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Chapter 3

The Future of Colonoscopy: The Use of Data Envelopment Analysis (DEA) for Colorectal Cancer Screening — Italian Experience

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1. Introduction

René Descartes (1596-1650) in the published Discourse on Method, wrote: "…And because the actions of life often brook no delay, it is certainly very true that, when it is not in our power to determine the truest opinions, we ought to follow the most probable ones, and even when we see no difference in probability among this group of truths or that one, nevertheless, we have to decide on some for ourselves and then to consider them, not as something doubtful with regard to the practical matter at hand, but as manifestly true and very certain, because the reason which made us choose them has these qualities". [1] Colonoscopy (COL) issues this doubt.

Everybody known the effect of COL on colorectal cancer (CRC) until 2009, when an observational case–control study did not identify a reasonable explanation for COL: much less effective in preventing death from colorectal cancer (CRC) of the right colon compared with the left colon [2]. Moreover to prevent one cancer death, 1,250 colonoscopies need to be performed, but perforation of the colon occurs at a rate of about 1 in 1000 procedures [3].

Since polyps often take 10 to 15 years to transform into cancer, in someone at average risk of colorectal cancer, guidelines recommend 10 years after a normal screening COL before the next COL. [4,5]. By removing premalignant adenomas and detecting early cancer, COL should lower colorectal cancer mortality. Although gastroenterologists strongly believe that

COL lowers colorectal cancer mortality, evidence in support of this belief is indirect. Robert S. Sandler in 2010 wrote: "The mortality from colorectal cancer has actually been decreasing steadily since 1980, long before widespread use of COL or any other screening, and before use of effective adjuvant therapy for cancer" [6].

However the high cost of biological therapy for advanced CRC, and the high risk of CRC in low-income population are likely to affect the cost-effectiveness of COL in the future [7,8].

In Italy CRC rank third for incidence among male (second among female) and second among the most frequent causes of tumour death for both men and women [9]. The current trend of the incidence shows a slow-down among male patients and stabilization among women. Mortality seems to be in decrease in particular in the population under 50 years old. In Southern Italy and in the Italian islands the incidence is lower (like mortality), but its trend is less favourable than in central-northern Italy. In the Southern Italy trends on the increase are reported both among men and women. The success of Colorectal cancer screening (CCS) is the success of COL. However there are critical points: complications of COL programmes; low coverage; low compliance; overload on endoscopy facilities. Faecal occult blood screening (FOBT) for CRC in men and women aged 50 to 74 is the Italian and European Union recommendation [10]. CCS is widely accepted as a public health policy in Italy [11]. On the contrary few regions have adopted widespread CCS programmes, although some are inching their way to that goal [12]. The reason, is the burden that extensive CCS places on COL services [13]. Behind every CCS test, no matter what kind, is the potential need for a COL, who can detect and remove adenomas, and detect asymptomatic cancers [14-19].

The social and economical impact of CRC is such, to warrant the decisions of the Italian government to implement the screening as a form of prevention. According to the Italian government agreements, on September 30th 2010, the Italian Regions should have implemented the Plan of National Prevention and transformed it into Plan of Regional Prevention: April 24th 2010 agreement between Government, Regions and Autonomous Provinces of Trento and Bolzano: "… the regions are committed to implement by September 30, 2010, the Regional Plan of Prevention to carry out the interventions established by the National Plan of Prevention …" [20].

Two authorities coordinate activities and research projects for both general and specific, population. The Italian Network of Cancer Registries (AIRTUM), and the National Centre for Disease Prevention and Control (Ccm) [21,22].

AIRTUM, called AIRT until 2006, was born in 1997, in 2005, AIRTUM created a centralized database where data from Cancer Registries are stored and, after checked for quality and completeness, used for collaborative studies on cancer epidemiology in Italy [14]. Cancer registration in Italy began in the 1970s with a steady increase in experiences and coverage of an increasing proportion of the Italian resident population. The density of registries is greater in northern Italy, especially in the North-east, compared with Central and Southern Italy (Figure 1).

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Figure 1. Italian Network of Cancer Registries: red actived, white not yet actived.

