LUISS

Dipartimento
di Governo e Politiche

Cattedra in Health Care Policy

The economic and managerial impact of anorexia: Innovation of the Italian approach

Prof. Daniele Mascia
RELATORE

Prof.ssa Donatella Morana
CORRELATORE

Rossella Arcomano
Matr. 635332
CANDIDATO

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Introduction

The purpose of this paper will be to evaluate, understand and analyse the various references to the costs that the treatment of anorexia pathology has on the national and on the regional health care system.

The paper will be organized in five different chapters, allocated to give an adequate explanation and illustration of accounting consequences of anorexia starting from the origins, the impact it has in Italy, the various prevention policies applied by the health care system, concluding with a reference to an exceptional treatment center located in southern Italy.

The first chapter illustrates the historical and cultural social background that has allowed the affirmation and development of anorexia in today's society. The origins of pathological contributions related to the lack of deliberation are to be found many centuries ago: such as the fasting tendency of some Christian saints, which can be reported as in unequivocal examples of anorexic behaviors, or the insatiable hunger present in Greek and Jewish literature. The studies achieved at the beginning of the nineteenth century, which defined the pathology also as anorexia nervosa, it has often been considered a disease in its own right, other times it is considered a variant of other pathologies. Starting in the second half of the nineteenth century, several doctors considered anorexia as an end result of a hysterical phenomenon. Freud himself, starting from 1895, spoke of a

melancholic structure of anorexia by establishing a link between anorexia and depression.

Tendentially and cyclically, socio-cultural factors have brilliantly explained and illustrated how some distinct traits are shared throughout history. First, the emergence of a new ideal of lean and tubular beauty that has become above all famous and popular through the media of the West, promoting a psychological edict of ability especially for adolescents, subjected to the judgment of peer groups.

Only recently have these diseases been the subject of research and clinical studies, considered for a very long time a disorder or endocrine I have symptoms or consequences of other pathologies such as hysteria, obsessive neurosis, schizophrenia and mood disorders.

Barely in the last decades of the twentieth century did we begin to speak of the so-called "diet industry", the sponsorship of tools, strategies and programs that could be used for weight loss without taking into account the cost-benefit ratio. According to the latest statistics from the World Health Organization, the incidence (i.e. the number of new cases of a disease, in a defined population, over a given period of time) of anorexia nervosa is estimated to be at least eight new cases percent thousand people among women per year, while between 0.02 and 1.4 new cases percent thousand people among men per year. The age group in which the disease occurs and more often between 15-19 years, some recent clinical observations have reported an increase in onset in pre-adolescent age.

Central question to answer to better scrutinize the efficient results of good policies, is: who is the patient?

The increase in cases in this new society is partially explained by the lower age of the first menarche observed in the last decades, but it could also be connected to an anticipation of the ages in which the adolescent is exposed to social and cultural pressures towards thinness,

as the Internet and social media can be. A first approach can also provide a greater risk of permanent damage in addition to naturally malnutrition, particularly if the damage occurs in subjects who have not yet matured the adult body characteristics. In contrast, environmental factors are multiple and can be divided into early - those risk factors that interfere with the early stages of neurodevelopment and with the maturation and programming of stress response systems- and late - childhood abuses, psychosocial stresses.

The premorbid peculiarities of patients with eating disorders are generally similar: timid, submissive, obedient, perfectionist children or adolescents competitive; conscientious and aiming to get the most out of every performance, they have an academic performance that is often above average. At times, on the contrary, we find temperamental characteristics of greater extroversion, with behavioural methods of an oppositional type and with a propensity to compete.

The second chapter describes the model for the management of therapy applied for the care of eating disorders. It is based on two general principles: multidisciplinary management and the multiplicity of care contexts.

The major advantage of the multidisciplinary approach is the presence of clinicians with multiple skills. They can facilitate the evaluation and management of complicated patients with serious medical and psychiatric problems coexisting with the eating disorder.

The disadvantages can be divided into two main categories of problems: often none of the therapists observes and appreciates the patient’s entire clinical picture. Second, facilitates the administration of contradictory information to patients about their disorder and strategies to deal with it.

To avoid the insurgence of abysmal consequences, it is essential the clarification of the level of intervention and competences.

In Italy, five levels of intervention are available in the treatment of eating disorders:

- First level: general practitioner or freely chosen paediatrician;
- Second level: specialist outpatient therapy;
- Third level: intensive outpatient therapy or day centre or day hospital (diagnostic / therapeutic / rehabilitative);
- Fourth level: intensive residential rehabilitation (code 56 or ex art. 26);
- Fifth level: H24 admissions (ordinary and emergency).

The role of drugs in the treatment of eating disorders is limited, and however not determined during the evaluation of the instrument's levels. For anorexia nervosa there are no empirically supported pharmacological treatments, although numerous drugs have been tested, such as antidepressants, antihistamines and recently atypical antipsychotics. However, none has been shown to have a useful clinical effect in improving the psychopathology of eating disorders.

The third chapter illustrates the effectiveness of prevention. Some authors believe that giving information about eating disorders can even be counterproductive and harmful. The risk may be to indicate to those litters who are experiencing difficulties or discomfort the "way out", a system that is followed through processes of imitation and identification since, in effect, for some people anorexia and, in less bulimia, are idealized conditions. However, it is important to evaluate the effectiveness of preventive programs. Only recently have some prevention programs been developed whose effectiveness is not yet established.

These programs are generally carried out at school level and normally involve the discussion of problems related to food and their

consequences or, more commonly, problems related to growth and adolescence. There is also another type of prevention, called "secondary", which aims to identify the cases as soon as possible with respect to the onset of the disorder, since it has been established, at the clinical level, that a treatment undertaken in the early stages of the disease is much more effective. Not always, nevertheless, especially in the early stages of illness, the adolescent with a feeding problem admits that he needs help. At this level too, environmental awareness is important: starting with the young people themselves, families and school staff. In Italy, prevention is applied and regulated through the National Prevention Plan. The areas in which the Ministry of Health intends to apply greater prevention policies are described in the Plan, and it is generally divided into periods of 3 or 5 years. The macro objectives of this Plan have been the reduction of the burden of disease, the investment in the well-being of young people, the strengthening and confirmation of the common heritage of preventive practices, the improvement and the systematization of the attention to fragile groups and, finally, the attention to the individual and populations in relation to their environment.

In the field of prevention, it is significant to recall the activities aimed at guaranteeing food safety and veterinary health, which oversee food and feed hygiene and safety, animal health and welfare, and that promote nutritional safety. These prevention objectives are pursued through the establishment of rules, actions, procedures capable of being acted on large territorial and population areas, through legislative/regulatory instruments.

The Italian Ministry of Health did not develop, so far, a prevention policy regarding anorexia; the focus on a prevention strategy concerning an eating disorder was about obesity. A working group for the prevention and contrast of overweight and obesity was established

on 6th June 2019, established by Ministerial Decree of 18th January 2019 and subsequent additions to the Directorate General for Prevention health.

The fourth chapter is address at the explanation and the portrayal of the management of the cost in our healthcare system.

In 1995, following the reorganization of the National Health Service (NHS) (Legislative Decree 502/1992 and subsequent amendments and additions), a prospective type of hospital remuneration system was introduced in Italy, based on the classification of "Diagnosis Related Groups" (DRG), in Italian ROD (Raggruppamento Omogeneo Diagnosi).

Until then, the hospital activity was described in terms of admissions volumes and hospitalization days provided and was financed based on a retrospective assessment of the costs incurred.

The DRG is a system that groups, classifies and measures the characteristics of hospital admissions based on the type of organ involved, procedures performed and age. In this sense, the DRG system constitutes the natural evolution of the finalized studies "at providing decision makers in hospital planning and administration with a tool for generating useful information in the design and operation of a progressive patient care facility". Nevertheless, with the adoption of the DRG system for the classification and remuneration of admissions a standardized and meaningful definition was made in clinical and economic terms of the hospital product, allowing assessments and progressively more detailed analyzes, both retrospective and prospective, on a regional, national and international scale.

Currently, the DRG has undoubtedly been recognized, also in the Italian reality, as a valid tool in redefining the relations between producers and paying entities, in allowing a more rigorous regional planning and,

finally, in making available to professionals and managers a new unified and recognized evaluation language.

