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Session VI

The economic evaluation of a colorectal-cancer screening program

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Study motivations-Background

1. Colorectal cancer is a disease of extreme relevance and is an actual problem (Ransohoff DF, 1997; Sonnenbeg A., Lieberman DA, 2000).
   - colorectal cancer (CCR) is one of the most common form of cancer in western countries, representing 11,3% of all men's cancer and 11,5% of all women's cancer.
2. The most prevalent literature of cost-effectiveness analysis in this field is of Nord-American context (Lierberman DA, 1995; Sonnenberg A., Delcò F., Inadomi JM., 2000).
   - such studies refer to national health systems that differ substantially with the Italian context, which makes comparison difficult
   - need for studies applied to the national context able to contribute to the knowledge about the cost-effectiveness of colorectal cancer screening program.
3. Generalizability of a cost-effectiveness model.
4. Parametric cost of all the assistance activities involved.

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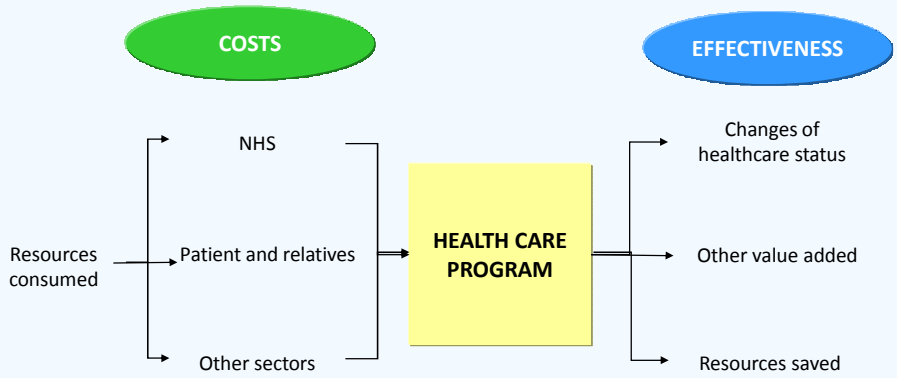
Cost Effectiveness analysis: logic scheme



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Aims of the study

- The project focuses on the analysis on the Regional Prevention Plan for CCR applied to the case of the Province of Ferrara, started in march 2005 and is aimed to:

1. Determine the full cost of the screening program
   (program implementation, development and management)
2. Evaluate the effectiveness of the screening program
3. Compare the cost of the screening program with effectiveness analysis with refer to the *prevention technique* used (Faecal Occult Blood Test – FOBT - and colonoscopy) with respect to the situation "*in absence of screening*"

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Methods

- Setting: Province of Ferrara, S.Anna University-Hospital
- Type of study: prospective study
- Patients: male and female between the ages of 50-69 years, residing in Ferrara and province.
  - In 2005-2007, almost 96.500 tenants 50.200 women and 46.300 men, invited to have a FOBT test and almost 21.900 subjects at risks, between the ages of 70-74 years invited to have colonoscopy.
- Intervention: FOBT + colonoscopy + treatment + Follow-Up
- Methods: micro-costing analysis to evaluate costs (ABC) and effectiveness analysis based on incidence measures
- Perspective: NHS and hospital

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Preliminary results of screening compliance

DESCRIPTIVE DATA			
Invited population at the end of first wave 99.215			
FOBT compliance	45.049	**45,4**%	of compliance
positive FOBT	**2.831**	**6,3**%	of total FOBT made
Colonoscopies made at 31/12/06	**1.350**	**47,7**%	of positives at FOBT
for which result is known	696	24,6%	of positives at FOBT
Benign Cancer	237	**34,1**%	of colonoscopies
Malignant Cancer	**60**	**8,6**%	of colonoscopies

