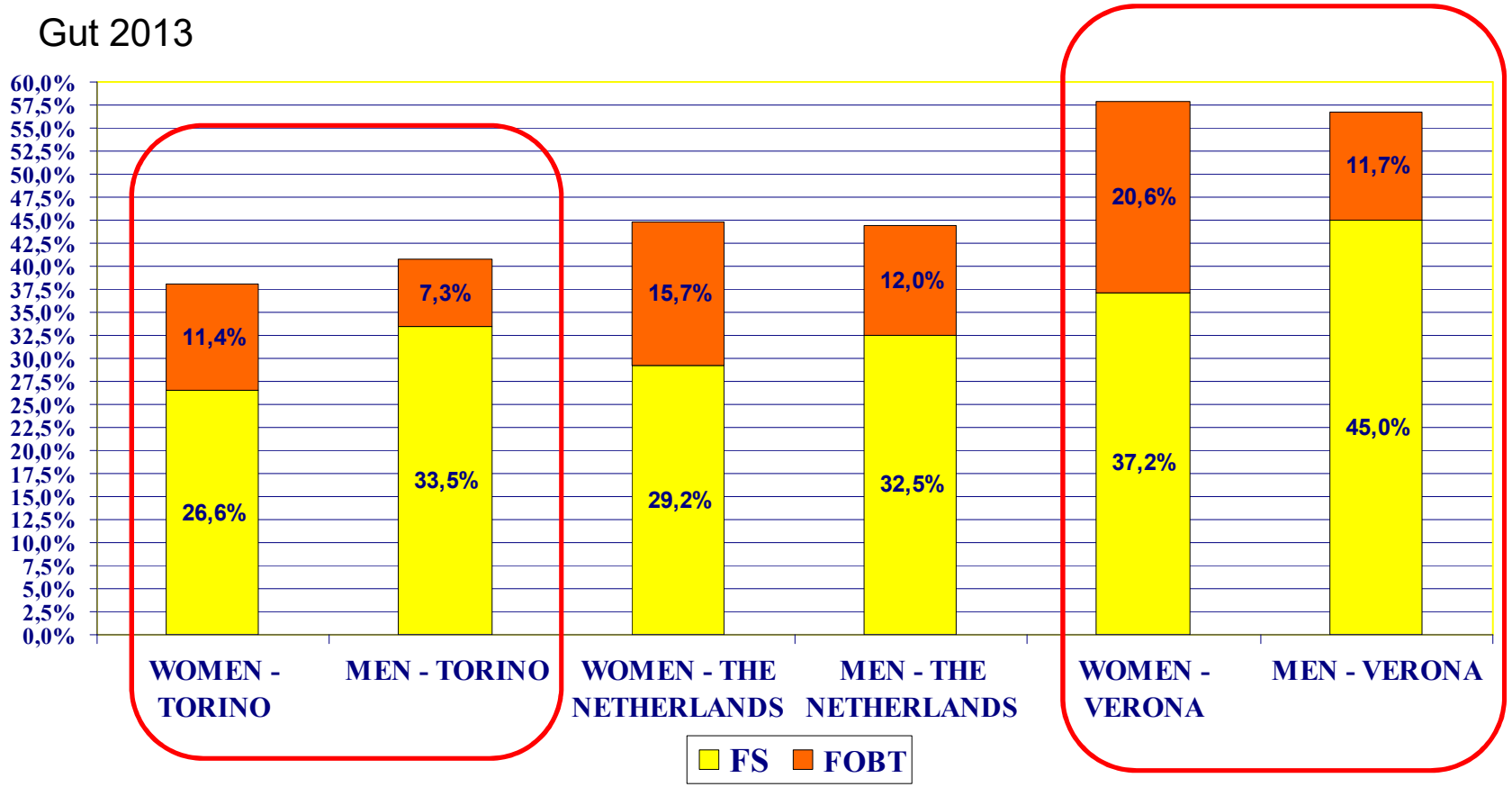
Offering people a choice for colorectal cancer screening

Carlo Senore,[1] Andrea Ederle,[2] Luca Benazzato,[2] Arrigo Arrigoni,[3] Marco Silvani,[1] Alberto Fantin,[2] Mario Fracchia,[4] Paola Armaroli,[1] Nereo Segnan[1]

Uptake of faecal immunochemical test screening among nonparticipants in a flexible sigmoidoscopy screening programme

Lieke Hol[1], Ernst J. Kuipers[1,2], Marjolein van Ballegooijen[3], Anneke J. van Vuuren[1], Jaqueline C.I.Y. Reijerink[4], Dik J.F. Habbema[3] and Monique E. van Leerdam[1]

Gut 2013



Adesione all'invito sequenziale (RS+FIT) Regione Piemonte anno 2018. *fonte: survey ONS*

	2018
N° programmi	9
Popolazione target	63.027
N° invitati	68.893
Estensione inviti (%)	108,7
N° screenati	15.696
Adesione all'invito (%)	23,3
Adesione all'invito sequenziale (RS + FIT) (%)	39,8

Compliance (%) alla colonscopia dopo FIT positivo

fonte: survey ONS

2020	uomini	donne		2019	uomini	donne
ITALIA	75,6	74,0		ITALIA	78,0	74,9
NORD	81,8	80,8		NORD	82,3	80,4
CENTRO	68,3	67,3		CENTRO	76,6	75,5
SUD	62,4	56,1		SUD	62,8	56,2

- A parte le preferenze di genere una differente offerta per i non rispondenti può permettere di raggiungere una più vasta platea

- La partecipazione ai programmi di screening è purtroppo bassa

- Sforzo organizzativo

➔ importanza di una comunicazione corretta

Conclusioni (1)

- La stratificazione dell'intensità di screening sul livello di rischio può aumentare l'efficienza del programma

- Più difficile valutare il rapporto su effetti desiderati/indesiderati

- Chi è a più basso rischio potrebbe sentirsi svantaggiato

➔ Sforzo comunicativo essenziale

Conclusioni (2)

Offrire ai non rispondenti una differente proposta di screening può aumentare la partecipazione

Tutte le proposte devono essere evidence based e sostenibili

Grazie per l’attenzione

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