The main advances in Italy due to the use of the DRGs are qualitative and quantitative improvement of information assets, an increased monitoring and control capacity for health expenditure and a greater appropriateness in the use of the hospital with transfer of casuistry to levels of care more consistent with the needs of patients.

Therefore, as can be seen, the models for the evaluation of the costs of pathologies in Italy have been multiple, applied with more or less success to the universally recognized pathologies to which departments are destined. But what happens if a condition that is not yet recognized as such must be treated, as in the case of specific eating disorders as anorexia?

The doctors Abbate Daga, Facchini, Delsedime, De Bacco, Leone and Fassino have tried, successfully, daring an answer to this question through an experiment carried out in the Piedmont region. Their study was aimed to calculate operative costs of hospitalization and assume if DRG reimbursements are plenty – stating to approximations of the Piedmont Region and establish if the cost of a hospitalization is acceptable, as linked to clinical advancement and inpatient outcome.

The total cost of staff and medical equipment for the year 2007 divided by the number of days of hospitalization in 2007 (1,082 days) gives an average cost per day of hospitalization of € 390,00. The average cost per day multiplied by the number of average days of hospitalization gives the cost of an admission on average, that is € 9.235. An admission for anorexia has a DRG value of 428, a threshold value of 51 days and a weight equal to 0.7242. The amount calculated for a hospitalization within the threshold value is € 2,231.85 (Amount calculated based on the Piedmont rates - Public Institutions of

01/01/2006), while if above the threshold value the amount corresponds to € 3,894.96. The cost of admission to the specialized psychiatric ward for eating disorders is about € 9500, or € 390 per hospital day. This value is higher than that assessed according to the ClinGrouper software which is the basis for the calculation of the DRG, which corresponds to € 2231.00 for anorexia and € 1959.00 for bulimia, or about € 178.00 per day of hospitalization.

Finally, the fifth and last chapter, labels an excellence in the care of eating disorders, the Gioia Centre in Chiaromonte, Basilicata. It is the only public care center in the South, and the second in Italy, with its twin in Todi, Umbria. It is a manifesto regarding the deals of the intentions of treatment into pragmatic operations and enriched the methodology by enhancing the experiences and contributions of individual professionals, finalizing the methods applied and inspired by consolidated experiences in the sector. The therapeutic purpose of Centre Gioia: to create the conditions so that mechanisms that lead to a desirability of life and consequently awaken nutritional appetite, overcoming the instinctual need denied. It is responsible for treating patients with DCA (Anorexia, Bulimia, Bed) where outpatient treatment is ineffective. It is a treatment area, alternative to the hospital, where girls and boys can live an intensive psycho-nutritional therapy experience, accompanied by a rich and welcoming life experience. It has 20 beds in a residential regime and 10 beds in a semi-residential regime; double rooms and spacious living spaces. It represents the therapeutic continuation in a protected environment of a hospital stay or the alternative to hospitalization itself. The duration of the residential program varies from 3 to 5 months and is such as to allow a weight recovery and the construction of an awareness of the disease that can be accepted by the patient.

The account of the chapter has been based likewise on the interviews to the biologist of the center and to the regional executive secretary of the General Affairs and administrative manager. The first was essential to the explanation on how are organized the several phases of the recovery, ranging from group meetings with guests during which the various topics ranging; the second was essential for the data's recollecting regarding the financing of the Gioia center care, the agreement with the regions of origins of the patients and the consequential affection on the regional healthcare market.

Chapter 1
General Approach to Eating Disorders: the Engraftment of Anorexia

1.1 Historical and Socio-Cultural Background

The well-being that has characterized Western countries over the last 50 years has led to the disappearance of most nutritional deficiency illnesses, but has favoured the development of some chronic diseases, such as obesity and type 2 diabetes mellitus. Life of the general population seems to have played a role also in the increased incidence of eating disorders observed in these countries since the 1960s. The combination of an obesogenic environment leads to a sedentary lifestyle, but at the same time offers repeated incentives to the consumption of food. A cultural context strongly influenced by the diet and fashion industry, which idealizes thinness and despises the excess weight, can favour the development of eating disorders, first of all anorexia.

Anorexia is defined as lack or loss of appetite for food as a medical condition, seen often as an emotional disorder characterized by an obsessive desire to lose weight by refusing to eat.

However, although in recent decades we are witnessing an increasingly wide spread of eating disorders, these diseases, in particular anorexia, cannot be considered entirely as "new pathologies".

The first clinical descriptions of abnormal eating behaviours date back to many centuries ago: the reconstructions of the life of some Christian saints are unequivocal examples of anorexic behaviour, and the entrances of compulsive and insatiable hunger are present in ancient Greek and Jewish literature. Even contemporary anorexia is inscribed in the spirit of our era, no longer within the framework of dominant religious values, but within the aesthetic values that predominate in our civilization.

To a greater extent, in today's anorexias there is a practice, the diet, allowed and recommended by the current culture, but also brought to exasperation. In modern anorexias, the fundamental element is the relationship with the image of the body, the rejection of the idea of excessive body weight and the feeling of being overweight despite being underweight.

For over a century, starting from the historical studies of prominent nineteenth century medical personalities as Lasègue and Gull, anorexia, also called *anorexia nervosa,* has sometimes been considered a disease, sometimes a variant of other pathologies. In the second half of the nineteenth century, many clinicians considered it a hysterical phenomenon. The same Lasègue called this disease "*anorexie hystérique*" and Gilles De la Tourette distinguished a form due to "hysteria" from a "gastric" form caused by gastrointestinal disorders.

Freud, in a letter to Fliess of 1895, spoke of a melancholic structure of anorexia, establishing a link between anorexia and depression[1]; later he inscribed it in the hysterical pathology and correlated it to the perversions of the character. Janet, at the beginning of the twentieth century, spoke of hysterical forms and obsessive forms of anorexia (about the "famous" case of Nadia, asserting that it was "obsession de la honte du corp", "an obsessive shame of the body"). In fact, some anorexics, but not all, have a hysterical personality disorder.

Various authors have compared periodic fluctuations of some patients between anorexia and bulimia to the phases of mania and depression of manic-depressive psychosis, respectively. In the early part of the 20th century, anorexia nervosa was erroneously considered to be an endocrine disease (Simmond's syndrome) and was treated with thyroid extracts.[2] Nowadays, anorexia is described and presented as a specific disease of Western civilization, the fruit of our times. And yet there have been repeatedly reported, possible relationships between this morbid manifestation and other phenomena that belong to different historical and cultural contexts such as, for example, asceticism and fasting. In understanding the experience of anorexic subjects, we often find references to behaviours and manifestations that have an ancient flavour (ecstasy, excess, control, vehemence, enthusiasm, challenge).[3]

Beyond the debates on the historical continuity or otherwise of eating disorders, Garfinkel and Garner, in the multifactorial etiological model, consider some factors of a socio-cultural type to be of great importance. These factors are generally considered to be typical of the

[1] S. Freud, *The origins of psychoanalysis*, (1889), Basic Books, New York, 1954.
[2] R.A. Gordon, *Anoressia e bulimia. Anatomia di un'epidemia sociale*, Raffaello Cortina, Milano, 1991.
[3] B.G.Bara, *Manuale di psicoterapia cognitiva*, Cap. XIV: *UN APPROCCIO COSTRUTTIVISTA AI DISTURBI DEL COMPORTAMENTO ALIMENTARE*, a cura di S. Blanco, L. Canestri,M.A.Reda, Bollati Boringhieri, 1996.

so-called highly industrialized and high standard of living Western societies. The emphasis given to the socio-cultural elements is explained by the fact that, starting from the 1960s, eating disorders took on an epidemic spread precisely in the Western societies. [4]

In turn and circularly, these socio-cultural factors serve to brilliantly explain some particular characteristics assumed by eating disorders after their widespread diffusion. Among these peculiarities there are: the great importance assumed by some phenomenological aspects, such as the fear of gaining weight and the consequent disturbances of the body image; the emergence of a new ideal of so-called "tubular" female beauty, (first of all introduced with the super-model Twiggy) which has become popular among Western media, increasing in the psychological vulnerability of Western adolescents to teasing in the peer group.[5]

Vandereyken and Van Deth studied fasting cases with the prospect of understanding the socio-cultural antecedents of anorexia understood as a multifactorial disease, strongly linked to the historical context (even tough to the specificity of this observation it can easily be objected to wonder what psychiatric illness is not related to the socio-cultural environment). Explaining fasting behaviours and in collecting an exhaustive quantity of material ranging in different areas of social and cultural life (from the sacred to the profane, from the scientific to the show), it is highlighted the elements of continuity and discontinuity between these and modern anorexia.