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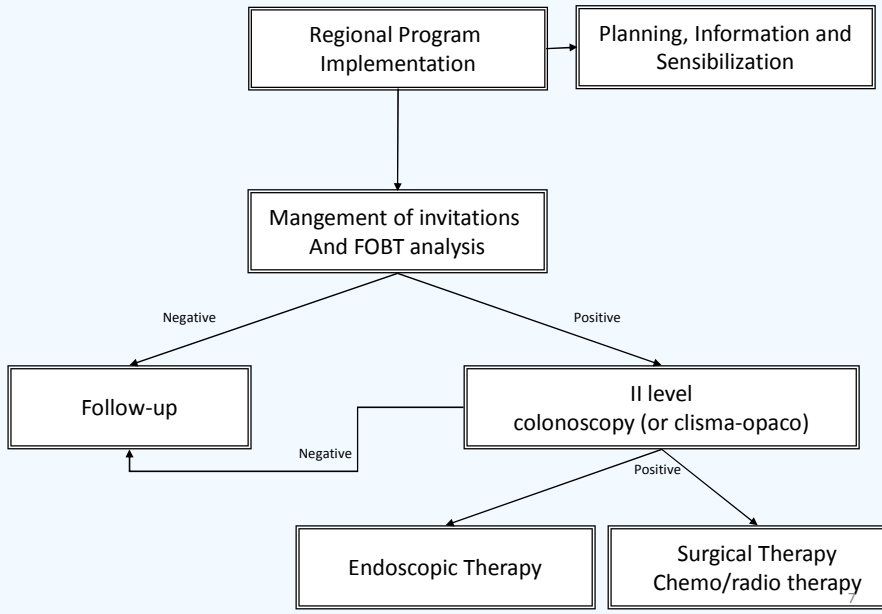
Step 1: macro-activities



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Step 1: which costs?

Aim of the study is determine a Full Cost configuration taking into consideration:

- Human resources costs

  (direct and indirect)

- Direct costs of production

  (materials, drugs, pharmaceutical therapy, disposable instruments)

- Indirect costs

  (materials amortization and general-administrative costs)

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Cost analysis: methodology

- **Human Resources**
  - for each activity: number, qualification and time spent by each figure.
  - Economic evaluation: cost/hour
- **Materials**
  - For each activity: type, quantity of material used
  - Economic evaluation: cost for the structure
- **Pharmaceuticals and drugs**
  - For each activity/treatment: type, quantity used
  - Economic evaluation: unit cost for the structure
- **Instruments**
  - For each activity/treatment: type, quantity used
  - Economic evaluation: utilization, unitary coefficient of allocation

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Cost-analysis synthesis

- Complete Cost Analysis for the following phases :
  - Organization-planning, information, implementation and management
  - First level screening investigation (FOBT)
  - Second level investigation (colonoscopy)
- Complete Unit Cost Analysis (for single patient) for the following phases:
  - Second level investigation (colonoscopy)
  - Surgical intervention and in-stay
  - Oncologic therapy
  - Costs estimation for follow up
- The final report of screening cost will be available at the end of year 2007

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Results: costs of macroactivities

Project planning and implementation		
(1) concl. activities	€	24.552,02
(2) current activities (monthly cost)	€	4.090,72
(3) Total cost current activities	€	110.449,44
TOTAL [(1)+(3)]	**€**	**135.001,46**
ARISING	**€**	**29.241,10**
Estimated cost at the end of first wave	*€*	*122.729,30*

Information activities-Advertising		
(1) concl. activities	€	2.180,20
(2) current activities (monthly cost)	€	518,00
(3) Total cost current activities	€	13.986,00
(4) video clip	€	3.750,00
(5) advertising costs (depliant, advert ecc.)	€	20.000,00
TOTAL [(1)+(3)+(4)+(5)]	**€**	**39.916,20**
ARISING	**€**	**37.995,00**
Estimated cost at the end of first wave	*€*	*38.362,20*

Management activities		
(1) concl. activities	€	41.796,92
(2) current activities (monthly cost)	€	4.842,16
(3) Total cost current activities	€	130.738,32
(4) variable activities (compliance)	€	75.543,39
TOTAL [(1)+(3)+(4)]	**€**	**248.078,63**
ARISING	**€**	**242.931,71**
Estimated cost at the end of first wave	*€*	*232.802,46*