On the other hand, especially in the South of Italy, cancer registration has remarkably expanded in recent years with several new registries, which provide a more detailed and descriptive dataset of the oncologic illnesses in this area of Italy. Figure 1 shows the proportion of the resident population covered by cancer registries according to region and geographic macroareas (Northwest, Northeast, Centre, and South). Regional coverage varies from 0% in several southern regions (Puglia, Basilicata, Abruzzi, Molise), as well as Val d'Aosta, to 100% (e.g., Umbria, Friuli Venetia Giulia, Trento, and Bolzano). Nevertheless, Southern Italy reported an increase in cancer reporting. Today more than a third of the Italian population lives in an area with an active cancer registry. This proportion differs between areas (37% in the Northwest, 68% in the Northeast, 26% in the Centre, and 18% in South). Overall, AIRTUM Registries involve more than 19.000.000 subjects, or 34% of the entire Italian resident population. The importance of AIRTUM, is supported by the growing number of accredited registries contributing to the centralized dataset, thus improving representation at the national level. Furthermore, the presence of historic registries, operating since the 1980s, has helped calculate 20-year incidence trends, and stable, robust prevalence estimates. Ccm is to liaise between the Ministry of health on the one side, and regional governments on the other as regards surveillance, prevention and promptly responding to emergencies [23-25]. Over the years, Ccm has acquired a specific identity, which makes it unique within the framework of Italian public health; its main features are: analyze health hazards implementation in prevention secondary and tertiary prevention. The Centre is a bridge between the world of research and health facilities on the one hand, and the best practices and entities being developed on the other, by activating institutional partnerships and professional collabora-

tions: its aim is to build an Italian prevention network. The goal of Ccm is to optimise the national prevention Plan checking surveillance plans and active prevention with the Regions.(Figure 2).

Figure 2. Regional colorectal cancer screening: red actived, white not yet actived, red and white partial actived.

The cooperation with these two authorities introduced design standards and evaluation criteria, as part of an active collaboration relationship between AIRTUM, CCM and the partners with which it has agreements, both in the design and monitoring phase of programmes and projects of CCS.

At the present days, no studies are ongoing to define the cause-effect relationship between costs, CCS programme, and COL.

In this paper we show how both the choice of specific constraints on output weights (CCS programme) can affect the measurement of COL efficiency using the "Data Envelopment Analysis" (DEA).

In their originating study, Charnes, Cooper, and Rhodes on 1978, described DEA as a “mathematical programming model applied to observational data [that] provides a new way of obtaining empirical estimates of relations - such as the production functions and/or efficient production possibility surfaces – that are cornerstones of modern economics” [27].

DEA is a relatively new “data oriented” approach for evaluating the performance of a set of peer entities called Decision Making Units (DMUs) which convert multiple inputs into multiple outputs.

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DEA is applied by the management control to evaluate the relative efficiency of human resources, the results are related to the cost of diagnostic procedures, standardized by the case-mix, and both scatter plot and cluster analysis are produced to find out related area of performance and to plan a strategy for the continuous quality improvement. The objective of this study therefore, is to propose one model of study of the costs in the strategy of CCS supporting the benefits of COL using DEA model.

2. Materials and methods

The absence in the literature of previous experience or analogous models can makes difficult to create a logistic model. At the present days, there are many studies to define the cause-effect relationship between costs, and CCS programme, or between costs and COL. The objective of this study is to propose one model of study of the costs in the strategy of CCS supporting the benefits of COL using DEA model. Since the incidence of colorectal cancer shows a geographical variability, we considered the epidemiological data in the light of the different Italian cancer records, which are often referred to provincial or regional results and we compared them with the screening tests available in each Region.

In the first part of the paper, we calculated the global population in Italy and the number of current colorectal cancer cases using the historical archive of ISTAT (Italian National Institute of Statistics). The ISTAT produces and distributes information that describes the social, economic and environmental conditions of the Country, and the changes taking place within it, in strict compliance with legal provisions on confidentiality. As the main producer of national statistics, it provides data and releases information to European statistical authorities and international organizations. We then evaluated the economical impact considering every single available regional result obtained from the archives of Age.Na.S. (Italian Agencies for Regional Health Care Services), AIRTUM, and CCM, and comparing them with the available Italian data obtained from the Italian Ministry of Health and the statistical registers of INAIL (Italian institute for insurance against industrial accident) and INPS (Italian Institute of social insurance). The Age.Na.S. is a public agency founded in 1993. In the Italian healthcare service the Agency plays as a technical body supporting the Ministry of Labour, Health and Social Services and Regions. The Agency also coordinates health research programs financed by the Ministry of Labour, Health and Social Services or by the Regions. The National Fund against Accidents created on 1883, took the name of INAIL on 1933. INAIL took up the management of compulsory insurance against occupational diseases in the industrial and agricultural sector, diseases caused by X-rays and radioactive substances; compulsory insurance has also been extended to "housewives". It produces and distributes information on occupational diseases. The INPS, established in 1933, is the large Italian public body that pays out old-age pensions to workers, after receiving contributions from them throughout their working lives, and manages the types of assistance provided for by the “social state”, sickness, maternity and unemployment benefits, invalidity payments and social payments for citizens who are in need. INPS is one of the biggest public body in Europe, produces and distributes information that describes National Health Service.