After having examined the fluctuations of the religious fasters or of the ascetics and the phenomena of the "lay" fasters, rather than

[4]P.E. Garfinkel, D.M. Garner, *Anorexia Nervosa: A Multidimensional Perspective*, Brunner-Mazel, New York, 1982.
[5] R.A. Gordon, *Concepts of eating disorders: A historical reflection. In: Neurobiology in the Treatment of Eating Disor-ders*, Chichester: Wiley & Sons Ltd, 1998.

trying to diagnose anorexia in retrospect, they are concerned with how fasting has progressively entered the medical language and psychiatric clinic as a specific syndrome.

The captivating history of this entrance is not without contradictory situations and even painful events. It is therefore more important for these scholars to recognize the cultural roots of the discovery of anorexia, to which they attribute a "Victorian" matrix, rather than discriminating which behaviours of the past should be attributed to the psychopathological field and which are not.[6]

Only recently these diseases have been the subject of research and systematic psychopathological and clinical studies; considered for a long-time endocrine disorder, or symptoms or variants of other pathologies such as hysteria, obsessional neurosis, schizophrenia and mood disorders, eating disorders see their nosographic autonomy recognized today.

More newly, it has been pointed out that every age of human consciousness has been characterized by a criterion of ordering reality, with at least two orders of factors that contribute to the development of the phenomenon. First, it is clear that in a civilization concerned with the satisfaction of hunger, a disease linked to the refusal of food cannot emerge on a large scale. With emancipation from material needs, food, while losing the character of necessity, enters a more abstract sphere; in large strata of the Western population we think how, when and what to eat, rather than to feed oneself. The second determining factor is the advent of information technology. [7]

The West has seen, starting from the Sixties, the progressive development of technologies and mass media. The change in the human

[6] W. Vandereycken, R. Van Deth, *Dalle sante ascetiche alle ragazze anoressiche*, Cortina, Milano, 1995.
[7] G. Arciero, *Studi e dialoghi sull'identità personale*, Boringhieri ed., Torino, 2002.

environment, generated by the new perspectives offered by the world of technology, has favoured the appearance of unexplored forms of construction of personal identity.

Individuals begin to seek confirmation from the media, the lines on which to shape their actions and their emotions; search for external sources to which to conform, shared images to adapt to and to identify with. Inevitably, exteriority thus begins to orientate interpersonal interests and transactions, as well as defining internal states.[8] Nowadays, media and internet typify everyone's daily life, emphasizing inevitably the personal need to belong to styles and conformities.
In this scope found its roots the so-called "diet industry".

The term "diet industry" refers to the production of tools, strategies, programs and any other means that can be used to lose weight, regardless of the cost-benefit ratio. Such options are often promoted through stereotyped and misleading messages, which give the impression that it is possible to achieve the maximum result with minimum effort. The programs for weight loss, in fact, are touted by referring to sophisticated diagnostic tools or miraculous substances or devices of various kinds that almost exclusively involve passive movements. The diet industry is strongly implicated in the development of social disregard for people suffering from obesity and, indirectly, in favouring the development of eating disorders, because it emphasizes, through advertising slogans, the idea that people who have an excess weight are unattractive, weak, lazy, greedy and sick, and can only be happy and solve their problems with weight loss.

Over the past 50 years, there has been a progressive change in the canons of the female physical aspect, as promoted by the fashion

[8] S. Blanco, M.A. Reda, *Qualità dell'informazione e prevenzione, Indagine sulle conoscenze relative all'anoressia in una popolazione scolastica*, Rivista Italiana di Psicosomatica, 2004.

industry and advertising. In particular, the body mass index of the models went from an average value slightly below 20.0kg / m2 in the 1950s to an average value of 18.0 kg / m2 in 2001.

Although it is not possible establishing a causal relationship, the decrease in the weight of the models has gone gradually with the increase in the incidence of eating disorders and anorexia nervosa which, in Western countries, has increased from 0.2 to 100,000 inhabitants per year in the decade 1941-1950 at 5.4 per 100,000 inhabitants per year in the decade 1991-2000. [9]

On the other hand, a greater prevalence of the symptoms of eating disorders and/or partial forms of eating disorders among the models with respect to peers of the general population has been widely documented.

Despite the obvious unreality of the precepts established by fashion, many people, with the hope of adapting to these standards, undertake a control of their own food supply, which becomes increasingly rigid until it ends, in cases where a vulnerability is present, in a real eating disorder. In western societies, moreover, women are encouraged to pursue thinness, because lean ones are considered more intelligent, competent and successful ("positive stereotyping" of thinness). This may explain why some women internalize the ideal of thinness and develop an evaluation of themselves that is overly dependent on weight and body shape.

In this regard, it seems worthy of attention to mention the researches that underline how the incidence of these disorders are actually present, even if in a significantly reduced way, also among males. The presence of some form of eating disorder is also manifest in the category of homosexuals and in the subjects who live in a

[9] H.V.Hoek, *Incidence, prevalence and mortality of anorexia nervosa and other eating disorders*. Curr. Opin. Psychiatry, 2006.

conflictual way the definition of the sexual role; in effect, highlighting a wider presence of attitudes and atypical sexual manners associated with food behaviours.[10]

Specification of the male sex is a form, called "Reverse Anorexia", which usually begins in adolescence: the dissatisfaction with the physical aspect and the distortion of the body image are expressed with the unrealistic belief of being too small or puny; they mature the conviction of an insufficient development of the body and muscular mass, often centred on the dimensions of the limbs, and associated to the purpose to increase of weight through an increase of the caloric introduction and the sport activity.[11]

Eating disorders have been the subject of increasing attention from the scientific world and the community of health and social workers for some years, due to their diffusion among the younger age groups of the population and their complex multifactorial aetiology.

They include anorexia nervosa, bulimia nervosa, binge-eating disorder (BED) and food disturbances not otherwise specified.

1.2 Epidemiology, etiopathogenesis and clinical features of eating disorders

According to the definition of eating disorders as stated by WHO, the main characteristics of anorexia nervosa are:

[10] D.B. Herzog, I.S. Bradbum, K. Newman, *Males with Eating Disorders,* Arnold E. Andersen,1990.

[11] B.G.Bara, *Manuale di psicoterapia cognitiva,* Cap. XIV: *UN APPROCCIO COSTRUTTIVISTA AI DISTURBI DEL COMPORTAMENTO ALIMENTARE,* a cura di S. Blanco, L. Canestri,M.A.Reda, Bollati Boringhieri, 1996.

- Refusal to maintain body weight at or above a minimally normal weight for age and height (e.g., weight loss leading to maintenance of body weight less than 85% of that expected; or failure to make expected weight gain during period of growth, leading to body weight less than 85% of that expected);
- Intense fear of gaining weight or becoming fat, even though underweight;
- Disturbance in the way in which one's body weight or shape is experienced, undue influence of body weight or shape on self-evaluation, or denial of the seriousness of current low body weight. [12]

All eating disorders are more frequent in women. In studies conducted on clinical populations, men represent 5-10% of cases of anorexia nervosa, whose age of onset is generally between 15 and 19 years.[13]

In the aetiology of eating disorders there are various factors, both genetic and environmental.

The medical complications of eating disorders are relatively frequent and can affect all organs and diseases, especially in cases of malnutrition accentuated by defect or excess.

Eating disorders mainly affect adolescents and young adults, mainly affecting the female sex. According to some epidemiological

[12] WHO European Office. Mental health of children and adolescents. *Facing the challenges and finding solutions. Geneva*, World Health Organization, 2005.
[13] *Appropriatezza clinica, strutturale e operative nella prevenzione, diagnosi e terapia dei disturbi dell'alimentazione, Report del Ministero della Salute,* 2013.

data, their incidence has increased considerably over the last three decades, while according to other studies this is an apparent increase due to a better knowledge of the disorders and to the greater number of correct diagnoses.

Although considered primarily psychiatric disorders, they often produce physical complications, secondary to malnutrition and/or improper behaviour put in place to achieve control over body weight and shape. For these reasons, they represent one of the most frequent causes of disability in young people and are burdened by a significant risk of mortality.