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Results: costs of macroactivities

FOBT		
(1) fixed costs (kit reagent)	€	209.181,60
(2) byologist cost	€	21.600,00
(3) transport costs	€	21.108,60
(4) refert. POSITIVES	€	19.842,46
(5) refert. NEGATIVES	€	56,62
(6) telephonic calls	€	1.132,40
(7) interviews	€	31.685,97
TOTAL	**€**	**304.607,65**
ARISING	**€**	**304.607,65**
Estimated cost at the end of first wave	*€*	*360.223,75*

Simple colonoscopy	**171,00**
Colonscopy + Biopsia	**179,53**
Polypectomy	**232,10**
Partial colonoscopy	**140,54**
Partial polypectomy	**171,64**
Colonscopy + Biopsia (partial)	**149,07**

SECOND LEVEL		
colonoscopy preparation	€	2.381,40
colonoscopy total (a)	€	246.490,83
emost. And tat.	€	45,27
refert and results+call of NEGATIVES *	€	822,03
refertart and invitation to follow up POSITIVES*	€	111,39
TOTAL	**€**	**249.850,92**
ARISING	**€**	**69.804,41**
Estimated cost at the end of first wave	*€*	*1.404.327,03*

(a) province data are June 06, AO data 31/12/06
*must be updated

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Results: costs of macroactivities

CHEMOTHERAPY (one patient)(b)		
polyps and stages A-B not at risk (F-U)	**€**	**23,62**
stages A - B not at risk (F-U)	**€**	**23,62**
stages B at risk and C good condition		
Folfox (6 c. in 3 months))	**€**	**4.496,42**
stages B at risk and C bad condition		
Capacitabina (8 c. in 6 months)	**€**	**3.383,16**
stages D I line		
Folfiri+Bevaciz. (3 months)	**€**	**2.882,81**
stages D II line		
Folfiri+Cetuximab (3 months)	**€**	**11.082,03**
CPT-CET (3 months)	**€**	**13.949,69**
Folfox (3 months)	**€**	**4.496,42**
stages D III line		
Fumit-Mitomicina (3 months)	**€**	**772,95**
Stages D with comorbidities		
Capox (3 months)	**€**	**5.023,81**
Fufaset (3 months)	**€**	**863,92**
(b) to treat one patient		
CHEMOTHERAPY (total of treated patients)	**€**	**138.714,49**
ARISING	**€**	**131.022,57**

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Results: costs of macroactivities

SURGICAL TREATMENT (unit patient)		
surgical intervention (human resources and material)	€	1.989,04
anestesia	€	231,06
general costs	€	38,17
TOTAL	**€**	**2.334,61**
ARISING	**€**	**1.359,20**
IN-STAY (average of 7 days)	**€**	**666,60**
TOTAL IN STAY for all patients	**€**	**58.660,54**
ARISING	**€**	**14.438,78**

FOLLOW UP (for patient) (c)		
FOBT negative	**€**	**15,23**
FOBT positive and Colon negative	**€**	**9,14**
1-2 adenomas < 1 cm	**€**	**174,05**
1 adenomas > 1 cm 3 or more < 1 cm	**€**	**342,00**
polyp	**€**	**513,00**
non invasive neoplasia	**€**	**342,00**
high displasia NEGATIVE Byopsia	**€**	**684,00**
c) for 10 years follow up		
FOLLOW UP CHEMOTHERAPY (d)		
for chemoterapy up to stage B and C	**€**	**2.490,72**
(d) 10 years follow up		

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Results: Costs of macro activities