In view of the geography of the Italian territory and the distribution of the population we analyzed the data considering three macro-areas which include different regions, i.e. the regions of Northern Italy: Piedmont, Emilia Romagna, Liguria, Friuli Venetia Giulia, Veneto, Trenton Alto-Adige, Lombardy and Valle d'Aosta; the regions of Central Italy: Tuscany, Umbria, Latium, Marche, Abruzzi, Molise and Sardinia; the regions of Southern Italy: Campania, Puglia, Basilicata, Calabria and Sicily.

For each Region we considered the following indicators in order to assess a possible plan of screening campaign of colorectal cancers: global population, mean age and population older than 65 years; relationship between Gross Domestic Product (GDP) and per capita income; incidence of colorectal cancer and possible screening campaign on the territory; index of patients' emigration and reimbursement through Diagnostic Related Group (DRG) of the pathology as a ratio versus the unit value represented by Italy as a system.

The second part of the paper is the object of the article: the implement of particular methodologies in order to determine which COL is cost-effective in the mass CCS programme. In this chapter a method for efficiency measurement in CCS programme has been described.

First an overview of efficiency measurements applicable is given. Calculation methods is described and examples of inputs and outputs are provided.

A method to measure efficiency is proposed. This method proves to be particularly successful in cost-efficiency analysis, when the performance indicators are numerous and hard to aggregate. The results show that there are two cost-effective strategies after a positive FOBT: COL.

We performed an explorative study to efficiency measurement in CCS. To construct an efficiency measure or measures for the CCS programme, literature has been searched for different types of efficiency measures used in healthcare. Hence a selection of criteria and methods is made which tend to be suitable to evaluate which COL is cost-effective in the mass CCS programme.

Besides Italian CCS programme were carried out to gain understanding of the care process for CRC patients. The proper knowledge of the process it is useful to choose suitable performance indicators.

3. Results

Out of a population of 60.387.000 inhabitants (data updated at 2010), the incidence of colorectal cancers was almost of 49.000 cases, with a prevalence of over 310.000 cases and mortality higher than 18.000 cases (data updated at 2006). The analysis of the abovementioned three macro-areas is characterized by strong differences both in general and in particular terms.

There are considerable imbalances between the Northern, Central and Southern areas considering their input, output and outcome.

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Data in terms of distribution of population, mean age and population older than 65 years are distributed in the different macro-areas according to the distribution recorded by the Italian Institute of Statistics which depicts particular realities partially due to the industrial development and the local health level. We can differentiate in detail the following data for each Region (see Tables 1-3).

	Population (pop)	Mean age	% pop ≥ 65 years	GDP/ capita index	Incidence colorectal cancer	Screening plans	Migration Index	DRG Index
Piedmont	4.432.571	44,9	22,6	1,09	90,79 64,11	4 plans sigmoidoscopy	8,43	1,01
Emilia Romagna	4.337.979	45,0	22,8	1,21	139,58 82,86	11 plans (100% territory)	6,31	1,06
Liguria	1.615.064	47,3	26,7	1,03	104,16 82,5	1 plan	11,19	1
Friuli-Venetia Giulia	1.230.936	45,4	22,7	1,11	140,17 95,52	Global regional plan	6,4	1,22
Veneto	4.885.548	42,9	19,3	1,15	124,02 83,94	17 plans	5,31	1,17
Trenton Alto-Adige	1.018.657	41,3	17,8	1,25	113,60 76,14	Global regional plan TRENTO	10,56	1
Lombardy	9.742.676	43,0	19,6	1,30	107,93 74,5	15 plans (100% territory)	3,9	0,81
Valle d'Aosta	127.065	43,6	20,3	1,32	82,83 60,04	Global regional plan	22,17	1
ITALY	60.387.000	42,8	19,9	1	107,8 69,64	L.D. 138 2004 art. 2 bis Sof > 50 years	- -	1

Table 1. Macro-area: Northern Italy

Piedmont is a Region with a large-size population with mean age and rate of elderly population higher than the Italian average. It has at its disposal a bit more resources than the Italian average and its screening campaign covers only some provinces; the incidence of the disease is lower than the Italian average; the emigration index is low and the refund of the health expenditure is a little bit higher than the national average. Emilia Romagna is a large-size population with mean age and rate of elderly persons higher than the Italian average. It has at its disposal more resources than the national average and its screening campaign covers all the provinces, the incidence of the disease is higher than the Italian average; the emigration index is low and the refund of the health expenditure is a little bit higher than the na-

tional average. Liguria has a middle-size population with mean age and rate of elderly definitely higher than the Italian average. It has at its disposal a little bit more resources than the Italian average and its screening campaign covers only one province; the incidence of the disease is lower than the National average; its emigration index is high and the refund of the health expenditure is on the average. Friuli Venetia Giulia Region has a middle-size population with mean age and rate of elderly persons higher than the Italian average. It has at its disposal more resources than the Italian average and its screening campaign covers all the provinces with a regional plan; the incidence of the disease is higher than the national average; its emigration index is low and the refund of the health expenditure is higher than the national average.