The World Health Organization has included eating disorders among the priorities for the protection of mental health in children and adolescents.

Even if the causes of eating disorders are not yet fully known and some patients are resistant to currently available treatments, considerable progress has been made in the last thirty years, both in understanding risk factors and pathogenetic mechanisms in clinical-therapeutic management.

The incidence (the number of new cases of a disease, in a defined population, in a given period of time) of anorexia nervosa is estimated to be at least 8 new cases per 100,000 people among women per year, while it is between 0.02 and 1.4 new cases per 100,000 people among men per year.

In anorexia nervosa the age group in which the onset occurs more often is between 15 and 19 years. Some recent clinical observations have reported an increase in early-onset cases. This increase is partly explained by the lowering of the age of menarche observed in recent decades, but it could also be linked to an anticipation of the age in which adolescents are exposed to socio-cultural pressures

to thinness, through broadcasting such as internet and social media. An earlier onset can carry a greater risk of permanent damage secondary to malnutrition, especially for those tissues that have not yet reached full maturity in adolescence, such as bones and the central nervous system.

It is also important to point out that cases of late-onset anorexia nervosa are not infrequent, although still poorly studied. In general, a late onset age appears to be associated with a greater risk of chronicity and a greater presence of comorbid psychiatric disorders, especially anxiety and depression.[14]

1.3 Psychopathology and psychiatric comorbidity: who is the patient

Anorexia nervosa is a disorder whose aetiology involves various factors, both genetic and environmental. In general, the greater vulnerability observed in female adolescent or young adult subjects seems to indicate that these disorders are associated with difficulties in the phases of transition from childhood to adult life, triggered by the physical and hormonal changes that characterize puberty.

In contrast, environmental factors are multiple and can be divided into early and late.

By early environmental factors we mean those risk factors that interfere with the early stages of neurodevelopment and with the maturation and programming of stress response systems.

By late environmental risk factors, on the other hand, we mean childhood abuses, psychosocial stresses and family relationships

[14] A. Talluri, R. Liedtke, E. Mohamed, et al., *The application of body cell mass index for studying muscle mass changes in health and disease conditions.* Acta Diabetol, 2003.

characterized by a strong conflict between parents and between parents and children, the abuse of psychoactive substances and exposure to pressure the thinness of members of the family group or of the relational and affective area in which the subject lives.

The onset of anorexia nervosa is often gradual, with a progressive reduction in food intake. In most cases the disorder occurs following a hypocaloric diet started to change the weight and shape of the body; in other cases, due to digestive difficulties, diseases (including depression), surgery or trauma.

In the initial period we observe a phase of subjective well-being, due to the loss of weight, to the improvement of one's own image and also to the feeling of omnipotence produced by the ability to control hunger, while the awareness of the problem is low and a request for help is lacking (so-called "honeymoon" with the disorder). [15]

Later, concerns about body shape and weight become marked and the fear of gaining weight does not diminish with weight loss. Over time, patients become more irritable, depressed and socially isolated, and obsessive-compulsive symptoms get worse. In most cases these symptoms are subsequent and probably consequent to the reduction of caloric intake and weight; however, in a minority of cases, psychiatric symptoms arise before the eating disorder.

The psychopathological nucleus is constituted by a disturbance of the body image, responsible for a profound alteration of the way in which the subject experiences the relationship with his/her own body and with food.

The person evaluates him/herself in a predominant or exclusive way on the basis of the weight and shape of the body, often

[15] G.L. Jensen, J. Mirtallo,C. Compher, et al., *Adult starvation and disease-related malnutrition: a proposal for etiology-based diagnosis in the clinical practice setting from the International Consensus Guideline Committee*. J Parenter Enteral Nutr, 2010.

overestimates the size of his body, denies the consequences of weight loss and adopts dysfunctional behaviours of weight and body control (*body checking*), as frequently measuring the weight, repeatedly looking at specific parts of the body in the mirror, measuring the various circumferences of the body, taking in hand the folds of the fat, comparing the shape of the body with other people.

Anorexia nervosa has a marked psychiatric comorbidity. The most frequently associated diseases are major depression, obsessive-compulsive disorder and other anxiety disorders, alcohol or substance dependence. Among personality disorders, the most frequent are borderline disorder, histrionic, narcissistic and avoidant. Psychiatric comorbidity tends to decrease with weight recovery and normalization of nutrition.

Anorexia nervosa, as bulimia nervosa, is characterized by a conflictual relationship with the body.

In the body are focused perfectionism and the need for control, within an ideal of beauty and thinness, but the body can also be the object of direct and indirect self-injurious practices.

Non-suicidal self-injurious behaviour can be grouped into two dimensions:

- an impulsive dimension, which includes episodic behaviours such as cutting or burning the skin, banging the head or the fist against the wall;
- a compulsive dimension, which includes generally repeated behaviours such as biting nails or pulling hair.[16]

[16] R.H. Striegel-Moore, C.M. Bulik, *Risk factors for eating disorders*, Am Psychol, 2007.

In individuals with organization of the Psychogenic Dietary Disorders type, in general, the situations of decompensation are determined following pervasive unpleasant sensations activated in the contexts of reciprocity that imply a judgment on oneself. The intense feelings of inadequacy, incapacity, personal inconsistency that emerge in social and affective interactions are modulated, through a modification of one's own body image. In some individuals, this practice takes the form of an exasperated control of one's body and an obsessive search for a perfect external image, both in physical form and in intellectual faculties.

The strategies implemented involve the domination of biological oscillations of hunger/satiety and fatigue/rest and the search for continuous confirmation of one's competence and the power to control one's body's needs. The distortion of the body image nullifies the cognitive discrepancy between a model of external beauty and its own corporeity which is characterized in reality by extreme emaciation and consumption.

In other individuals, aspects related to one's own inability to control prevail. In this case the psychopathological picture is dominated by passivity and the control of urges with compulsive and unruly behaviour. An ugly and unacceptable body represents the attempt to limit one's own experience of negativity and incapacity to external aspects: any refusal on the part of others is thus relativized only to aesthetic aspects, and exhibiting an ugly body facilitates the maintenance of a sense of self acceptable. The experience of refusal, disappointment or disconfirmation can be traced back to one's aesthetic unacceptability rather than the inability to be loved and approved.[17]

[17] V.F. Guidano, *Il Sé nel suo divenire*, Bollati Boringhieri, Torino, 1992.

The food symptom sometimes represents the only possible way to stabilize an identity that is defined exclusively through external references; the different degree of coherence and organization of one's personal identity differentiate clinical expression.[18] Food symptoms tend to occur on their own or in association with other disorders in a clinical continuum that varies from mild to psychotic forms.[19]

In some individuals, decompensation occurs with a different expressiveness of symptoms, which can range from anxiety disorders and obsessive-compulsive spectrum to those of mood, from somatoform disorders to those related to substance abuse and the control of impulses, to conduct disorders, to psychosexual ones, up to frankly schizophrenic and dissociative pictures.[20]

The premorbid peculiarities of patients with eating disorders are generally similar: timid, submissive, obedient, perfectionist children or adolescents competitive; conscientious and aiming to get the most out of every performance, they have an academic performance that is often above average. At times, on the contrary, we find temperamental characteristics of greater extroversion, with behavioural methods of an oppositional type and with a propensity to compete.

The "outward" peculiarities allow to better understand how a destabilizing experience can lead to a pathological change of narrative identity and what are the particular modalities of such transformation. Self-knowledge and the identification of one's own perceptions,

[18] G.Liotti, *Le opere della coscienza*, Raffaello Cortina Editore, Milano, 2001.
[19] Y. Iwasaki, H. Matsunaga, N. Kiriike, H.Tanaka, T.Matsui, *Comorbidity of Axis I Disorders Among Eating-Disordered Subjects in Japan*, Comprehensive Psychiatry, 2000.
[20] B. Nardi, *Processi psichici e psicopatologia nell'approccio cognitivo*, Franco Angeli, Milano, 2001.

emotions and opinions take place through the adhesion to the world of a significant other.[21]

In the most rigid and concrete forms, any external source can be used to define an internal state (for example, it is sufficient to note that the balance signals a few more grams to "feel fat"), and one's existence must be credited by the relationship with a significant person. The perception of non-correspondence with external expectations generates a sense of inadequacy and is accompanied by emotions of guilt and shame, while the absence of the other one corresponds to a sense of emptiness, disintegration and fragmentation.