MACRO ACTIVITIES	Costs at the end of first wave 2005-2007	Estimated costs 2005-2007
Project adoption and coordination	€ **135.001,46**	€ *122.729,30*
Information activities	€ **39.916,20**	€ *38.362,20*
Management of patients	€ **248.078,63**	€ *232.802,46*
First level Test FOBT (RSO)	€ **304.607,65**	€ *360.223,75*
Second level (colonoscopy)	€ **249.850,92**	€ *1.404.327,03*
Surgical intervention and in-stay*	€ **270.132,60**	
Oncologic treatment *	€ **138.714,49**	
Follow-up healthy person (unit)*	€ 15,23	
Follow-up high degree displasia (unit) *	€ 684,00	
TOTAL	€ **1.386.301,94**	€ *2.158.444,74*
Arising costs	€ **951.010,37**	
* preliminary results (not concluded treatments)		

The average cost for single patient is € 30,77

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Step 2: Effectiveness analysis

- The effectiveness analysis is aimed to consider all the direct consequences of healthcare interventions and programs, and it is used in health care context to compare programs that can have different consequences.
- Different type of data can be used:
  - From literature (publications, guidelines, sector studies);
  - Experts'opinions;
  - Ad-hoc prospective studies of estimation.

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Effectiveness Criteria

- Effectiveness of the screening technique adopted (FOBT and colonoscopy).
- Effectiveness in terms of:
  - Early diagnosticated cases
  - Saved years of life with diagnosis and early treatment
  - Reduction in the disease incidence
  - Impact in terms of cost-saved for treatment and therapies in case of disease with late diagnosis
- Effectiveness in terms of impact on quality of life of the patients-citizens involved.

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Results: Effectiveness

- Since the start of the screening:
  - The incidence of hyperplasic polyps, adenomas and carcinoma is increased
  - Early diagnosticated cases of cancer:
    - The highest stages of cancer are stage-C with respect to all the other stages
    - but the stages A are increased
    - and the stages D are decreased

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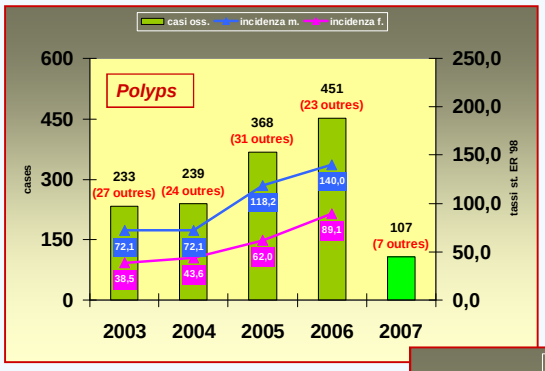
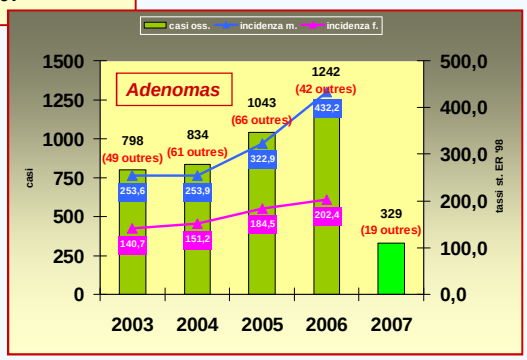


The incidence of hyperplastic polyps is increased:

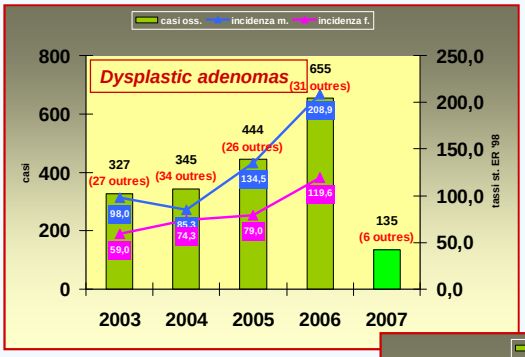
•368 new cases in 2005 and 451 in 2006 (against 239 in previous years)



The incidence of adenomas is increased:

•1.043 new cases in 2005 and 1.242 in 2006 (against 834 in previous years)