Veneto Region has a large-size population with mean age and rate of elderly in line with the Italian average. It has at its disposal more resources than the Italian average and its screening campaign covers all the provinces; the incidence of the disease is higher than the national average, its emigration index is low and the refund of the health expenditure is higher than the national average. Trenton Alto Adige Region has a middle-size population with mean age and rate of elderly persons lower than the Italian average. It has at its disposal more resources than the national average and its screening campaign covers the whole region, the incidence of the disease is higher than the Italian average; its emigration index is high and the refund of the health expenditure is in line with the national average. Lombardy has a large-size population with mean age higher than the average and a rate of elderly slightly lower than the Italian average. It has at its disposal more resources than the national average and its screening campaign covers all its provinces, the incidence of the disease is slightly higher than the Italian average, it has a low emigration index and the refund of health expenditure is lower than the national average. Valle d'Aosta Region has a small-size population with mean age and rate of elderly persons higher than the national average. It has at its disposal more resources than the national average, its screening campaign covers the whole Region, the incidence of the disease is lower than the national average; it has a high emigration index and the refund of health expenditure is in line with the national average.

Tuscany Region has a large-size population with mean age and rate of elderly persons higher than the Italian average. It has at its disposal more resources than the Italian average and its screening campaign covers the whole territory; the incidence of the disease is lower than the national average; its emigration index is mean and the refund of health expenditure is lower than the national average. Umbria Region has a small-size population with mean age and a rate of elderly persons higher than the Italian average. It has at its disposal fewer resources than the Italian average and its screening campaign covers the whole Region; the incidence of the disease is higher than the national average; the emigration index is high and the refund of health expenditure is higher than the national average.

Lazio Region has a large-size population with mean age and a rate of elderly persons lower than the Italian average. It has at its disposal more resources than the Italian average and its screening campaign covers only some provinces; the incidence of the disease is lower than

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the national average; its emigration index is intermediate and the refund of health expenditure is lower than the national average.

	Population (pop)	Mean age	% pop ≥ 65 years	GDP/ capita index	Incidence colorectal cancer	Screening plans	Migration Index	DRG Index
Tuscany	3.707.818	4,3	23,3	1,09	106,5 61,01	12 plans (100% territory)	5,92	0,79
Umbria	894.222	44,9	23,3	0,95	123,73 78,80	4 plans (100% territory)	11,28	1,72
Lazio	5.626.710	42,6	19,2	1,22	89,06 52,57	4 plans	6,64	0,89
Marche	1.569.578	44,3	22,6	1,00	109,89 67,70	2007 pilot project	10,75	1
Abruzzi	1.334.675	43,4	21,3	0,81	113,25 42,75	6 plans	10,2	1
Molise	320.795	43,6	22,0	0,72	113,29 43,16	Global Regional plan	20,62	1
Sardinia	1.671.001	42,2	17,8	0,80	101,42 54,12	1 plan	4,24	1
ITALY	60.387.000	42,8	19,9	1	107,8 69,64	L.D. 138 2004 art. 2 bis Sof > 50 years	- -	1

Table 2. Macro-area: Central Italy

Marche Region has a middle-size population with mean age and rate of elderly persons higher than the Italian average. It has at its disposal resources in line with the national average and implements no screening campaign; the incidence of the disease is higher than the national average; its emigration index is high and the refund of health expenditure is in line with the national average.

Abruzzi has a middle-size population with mean age and rate of elderly persons higher than the Italian average. It has at its disposal fewer resources than the national average and its screening campaign covers only some provinces; the incidence of the disease is higher than the national average; its emigration index is high and the refund of health expenditure is in line with the national average.

Molise Region has a small-size population with mean age and rate of elderly higher than the Italian average. It has at its disposal fewer resources than the national average and its screening campaign covers the whole Region; its emigration index is high and the refund of health expenditure is in line with the national average.

Sardinia Region has a middle-size population with mean age and rate of elderly lower than the Italian average. It has at its disposal resources in line with the national average and its screening campaign covers only one province; the incidence of the disease is lower than the national average, its emigration index is low and the refund of health expenditure is in line with the national average.