The family context of patients with eating disorders is also fundamental. It is characterized by a scarce or a distorted explicit communication of the affections. Moments of understanding alternate with moments of detachment, and parental relationships oscillate back and forth between full approval and ruthless criticism. The affective style of the family determines, in these individuals, the structuring of peculiar modalities in the management of emotional relationships: on the one hand we are witnessing an exasperated search of a sincere feeling, which in the initial phases of relations they perceive in the partner, on the other is always present the expectation of disappointment. The experience of disappointment, on the part of a figure perceived first as an emotional reference and then, suddenly, inadequate with respect to expectations, triggers emotional reactions of distrust and anger that, while episodic and transient, are recurrent. For them, relational love is a central opportunity for personal approval and, therefore, the environment in which the most painful apprehensions of disappointment are poured.

[21] V.F. Guidano, *La complessità del Sé*, Bollati Boringhieri, Torino, 1988.

In order to confirm, even if unknowingly, their own inevitable disappointment expectations, they usually develop an interest in impossible or geographically distant objects of love, and generally valued in terms of fame, social success and / or personal security. The reports are characterized by the anguished search for absolute certainty of the partner's loyalty and affective security, in order to neutralize disappointment expectations; the strength of the relationship must be constantly strengthened through a constant request for reassurance and a series of continuous tests, aimed at confirming the expectations of understanding, trust and sincerity. The obsessive search for reassurances and the assiduous ones tested against the partner, if on the one hand they provide security and approval, on the other end up wearing down the emotional relationship, generating situations of profound conflict and rejection. A persistent and constant mental and emotional control is exercised on the partner: it is necessary to be sure of what the other tries and thinks about himself, since his judgment is connected to the definition of his own personal identity.[22]

1.4 Medical complications

Health problems during anorexia nervosa are relatively frequent, representing the consequences of:

- malnutrition, with poor nutrition both in quality and quantity of nutrients;
- excess food intake, in particular simple and complex fats and carbohydrates;

[22] D. Amoni, A. Caridi, *Strategie di controllo sul partner affettivo in pazienti fobici e con disordini alimentari in campo cognitivo*, in Chiari e Nuzzo, *Le prospettive comportamentali e cognitiva in psicoterapia*, Bulzoni Editore, Roma, 1982.

• the presence of elimination behaviors, in particular self-induced vomiting, improper use of laxatives and / or diuretics;
• an exaggerated physical activity.

Medical complications can affect all organs and systems. In particular, the consequences of malnutrition concern the cardiovascular system, the hematopoietic and immune system, the endocrine and metabolic system, the nervous system, the kidney, the osteo-skeletal system, the muscular system, the skin and annexes, the gastrointestinal system, the liver and pancreas, the respiratory system.

In general, the frequency and severity of medical complications are directly related to the intensity and duration of the eating disorder and, in most cases, are resolved after the restoration of adequate eating habits and / or the recovery of a normal body weight.[23]

During anorexia nervosa, organic changes can affect all organs and systems and are related to malnutrition by default and hydroelectrolyte disorders resulting from elimination behaviours. The main alterations to which the skin and its appendages may go are represented by dry and dystrophic skin, in colour yellow-orange, with hair that is diffuse but more evident on the back (lanugo), brittle and drooping hair, acne, perioral inflammatory lesions.

Less frequently, edema may be present, localized to the lower limbs or widespread, and subcutaneous emphysema in the neck (present only in the form of self-induced vomiting). The “sign of Russell” may appear, characterized first by redness and cutaneous erosion and then by calluses of the knuckles of the hands, all signs related to the rubbing

[23]F. Brambilla, P. Monteleone, *Physical complications and physiological aberrations in eating disorders: a review*. Wiley, 2003.

practiced on the area by the teeth and by the palate while trying to cause vomiting by introducing the hand into the mouth.

At the oral level there may be erosion of the dental enamel, caries, gingivitis, hypertrophy of the salivary glands, generally secondary to self-induced vomiting. Dental enamel erosion typically affects the inner surface of the teeth. At the level of the gastrointestinal system may occur oesophageal reflux, esophagitis, erosions and oesophageal ulcers with risk of perforation, hiatal hernia.

More frequently, the gastric wall can become atrophic-atonic, with delayed emptying of the stomach, and this is due to the sensation of fullness that patients experience following the ingestion of even small quantities of food when they start to feed again, which thing hinders the re-feeding process. There may be impairment of liver function, hepatomegaly and hepatic steatosis. In the forms with acute malnutrition by default, an increase in liver enzymes can be found (so-called fasting hepatopathy).

With regard to cardiovascular changes, sinus bradycardia (heart rate <60 beats per minute) and arterial hypotension (systolic pressure <90 mmHg and / or diastolic pressure <50 mmHg) are the most frequently observed and most precocious manifestations. They reflect energy savings resulting from decreased caloric intake.

At the level of the skeletal system osteopenia often appears at the beginning of the disease, osteoporosis follows, with consequent risk of bone deformation and fractures. This is due both to a decrease in bone formation and to an increase in bone resorption (consequent, among other things, to oestrogen deficiency and reduction of muscle mass). It has been reported that around 40% of patients with anorexia nervosa experience osteoporosis and 90% with osteopenia.

Young women who have suffered from anorexia nervosa seem to have greater difficulty with conception and a maternity rate of 70%

of healthy women. Women with eating disorders may more often have perinatal complications and appear to be more at risk of postpartum depression. With the recovery of a correct and healthy diet and with the abandonment of the conduct of compensation, almost all of the aforementioned medical complications are resolved.[24]

However, some of them tend to remain even after recovery. These include the "Russell's sign", the dental alterations and the hypertrophy of the salivary glands in the form with self-induced vomiting, atony-atrophy and delayed gastric emptying, osteoporosis and bone deformations, blockage of statural growth.

Of importance are the complications associated with re-feeding, which can be very serious and potentially deadly. In particular, the "refeeding syndrome", which occurs when the malnourished patient is subjected to a rapid reintroduction of liquids and nutrients through the natural pathway or artificial nutrition. In most cases the manifestations of the syndrome are mild (i.e. a transient edema of the feet and legs), but in some cases serious complications may occur, such as alterations of the QT tract of the electrocardiogram, confusional state, progressive neuromuscular dysfunction and collapse cardiovascular. The risk of developing refeeding syndrome is directly related to the extent of weight loss and the rapidity of the weight recovery process. The syndrome can be prevented by planning nutritional recovery with a calorie intake strictly corresponding to energy expenditure, avoiding a rapid increase in daily caloric intake and establishing careful monitoring from both a clinical and biochemical point of view.

The presence of medical complications can give rise to various signs and symptoms:[25]

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[24] F. Brambilla, C. Segura-Carcia, S. Fassino, et al., *Olan-zapine therapy in anorexia nervosa: psycho-biological effects*. Int. Clin. Psychopharmacol, 2007.
[25]F. Brambilla, C. Segura-Carcia, S. Fassino, et al., *Olan-zapine therapy in anorexia nervosa: psycho-biological effects*. Int. Clin. Psychopharmacol, 2007.

Table 1.1 Signs and symptoms in anorexia nervosa

Signs	Symptoms
Hypothermia	Amenorrhea
Bradycardia (<60 beats per minute)	Weakness
Hypotension (systolic pressure <90 mmhg)	Dizziness
Fatigue	Abdominal Pain
Dry skin	Polyuria
Brittle hair	Intolerance to cold
Brittle nails	Constipation
Hair loss	Polydipsia
Yellow-orange skin (especially on the palms of the hands and soles of the feet)	
Lanugo (hair)	
Edema (around the eyes and ankles)	
Cardiac Murmured (due to mitral valve prolapse)	

1.5 Clinical courses and outcomes

There is talk of remission when the person no longer meets the diagnostic criteria for an eating disorder, has not had fasting episodes, bingeing or purgative in the last 3 months and has a body mass index of at least 18.5 kg / m2.

In anorexia nervosa, the remission rate is 20-30% after 2-4 years from onset and 70-80% after 8 or more years. In 10-20% of the cases a chronic condition is ignited that persists for the whole life, seriously damaging the interpersonal ego and the scholastic or working career.