Source: Ferretti S., Registro Tumori della Provincia di Ferrara

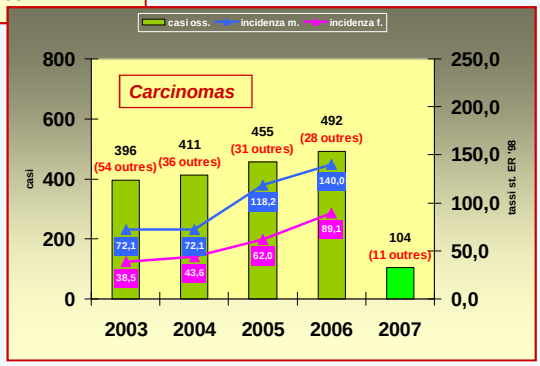


Dysplastic adenomas are increased

from 345 before 2005

to 444 and 655

in 2005 and 2006



The incidence of carcinomas is increased:

•455 new cases in 2005, 492 in 2006

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Source: Ferretti S., Registro Tumori della Provincia di Ferrara

Effectiveness of screening

- STADIATION Since 2005 (with respect to 2004):
  - StagesA : increased from 10% to 14% in 2005
  - StagesB: decreased from 9,4% to 8,1%
  - StagesC: decreased from 53,2% to 50,6%
  - StagesD: decreased from 17,1% to 16,5%
- In 2005-2007 the incidence of:
  - Polyps: 12,6% (13,1% before screening)
  - Adenomas: 47,6% (46% before screening)
  - Dysplastic adenomas: 29% (18,2% before screening)
  - Cancer: 10,8% (22,6% before screening)

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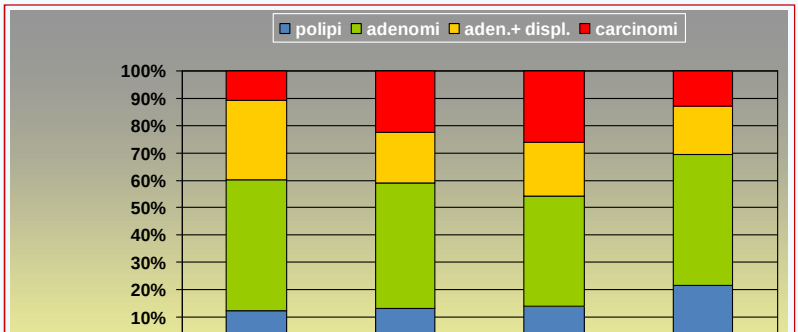
Incidence refer to screening

(2005-2007)



	SD	prec	esclusi	indet.
carcinomi	10,8	22,6	26,2	12,9
aden.+ displ.	29,0	18,2	19,4	17,5
adenomi	47,6	46,0	40,4	47,9
polipi	12,6	13,1	14	21,7

Source: Ferretti S., Registro Tumori della Provincia di Ferrara

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Incidence refer to screening
(2003-2007)

First diagnosis	SD %	NSD %	tot. %
Adenomatous Polyps :	9,4	13,8	13,1
Tubolar polyps:	48,5	40,8	41,9
Dysplastic Adenoma:	29,8	16,2	18,2
Cancer:	11,7	24,2	22,4
Other benign neoplasia :	0,7	4.7	4,1
Other malignant neoplasia:	-	0.4	0,3
Total patients	1.044	6.156	7.200

Source: Ferretti S., Registro Tumori della Provincia di Ferrara

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Conclusions

- Early diagnosis can detect a higher number of dysplastic adenomas and reduce the future incidence of colorectal cancer.
- An early detection and removal of adenoma can increase the possibility of total eradication without metastasis diffusion.
- The screening can reduce the incidence of cancer and save human lives.
- The screening can save future costs of surgical and oncologic treatments more expensive in the more advanced cancer stages.

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Further research

- The project intends to verify:
  - the screening impact in terms of **QoL** (quality of life) through a prospective study and questionnaire administration.
  - the reasons for participation/non participation to the screening program.
- Consider a societal perspective
- The study is intended to provide health and economic evaluation in relation to the policy choice between prevention, through screening, and cure the pathology when detected.

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