	Population (pop)	Mean age	% pop ≥ 65 years	GDP/ capita index	Incidence colorectal cancer	Screening plans	Migration Index	DRG Index
Campania	5.812.962	39,0	15,4	0,64	60,09 41,07	4 plans	7,55	0,89
Puglia	4.079.702	40,7	17,4	0,66	68,89 35,98	- -	7,64	1
Basilicata	590.601	42,1	20,0	0,70	104,31 35,98	Global regional plan STOP 2007	24,01	1
Calabria	2.008.709	41,1	18,4	0,65	83,08 35,93	4 plans	14,82	1
Sicily	5.037,799	40,7	18,0	0,66	71,15 45,33	- -	6,09	1
ITALY	60.387.000	42,8	19,9	1	107,8 69,64	L.D. 138 2004 art. 2 bis Sof > 50 years	- -	1

Table 3. Macro-area: Southern Italy

Campania Region has a large-size population with mean age and rate of elderly lower than the Italian average. It has at its disposal fewer resources than the national average and its screening campaign covers only some provinces; the incidence of the disease is lower than the national average; its emigration index is intermediate and the refund of health expenditure is slightly lower than the national average.

Puglia Region has a large population with mean age and rate of elderly lower than the Italian average. It has at is disposal fewer resources than the national average and it has no screening campaign; the incidence of the disease is lower than the national average and its emigration index is intermediate. The refund of health expenditure is in line with the national average.

Basilicata has a small-sized population with mean age and rate of elderly higher than the Italian average. It has at its disposal fewer resources than the national average and the screening campaign was discontinued in 2007, the incidence of the disease is lower than the national average, its emigration index is high and the refund of health expenditure is in line with the national average.

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Calabria has a middle-sized population with mean age and rate of elderly lower than the Italian average. It has at its disposal fewer resources than the national average and its screening campaign covers only some provinces; the incidence of the disease in lower than the national average; its emigration index is high and the refund of health expenditure is in line with the national average.

Sicily has a large population with mean age and rate of elderly lower than the Italian average. It has at its disposal fewer resources than the national average and has no screening campaign; the incidence of the disease is lower than the national average, its emigration index is intermediate and the refund of health expenditure is in line with the national average.

4. Discussion

The average cost of colo-rectal cancer treatments in Italy has been estimated to be approximately € 9.149,00 per patient per year including chemotherapy [27]. Some authors estimate that for the city of Ferrara the overall cost related to the introduction of a CCS programme was approximately € 1.400.000,00 (from October 2005 until March 2007 with more than 99.000 individuals invited) with a large proportion of these costs related to the implementation and management of the programme [28]. FOBT plus COL, increase cost relative to cheapest strategy. As a consequence of screening, some individuals with low risk receive a recommendation for a follow-up COL. However follow-up colonoscopies will increase the cost consequences of introducing screening, but not the expected colorectal cancer treatment costs. The Italian Observatory on screening Practices has been collecting data on CCS since 2004 [29]. In 2007 there were 71 CRC screening programmes in Italy, covering 46,6% of the total eligible population, with a higher coverage in the North (71,6%), and in the Centre (52,1%) than in the South (7%). The majority of programmes (65) used the guaiac FOBT (gFOBT) as first-line test. Only seven programmes used the flexible sigmoidoscopy (FS), of which three used a combination of FS and gFOBT. The quality and efficacy of the screening programmes are evaluated using ad hoc indicators developed by the Italian Group for Colorectal Screening (GISCoR) [28]. In 2007, on average 79,1% of the eligible population was invited for FOBT screening, with only Lombardy, Umbria, and most of the programmes in Emilia Romagna reaching the 90% target. Among the invited individuals, 46,3% underwent FOBT with significant variations across (from 26,5% in Lazio to 65% in Veneto) and within regions (from 11 to 80%). Among the people invited for the first time, the average percentage of individuals with a positive test was 5,6%, while among people who were recalled it was 4%. The probability of having a positive result was higher for men than for women and increased with age. Among people with a positive test, only 78,7% underwent a COL [2]. The South and Centre had a lower rate of COL attendance than the North. Men were slightly more likely to undertake a COL after a positive FOBT than women, mainly because of the uncomfortable feeling and concern of women having a male physician performing the tests. The risk of bowel perforation and bleeding during COL was negligible. For FS, on average 66,5% of the eligible population was invited with large variations across programmes. Only 27,7% of those invited underwent FS with a slightly higher proportion among men than

women. The response rate was higher whenever FS was combined with FOBT [30]. The percentage of FS successfully completed was 88%, with again a higher level among men than women; 14,3% of men and 7,6% of women were sent for a COL for further analysis and 90% of these attended the test. In 2007 overall FOBT and FS detected 20.796 adenoma of which, 2.449 were carcinomas. An additional 295 carcinomas were diagnosed in individuals who underwent further follow-up tests. Most of the adenomas identified were in Stage I, (54.5%), followed by increased widely Stages III and IV (24,9%), and then in Stage II (20,7%). The critical points are: complications of COL (40 programs) with average perforation rate of 0,08% (2,5% operative COL) and average bleeding rate of 0,55%; low coverage and delay in Southern Italy; low compliance; overload on endoscopy facilities.