Favourable prognostic factors are the young age which implies a shorter duration of illness, as well as the presence of a good pre-existing social and work adaptation. Dosing of a chronic disorder and rigorously studied for relatively short time compared to other psychiatric illnesses, studies exempt from methodological limitations are rare: the follow-up period is generally too short, and the number of items found is insufficient. In about half of the cases treated remain residual symptoms or psychopathological sequelae, for example, such as the presence of depressive symptoms, obsessive-compulsive personality traits and drug addiction. The most frequent causes of death are malnutrition and electrolyte imbalance, more rarely suicide.

While, unfavourable prognostic factors are the presence of coexisting medical or psychiatric problems., a marked amount of weight loss, a serious disturbance of the body image, the obstinate denial of disease.

About 30% of patients present a change to bulimia nervosa or a feeding disorder not otherwise specified, usually within the first 5 years after the onset of the disease. The risk of death for a person diagnosed with anorexia nervosa is 5-10 times greater than that of healthy subjects of the same age and sex. Despite the normalization of body weight, abnormalities in the dietary pattern can remain and the relationship with food can remain altered for a long time, with caloric restrictions, constant concern for weight, bulimic crises.[26]

[26] B.G.Bara, *Manuale di psicoterapia cognitiva,* Cap. XIV: *UN APPROCCIO COSTRUTTIVISTA AI DISTURBI DEL COMPORTAMENTO ALIMENTARE,* a cura di S. Blanco, L. Canestri,M.A.Reda, Bollati Boringhieri, 1996.

Chapter 2

Model for the management of therapy in the treatment of eating disorders

2.1 The modern multidisciplinary approach

In recent years significant progress has been made in the management of eating disorders with the development of psychological treatments that have proven their effectiveness in numerous clinical trials and with the implementation of a model of care based on two general principles: multidisciplinary management and the multiplicity of care contexts.[27]

Eating disorders are complex pathologies that require management carried out by a multidisciplinary team, able to carry out a multidimensional diagnostic evaluation (psychiatric, psychological, internal and nutritional) and that can propose treatment models capable of dealing with psychopathology specific of the disorder and the associated psychiatric, internal and nutritional comorbidity.

Treatment can be managed by a single therapist, if some specific outpatient psychological treatments are applied for evidence-based eating disorders (such as improved behavioural therapy and interpersonal psychotherapy), or by multiple analysts if the presence of comorbidity related with the psychopathology of eating disorders or if

[27] L. M. Donini, M. Cuzzolaro, G. Spera, M. Badiali, et al, *Obesity and Eating Disorders. Indications for the different levels of care. An Italian Expert Consensus Document. Eating and Weight Disorders*, 2010.

the patient is treated with intensive care modalities. In any case, it is proper that the patient, even if she/he is following an individual evidence-based psychological treatment, is periodically seen by the case manager or another team member to assess the progress of the treatment, the presence of any comorbidities that require interventions additional (e.g. nutritional, psychiatric, internal medicine) and the need to implement more intensive treatments.

The multidisciplinary intervention has never been tested in randomized controlled trials and, although it is inevitable in severely malnourished patients and in intensive care settings (e.g. hospitalization or day hospital), it has advantages and disadvantages.

The major advantage of the multidisciplinary approach is the presence of clinicians with multiple skills. They can facilitate the evaluation and management of complicated patients with serious medical and psychiatric problems coexisting with the eating disorder.

The disadvantages can be divided into two main categories of problems.

First, treatment with multiple therapists encourages the patient to share her/his condition and talk about specific problems with specific therapists. The result is that often none of the therapists observes and appreciates the patient's entire clinical picture. Second, the administration of a treatment by therapists who share their knowledge without a shared theoretical and clinical model facilitates the administration of contradictory information to patients about their disorder and strategies to deal with it. This can create confusion in patients about issues to be addressed in order to overcome the eating disorder and develop the sense of not being in control during treatment.

Furthermore, it can increase the risk of divisions and conflicts between team members who may have different beliefs about how to treat and the problems that must be addressed; the division and conflictuality of the team can be used by patients to increase their

resistance to treatment. Finally, they are difficult to evaluate, replicate and disseminate treatment models.[28]

To avoid the problems described above it is desirable that the entire team receive training on the model of treatment applied and it is essential that therapists, while maintaining their specific professional roles, share the same philosophy and use a common language with patients. It is also essential to plan team meetings to improve team cohesion, formulate the objectives of the treatment, develop the knowledge of each patient, clarify the roles of the various therapists, monitor fidelity to care protocols, share knowledge and updates on eating disorders.

It can also be useful to plan supervisions with external experts to update the team on the most modern strategies and procedures for the treatment of eating disorders, to check whether the applied intervention areas are coherent and pursue common goals and to share and process the experiences of individual operators. Finally, it is desirable to develop a computer system to collect the patient's clinical data to assess the short and long-term outcomes of the intervention, an essential condition to understand the strengths and weaknesses of the treatment applied and to make improvements to the pathways of care.

2.2 Levels of intervention

Generally, the ideal place for the treatment of eating disorders is the ambulatory context because it does not interrupt the life of the patient and the changes made tend to persist because they are achieved by the patient in his usual environment of life. Unfortunately, around

[28]R. Dalle Grave, *La Terapia Cognitivo Comportamentale Multistep dei Disturbi dell'Alimentazione. Teoria, Trattamento e Casi Clinici*. Eclipsi, 2015.

30% of patients do not respond to outpatient treatment and need more intensive care. For this reason it is necessary to develop a network system that envisages a step-by-step approach in which the majority of patients should start the therapeutic path at the least intensive level of care and access the most intensive treatments in case of failure to improve, according to a model in successive steps.[29]

In Italy, five levels of intervention are available in the treatment of eating disorders:

- First level: general practitioner or freely chosen paediatrician;
- Second level: specialist outpatient therapy;
- Third level: intensive outpatient therapy or day centre or day hospital (diagnostic / therapeutic / rehabilitative);
- Fourth level: intensive residential rehabilitation (code 56 or ex art. 26);
- Fifth level: H24 admissions (ordinary and emergency).[30]

Moreover, the care network must be articulated both longitudinally and transversally. Longitudinally, because a patient may need, during the course of the eating disorder, heterogeneous care modalities in relation to the course of the disease and the presence of international and / or psychiatric complications.

Transversely because the patient with eating disorders, in relation to the degree of comorbidity-fragility-disability, can benefit from one or the other node of the care network.

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[29] NICE (National Institute for Clinical Excellence), *Eating disorders: Core interventions in the treatment and management of anorexia nervosa, bulimia nervosa and related eating disorders*, London, 2004.

[30] Ministero della Salute, *Appropriatezza clinica, strutturale e operativa nella prevenzione, diagnosi e terapia dei disturbi dell'alimentazione: Quaderni del Ministero della Salute* 17/22, 2013.

2.3 Identification of new cases

Available studies indicate that less than half of cases of eating disorders are identified at primary care level. Nevertheless, patients with eating disorders consult their family doctor frequently before being diagnosed for a wide variety of gastrointestinal, gynaecological and psychological symptoms that could, if accurately assessed, lead to suspect a diagnosis of a supply.

The doctors at the first level of care are in a good position to identify the patients presenting the prodromes or the first symptoms of the eating disorder. The use of some simple screening questionnaires can facilitate this process, but the most effective tool is that the doctor ponders about the possibility that the patient may have an eating disorder. In concrete terms, it is not practical or convenient for the general practitioner to screen for eating disorders in all his patients, because their prevalence in the general population is low. Instead, it is more useful to screen each new patient with a couple of questions during the medical history collection - for example: “Do you think you have a food problem?” And “Do you worry too much about the weight and shape of your body?”. If the patient answers in an affirmative way to one of these two questions, the doctor should ask, in an empathic and non-judgmental way, which behaviours he adopts to control the weight and shape of the body.

The high-risk groups that the general practitioner and the paediatrician should monitor are adolescents (<16 years) and patients with one or more of the following characteristics: low or high BMI, concerns about body weight and shape, menstrual disorders or amenorrhea dyspeptic symptoms and psychological problems. The warning signs that can make the doctor suspect the presence of an eating

disorder are the presence of important weight loss, the unreasonable fear of gaining weight, concerns about body weight and shape, the adoption of dietary rules extreme and rigid, particularly when these manifestations are associated with mood changes, social isolation, anxiety, gastrointestinal disorders.