The role of screening is an extremely topical question even though in the past it was already subject of discussion and until few years ago it was considered to fall within the competence of the central government [31]. Only in the last years we have observed a different interest especially in Italy due to the changed political conditions. Does a convergence really exist between federalism, screening and standard cost? The process which links the federal structure of the nation with the screening is a thin red line which began with the promulgation of the Constitution and over the years it has been fully implemented with Act No. 42 of year 2009 with enforcement of Article 119 of the Constitution which guarantees autonomy of revenues and expenditure of municipalities, provinces, towns and regions and assure principles of support and social cohesion [32]. In particular, it assures the funding of the essential levels of health care (which includes the practice of screening) referring to a benchmark of cost and requirements [32]. In year 2001 an agreement was made between Government and Regions for the guidelines about prevention, diagnosis and assistance in oncology, including indications for the screenings, and the promulgation of Decree of the President of the Council of Ministry No. 26 of November 29th 2001, which defines the Essential Levels of Care (LEA) including the plans of screening for the early diagnosis of colorectal, breast, cervix cancers [33]. Within the 2001 financial budget (law N. 388, 2000) it was decided that target population screening was free of charge [34]. In 2004 the Health Minister redistributed overall € 7.000.000, a minimum of € 50.000 per region, for reducing the gaps in cancer screenings and activating the CCS programme (€ 1.750.000 specifically for CCS). This agreement made these plans to be a right for women and men. The debate about the allocation of resources in regimen of federalism is very lively, in particular regarding the costs of Health Care System. We remind that the allocation of the funds to the Health Care System for the prevention of diseases remained constant at 5% for some years [35]. The criterion of the historical expenditure will be replaced by the standard cost. The standard cost is the tool to assure the LEA funding and consists of the expenditure for the following items: staff, equipment, consumables and general costs of the health performances of the production unit [36]. Moreover, a "direct" cost of production is predicted, i.e. a percentage to cover the general functioning costs of the equipment of the production unit [37]. The characteristics of the colorectal cancers show a strong geographical variability: chronic trend, increase in the incidence and a still too high mortality rate. The increase in the prevalence should be allotted partially to the ageing of the population, but mostly to the diffusion and implementation of screening plans. The cost of the screening campaign is defined by the following factors: first costs of tests,

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staff, confirmation procedure (selection of population at risk to reduce costs); second assessment of efficacy: sensitivity, specificity, productive value; third non-invasive method: it is addressed to probably healthy subjects; latter possibility of intervention: the disease or condition to be diagnosed should be susceptible of therapy.

In the first years 2000 the Italian Government, in view of the severe unbalanced offer of screening plans, established to allocate further financial resources (52 million euro between 2004 and 2006) for interventions promoting the re-balancing of the offer and the quality of the screening plan of cervix and breast cancers and the diffusion of the screening of colorectal cancer [33]. Even though in year 2008 in oncology the plans of screening of colorectal cancers had a significant increase exceeding the threshold of 50%, unfortunately they are not always able to achieve acceptable levels of efficacy. According to "The screening plans in Italy 2009", the screening campaigns for colorectal cancers carried out in the last years, showed some critical aspects: we observed a progressive increase in the compliance of the first years versus a progressive stabilization or decrease in the compliance afterwards [20]. There are extremely strong differences between Northern, Central and Southern Italy. However, the rate of detection of cancers by using faecal occult blood and endoscopy has always been lower than the acceptable minimum.

In fact, many differences are reported in relation with the ratio between regional and per capita income resulting into a three-speed Italy. This is mirrored also by the incidence of colorectal cancer, which exhibits a different distribution where the highest rate is in the Northern Italy and the minimum rate in the Southern Italy. According to the data of the National Screening Observatory, they are spread not uniformly throughout the territory. According to "The screening plans in Italy 2009", the real extension of colorectal screening plans (faecal occult blood plus endoscopy) for the macro-areas evidenced some critical aspects [20]. We passed from 5% in 2004 to 12% in 2005, then to 30% in 2006, which stabilized at 37% in 2007/2008 as global Italian data. Even though there were significant differences with a positive presence in the Northern Italy versus a delay in the Central Italy and an insufficient presence in the Southern Italy, these data showed a similar annual tendency for each macro-area. However, the rate of identification of cancers by using faecal occult blood and endoscopy has always been lower than the acceptable minimum. After an initial enthusiasm, we observed a progressive decrease in the percentage of compliance with the plan in both macro-areas. Regarding the emigration index, there are notable differences within the three macro-areas, which influence the general index. The value shows that the regions of Northern Italy have more attraction power versus the regions of Southern Italy, whereas the regions of Central Italy have not particularly high emigration indices.