Once the suspicion of a possible eating disorder has been confirmed, the general practitioner should assess the patient's physical risk through a thorough physical examination and the prescription of biohumoral and instrumental tests.

The physical examination should include:

- Weight and height measurement. The weight loss rate in the last three months is an important indicator to evaluate and a weight loss> 1 kg a week for several weeks can set the indications for an urgent hospitalization;
- Measurement of heart rate and blood pressure. The presence of marked bradycardia (eg <50 per minute) and severe hypotension (eg maximum arterial pressure <80 mmHg) indicate the presence of physical risk. Postural hypotension is often present;
- Body temperature measurement. Malnourished patients generally have cold hands and feet and a body temperature below 36 ° C;
- Examination of the extremities: the presence of acrocyanosis, palms of the hands and feet of yellow-orange colour and edema are signs of severe malnutrition;
- Cardiac auscultation: the presence of irregular heartbeats in a patient with eating disorder indicates the presence of physical risk.

Eating disorders are ego syntonic diseases: those affected do not often consider them as a problem and, especially in the early stages, they are happy with the weight loss achieved and their food control. In recent years, fortunately, specific interventions and procedures have been developed to encourage the motivation of patients suffering from eating disorders. The general practitioner should never criticize the patient for his/her behaviour, but help him/her in a non-judgmental way to analyse the meaning of his conduct, by assessing - in the short and long term - the advantages and disadvantages that has gotten from the weight loss and the benefits and costs that it could have from a possible change.

Other questions that can be helpful are the following: “I would like to understand what your current life is like ... How are things? You are happy? Can you do what other people do? Can you let yourself go and be spontaneous? Is there anything you'd like to be different? ... Really? Have you considered all things?”

The motivational interview must be accompanied by an educational intervention by informing the patient in a scientific and non-terrorist way of the medical and psychological risks of his disorder, of the available therapeutic options and of the positive results they can achieve. The general practitioner and the paediatrician should agree and have the possibility to easily communicate with the reference centres of eating disorders to request a specialized assessment, if they have verified the presence or suspicion of an eating disorder in their patient.

In case the management of the patient with eating disorder is shared between the general practitioner and the secondary care centre, a clear agreement must be made between the professionals who have the responsibility to monitor and manage the physical risk of the patient. This agreement should also be shared with the patient and his family.

The general practitioner, in any case, should reinforce the patient to engage and to be persevering in following with commitment the specialized treatment undertaken. It is also desirable that periodic contact should be maintained between the specialist and the general practitioner if the patient has poor adherence to the treatment. During the remission from the feeding disorder, the patient can arrive at the observation of the general doctor and the paediatrician. In these cases, the physician should monitor the weight, eating behavior and attitudes towards the weight and shape of the patient's body and, if signs of reactivation of the eating disorder re-emerge, encourage him to deal with them promptly to avoid relapse.

2.4 Specialized outpatient therapy

Specialized outpatient therapy must be managed by a multidisciplinary team that allows performing a multidimensional diagnostic evaluation (as above cited) to assess the most appropriate level of intervention for the patient and to manage any comorbidities associated with eating disorders. It is the ideal place to apply the currently available evdence-based therapies.

The role of drugs in the treatment of eating disorders is limited. For anorexia nervosa there are no empirically supported pharmacological treatments, although numerous drugs have been tested, such as antidepressants, antihistamines and recently atypical antipsychotics. however, none has been shown to have a useful clinical effect in improving the psychopathology of eating disorders.[31]

[31] P. Hay, D. Chinn, et al., *Royal Australian and New Zealand College of Psychiatrists clinical practice guidelines for the treatment of eating disorders*, Aust N Z J Psychiatry, 2014.

The situation is different for bulimia nervosa, where antidepressants, especially fluoxetine at 60 mg a day, produce a decrease in the frequency of binge episodes, although it is not clear whether this effect is lasting.[32]

Peculiar is the drug use for the case of the binge-eating disorder. It is an eating disorder not well defined in medical terms, but generally could be delineated as "eating significantly more food in a given period of time than most people would eat at the same time and in similar circumstances". [33] Numerous drugs (e.g. selective serotonin, topiramate and bupropion reuptake inhibitors) have been shown to be superior to placebo in reducing short-term binge episodes.[34] There are no studies showing the long-term efficacy of drug therapy for binge-eating disorder. Topiramate is the only drug that has shown positive effects both on improving psychopathology and on short-term weight loss, but its important side effects limit its clinical application. In the USA lisdexamfetamine dimesilato (a drug not available in Italy) has recently been approved for the treatment of binge-eating disorder based on the positive results obtained from the drug in the reduction of binge eating episodes in three randomized controlled trials of "only" 12 weeks of treatment.[35] The drug is a stimulant that is not indicated for weight loss and has a high risk of abuse / dependence.

The main evidence-based treatments for eating disorders, whose efficacy has been demonstrated by rigorous randomized controlled

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[32] NICE (National Institute for Clinical Excellence), *Eating disorders: Core interventions in the treatment and management of anorexia nervosa, bulimia nervosa and related eating disorders*, London, 2004.
[33] https://studicognitivi.it/disturbo/binge-eating-disturbo/.
[34] K. A. Brownley et al., *Binge-Eating Disorder in Adults: A Systematic Review and Meta-analysis.* Ann Intern Med, 2016.
[35] S. L. McElroy, J. I. Hudson et al., *Efficacy and safety of lisdexamfetamine for treatment of adults with moderate to severe binge-eating disorder: a randomized clinical trial*. JAMA Psychiatry, 72(3), 235-246.

trials, are psychological in nature and have been designed primarily to be administered on an outpatient basis.

This disorder, originally described as "intractable", can be successfully treated by a specific form of cognitive behavioural therapy (CBT-BN), developed at Oxford University by Fairburn and collaborators. CBT-BN was the first psychological treatment (for any condition) recommended as a first-choice intervention with level of evidence "A" by the NICE guidelines and subsequently by many other national guidelines. [36]

There is an emerging body of research on the treatment of binge-eating disorder. Studies show that an adaptation of CBT-BN and interpersonal psychotherapy (IPT) produce short- and long-term reductions in binge eating and psychopathology associated with the disorder, but do not have a significant effect on weight loss. On the other hand, behavioural treatment for weight loss (BWL) produces a reduction in binge eating associated with modest weight loss. Promising results on the reduction of binge episodes, but not on weight loss, have also been obtained from guided self-help based on manuals derived from CBT-BN. [37]

However, recently CBT-BN has been superseded by an improved transdiagnostic version of the treatment, called CBT-E, which was designed to address all diagnostic categories of eating disorders. The treatment, conducted by a "single therapist", addresses the common maintenance mechanisms that reflect the clinical reality of a shared and evolving psychopathology of eating disorders, not the DSM diagnosis, and is individualized to address the psychopathology

[36] NICE (National Institute for Clinical Excellence), *Eating disorders: Core interventions in the treatment and management of anorexia nervosa, bulimia nervosa and related eating disorders*, London, 2004.
[37] K. A. Brownley et al., *Binge-Eating Disorder in Adults: A Systematic Review and Meta-analysis.* Ann Intern Med, 2016.

operating in the individual patient. Treatment appears to be more potent than CBT-BN and results in a complete remission of the psychopathology of eating disorders in about two thirds of non-underweight patients (i.e. those suffering from bulimia nervosa, binge-eating disorder and other eating disorders) that have an average duration of the disorder of nine years. Similar results have been obtained in observational studies performed in clinical settings of the real world. Finally, CBT-E was more effective in determining remission of binge episodes following treatment and follow-up of IPT and psychoanalytic psychotherapy.[38]

There are few studies on the treatment of adults with anorexia nervosa. In part this is due to logistical problems, including the relative rarity of the disorder and the need to perform long term treatments. Some treatments, however, have some evidence of efficacy such as CBT, CBT-E, interpersonal cognitive therapy (MANTRA), focal psychodynamic psychotherapy (PP) and specialist clinical supportive management (SSCM), a combination of education, management general clinic and supportive psychotherapy. [39]

The ANTOP study compared an enlarged form of CBT-E with PP and an optimized "usual care" (UC) intervention.[40] At the end of the treatment the body mass index improved significantly in all three groups, without differences. The same thing happened at 12 months of follow-up, where the IMC continued to increase in parallel in the three groups.