This latter parameter: the DRG index shows clear imbalances within all regions and therefore it is not a useful element to discriminate the different macro-areas.

The lack of homogeneity on the territory, moreover, is still marked with evident consequences on mortality and morbidity [38]. The implementation of federalism poses a question: if these large differences already exist, will the situation be improved or will the disparity become even stronger? On April 29, 2010, the agreement between Government, Regions and Autonomous Provinces of Trento and Bolzano was undersigned. According to this agree-

ment the regions are committed to implement by September 2010, the Regional Plan of Prevention to carry out the interventions established by the National Plan of Prevention: among the macro-areas of interventions there are oncologic screening programs [39]. The critical points are: complications of COL (40 programmes) with average perforation rate of 0.08% (2,5% operative COL) and average bleeding rate of 0,55%; low coverage and delay in Southern Italy; low compliance; overload on endoscopy facilities.

The critical limit to implement the screening campaigns of colorectal cancers is the allocation of own resources to Regions and local bodies and the overcoming of the dichotomy between legislative and administrative (on the territory) competences and derived finance (transfer from Government to territory) [40]. Up to now the Government has been engaged in funding screening campaigns, from now on the Regions will be in charge of it [41]. Unfortunately since there is not yet an assessment of the costs of this procedure, the "promotion campaign", so far implemented, is risking to be reduced [42].

The concept of standard cost versus the historical cost is playing a crucial role in the fiscal federalism. The standard cost will contribute, in fact, to establish the "official" needs of each local body and therefore the contingent equalizing transfer to which it will have the right to in case of insufficient fiscal capacity [43].

Which approach should be used to calculate the standard costs of the federal finance?

There are two models among those currently used: micro-analytical (standard cost of each supplied performance) and macro-analytical (standard cost of easily measurable variables: demographic structure, epidemiological and social characteristics). The first approach is not very consistent with the purposes of the federalist reform (valid only as control mean) while the second model establishes a budget of expenditure resulting from merely political choices and not from the real needs of the population. What is the solution? To calculate the necessary resources the fundamental element to refer to is the efficiency [44-46]. The efficiency measures the economical employment of resources in the productive process. It is defined as the ratio between performances (screening) and resources (budget) according to the formula: efficiency= output/input [47,48].

A better approach, but for some aspects much more complex, could be the one of DEA [49]. Farrell (1957) in his preliminary work "The measurement of productive efficiency" introduced not only the well-known allocation between technique and price or allocative efficiency, but he also proposed a key to measure the comparative efficiency of the productive units which use various inputs to produce different outputs [50]. The efficiency of each unit would be equal to the ratio between real and potential output [51]. More than two decades after Charnes, Cooper and Rhodes (CCR), the idea of Farrell was developed and it was demonstrated that a linear mathematical program could be used to choose the most effective productive unit. The method, known as Data Envelopment Analysis, has been extensively used to measure the efficiency in many economical areas [52].

The analyses are non-parametric and its characteristic is that it can evaluate the relative efficiency of decisional units, and the like, through linear programming techniques without specifying whether the relative importance of the different factors of production or that of

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the prices [53]. In this sense the results of non-parametric methods are objective, because they do not require prior specifications. On the other hand, however, their disadvantage is that they do not admit errors being deterministic methods; the results could be therefore influenced. The relative efficiency of the responsibility centres is determined according to the following formula:

$$\max_{u,v} h_0(u, v) = \sum_r u_r y_{r0} \Big/ \sum v_i x_{i0}$$

Now the system of weights adopted strongly influences the efficiency, therefore through an algorithm of Charnes, Cooper and Rhodes (CCR), we try to find the optimal system of weights (among the proposed ones) in order to maximize the efficiency of the responsibility centre and the comparable ideal responsibility centre [54]. This suggests that the standard cost can be calculated in two ways: maximizing the numerator and fixing the denominator (output-oriented method – screening) or, vice versa, keeping the numerator and minimizing the denominator (input-oriented method – prevention budget) [55]. The difference is important since it determines the form of efficiency that we are assessing. Output-effective means there is no other unit that develops a larger screening with the same budget for the prevention [56].

A productive unit is called input-effective if there is no other unit able to obtain the same screening using a lower budget (DMUs).

This methodology assesses the efficiency as the ratio between quality of the screening and available budget. Some weights are obviously introduced to include demographic and health characteristics of the Region. Now for each unit we can obtain the optimal budget to be allocated to the Region for the screening campaign. In this way by adding the sum of every single regional budget, the necessary budget of national expenditure can be obtained to carry out an effective and really sustainable screening campaign.

In view of the above mentioned results, we can assume an equivalent model (Table 4).

The following example of three Regions (large, middle, and small) illustrate how DEA works.

Each Region has exactly 10 COL (the only input), and we are be able to measure a Region CCR programme based on two outputs: number of patients subject to screening, and number of found cancers. The data for these Regions is as follows:

Region “large”: 100 COL, 1000 number of recruited patients, 20 number of found cancers;

Region “medium”: 100 COL, 400 number of recruited patients, 50 number of found cancers;

Region “small”: 100 COL, 200 number of recruited patients, 150 number of found cancers.

Now, the key to DEA is to determine whether we can create a virtual Region that is better than one or more of the real Regions. Any such dominated Region will be an inefficient Region. Consider trying to create a virtual Region that is better than Region “large”. Such a Region would use no more inputs than a Region “large”, and produce at least as much output. Clearly, no combination of Regions “medium” and “small” can possibly do that. Region

"large" is therefore deemed to be efficient. Region "small" is in the same situation. However, consider Region "medium". If we take half of Region "large" and combine it with half of Region "small", then we create a Region that processes different outputs (600 number of recruited patients, 85 number of found cancers) with just input (100 COL). This dominates "medium" (we would much rather have the virtual Region we created than Region "medium"). Region "medium" is therefore inefficient. Another way to see this is that we can scale down the inputs to "medium" (number of COL) and still have at least as much output. If we assume (and we do), that inputs are linearly scalable, then we estimate that we can get by with 63 COL. We do that by taking 0.34 times Region "small" plus 0.29 times Region "medium". The result uses 63 COL and produces at least as much as Region "medium" does. We say that Region "medium"'s efficiency rating is 0.63. Regions "small" and "large" have an efficiency rating of 1.

	Region		
	Large	**Middle**	**Small**
Population size			
Average			
Range			
Input			
Equivalent number of hours of physicians of general medicine			
Equivalent number of hours of endoscopists			
Equivalent number of hours of anaesthetists			
Equivalent number of hours of nurses			
Equivalent number of hours of executives			
Equivalent number of hours of lab physician			
Number of evaluations			
Number of endoscopies			
Number of histological exams			
Equivalent number of hours of pathologists			
Equivalent number of hours of technicians of pathologic anatomy			
Number of histological analyses			
Output			
Number of recruited patients			
Number of patients subject to screening			
Number of found cancers			

Table 4. Example of sustainable screening campaign.

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After the definition of the population size and the observed input and output to assess the screening unit (DMUs), it is possible to calculate the index of efficiency by using the above-mentioned formula. This index can be referred to the single Regions or to the system Italy as a whole.

In many states, a larger question may be whether the overwhelming use of COL as the screening method is the appropriate choice.

Determination of the appropriateness of an indication for COL has been advanced as a means to help rationalize the use of endoscopic resources. Current guidelines regarding the appropriateness of COL are relatively inefficient in excluding a clinically meaningful CRC risk for patients, in whom COL is generally not indicated, raising serious concerns about their applicability to clinical practice.

A tailored navigation approach, which determines the particular concerns and barriers of an eligible individual and matches them with the strengths and weaknesses of each strategy to find the one most suitable, may be the optimal way to maximize the number of people who can benefit from COL.

In the end, a test can only provide benefit if it is actually done [57].

5. Conclusions

Nowadays the Italian National Health Service is distributed on extremely diversified regional realities. Needs and inefficiencies of production are inseparably correlated in the health expenditure of the Regions. In the future the issues that are now more critical will have to be adjusted: to implement screening plans, supply the Regions with the objectives related to common LEAs in view of the regional differences. According to the "National Centre for the Prevention and Control of the Diseases" (institution of coordination between Ministry of Health and Regions for the activities of surveillance, prevention and prompt response to the emergencies), it is necessary to "design the interventions of secondary prevention not as performances but rather as "paths" (profiles of care) offered to the citizen within various organizing activities on the territory aiming at the efficiency in the practice". Only in this way the efficiencies can be optimized and the necessary budget minimized for each Region for the screening campaigns. In order to avoid the funding of squandering, a formula of analytical calculation of the needs will be necessary [58]. A further problem in the future will be to make homogeneous the different kinds of screening currently in use on the territory to assure a higher allocative efficiency and COL will clearly has a future, which will expand even if the technology stands still. For a screening programme to be successful, multiple events have to occur, beginning with awareness and recommendation from the primary-care physician, patient acceptance, financial coverage, risk stratification, screening test, timely diagnosis, timely treatment, and appropriate follow-up. If any one of these steps is faulty or is not of high quality, the screening will fail. In this scenario we had to consider the COL as a means than an aim. In this regard DEA, which is an innovative methodology easy to be ap-

plied especially in the health care with diversified systems as ours, can be a useful tool to calculate the regional needs in order to carry out screening campaigns.

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