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[38] C. G. Fairburn, et al., *A transdiagnostic comparison of enhanced cognitive behaviour therapy (CBT-E) and interpersonal psychotherapy in the treatment of eating disorders*, Behav Res Ther, 2015.

[39] P. Hay, D. Chinn, et al., *Royal Australian and New Zealand College of Psychiatrists clinical practice guidelines for the treatment of eating disorders*, Aust N Z J Psychiatry, 2014.

[40] S.Zipfel, *Focal psychodynamic therapy, cognitive behaviour therapy, and optimised treatment as usual in outpatients with anorexia nervosa (ANTOP study): randomised controlled trial*, Lancet, 2014.

Nevertheless, the study has two important limitations. The first concerns internal validity, because the treatment administered differs substantially from CBT-E and the therapists have not received training or supervision from experts in the CBT-E. The second concerns the way in which patients were treated during the therapeutic course; approximately one third of patients were in fact hospitalized for a long period and included in the outcome, which does not allow to evaluate the effectiveness of the individual psychological treatments applied and to use the results of the study as a guideline for the choice of therapies by of clinicians.

Then, The SWAN Study. It is a randomized controlled trial that compared CBT-E, MANTA and SSCM. Patients allocated to CBT-E achieved a significantly higher average BMI compared to SSCM and MANTRA both at the end of treatment and at 6 and 12 months of follow-up .[41] The percentage of patients who reached a healthy weight at 12 months of follow-up was about 50% in those treated with ka CBT-E and less than 30% in those treated with SSCM and MANTRA. The results obtained by the SWAN Study replicate those of the UK-Italy study which assessed a court of adult patients suffering from anorexia nervosa treated at Oxford, Leicester and Verona.

Another noteworthy case is research on the treatment of adolescents. It focused mainly on anorexia nervosa. The only evidence-based treatment available is family-based therapy (FBT) or "Moudsley Method". FBT is a "complex" treatment that requires the involvement of the patient and parents and is administered by a therapist (psychologist, child neuropsychiatrist) and a co-therapist, a pediatrician, who sees patients weekly, and hospitalization in about 15% of cases. FBT has a good evidence of efficacy and reaches a full

[41] S. Byrne, *Principal outcomes of the SWAN Study: A randomized controlled trial of three psychoological treatments for anorexia nervosa in adults*, Taormina, 2015.

response in about 50% of cases.[42] Unfortunately, FBT is not acceptable to some families and patients, it is expensive, more than half of patients do not respond to them and many adolescents have feeding disorders of clinical severity other than anorexia nervosa. These limitations indicate that it is necessary to develop alternative treatments for adolescents. A possible candidate is CBT-E adapted for adolescents. Two studies carried out in Italy have in fact shown that this treatment can be used in adolescents with promising results both in those suffering from anorexia nervosa and in non-underweight nutrition.[43] A study that directly compares the two treatments would be of great clinical utility, especially to evaluate the moderators of remarried treatment that could emerge allocating patients to these two very different treatments between them.

It is important to have a distinction for the case of severe and long-lasting anorexia nervosa. Long-lasting anorexia nervosa is associated with important medical complications, such as osteoporosis, cardiovascular abnormalities and structural alterations of the brain, high levels of disability that damage work capacity, quality of life, reduced life expectancy and higher mortality than any mental illness. It also constitutes an important objective load for family members and represents a high cost for the National Health Service. Outcome studies on anorexia nervosa have shown that a longer duration of the disorder before treatment is a negative prognostic factor, but few data are available on how patients respond to evidence-based psychological treatments, such as CBT or FBT.

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[42] J. Lock, et al., *Randomized clinical trial comparing family-based treatment with adolescent-focused individual therapy for adolescents with anorexia nervosa*. Archives of General Psychiatry, 2010.

[43] R. Dalle Grave, et al., *Enhanced cognitive behaviour therapy for adolescents with anorexia nervosa: an alternative to family therapy?* Behaviour Research and Therapy, 2013.

Though, some clinicians, have suggested that the ambivalence of patients with severe and long-lasting anorexia nervosa intertwined with their lasting psychopathology may not make them suitable for healing-oriented treatments such as CBT or FBT. In some countries, such as the US, treatment of patients with severe and long-lasting anorexia nervosa is refused by health insurance and some specialist clinical services in the UK send these patients to general psychiatric services or palliative care.

Some clinicians, taking into consideration the difficulties posed by the treatment of severe anorexia nervosa and long duration, have recently proposed a new paradigm suggesting to move from a model of treatment based on healing to one that does not focus on weight recovery, but on the maintaining the patient in contact with clinical services, improving the quality of life, minimizing damage and preventing further therapeutic experiences of failure.[44]

A recent randomized controlled study compared two psychological treatments (CBT and SSCM) adapted for patients with severe and long-lasting anorexia nervosa (defined thus when the disorder had lasted for more than seven years). They had the primary objective of improving patient quality, rather than reducing symptoms (Touyz et al., 2013). Both treatments resulted in a significant improvement in psychopathology and a low drop-out rate (about 15%), despite the minimal increase in body mass index. Patients treated with adapted CBT showed at the 12-month follow-up a lower psychopathology of the eating disorder and greater willingness to heal than those treated with the adapted SSCM.

Contrary to this perspective, some clinical reports have reported that, even after many years of anorexia nervosa, some patients may

[44] P. Hay et al., *Treatment of patients with severe and enduring eating disorders*. Curr. Opin. Psychiatry, 2015.

achieve complete recovery. Furthermore, studies performed in Italy have shown that patients with severe and long-lasting anorexia nervosa treated with intensive hospital rehabilitation have the same drop-out and short-term and long-term improvement in weight (approximately 67% have a BMI> 17) and psychopathology one year after discharge, with a cure rate of about 33%. [45]

Italian data indicate that treatment intensification and rehabilitative hospitalization can be an effective strategy even for patients with long-term severe anorexia nervosa. With treatments not focused on weight recovery, mainly aimed at taking care of patients and improving their quality of life, they should be considered only after the repeated failures of hospital outpatient and rehabilitative treatments well administered and not only based on the duration of the eating disorder.

Currently, one of the crucial points for the cure/treatment of an eating disorder is the involvement of parents or partner or other significant persons. With the consent of the adult patient, it should be considered in two cases: (I) if they can help the patient in making some changes (e.g. helping him/her to manage the meals and daily difficulties) and (II) if they make change difficult (e.g. because they make critical comments about the patient's eating habits or physical appearance). If other significant people are involved, it must be explained to them, possibly in the presence of the patient, the rationale of psychotherapeutic and nutritional intervention, what they are trying to do at the moment, paying close attention to their point of view, answering their questions and facing the problems that emerge. Then it should be discussed how they can help. The help of other significant

[45] S. Calugi, et al., *Intensive enhanced cognitive behavioural therapy for severe and enduring anorexia nervosa: A longitudinal outcome study.* Behaviour research and therapy, 2017.

people, which must always be agreed and accepted by the patient, varies from case to case and can be provided in the management of meals, in creating a peaceful and warm family environment, avoiding critical, hostile comments and excessive control or in moments of crisis.

According to the Ministry of Health, parental involvement in the treatment of adolescent patients is always advisable for the following reasons:

- Parents have the responsibility and the right to make important decisions regarding the treatment of their adolescent children and such treatment cannot be started without their informed consent;
- Controlled studies have provided some empirical evidence of how family involvement represents a positive factor for the treatment of anorexia nervosa in adolescents;
- Some data indicate that the parents' reaction to the symptoms of a teenager with an eating disorder can positively or negatively influence the outcome of the treatment;
- Parents may be involved in the treatment to provide assistance to adolescents during meals;
- Parents can create an environment that facilitates adolescent change.

In general, it is advisable to always have a meeting only with the parents to evaluate the family environment. In particular: (I) their knowledge of general eating disorders; (II) the presence of dysfunctional interpretations of the patient’s disturbed eating behaviour (e.g. thinking that the eating disorder is self-condemned or a form of self-destruction resulting from their poor parenting skills); (III) the presence of dysfunctional reactions to the patient's disturbed eating behaviour; (IV) the effects of their reactions on patient behaviour; (VI)

the presence in the home environment of stimuli that promote diet and increase concern about body weight and shape.

Parents should then be educated about eating disorders and treatment and, depending on the type of therapy performed, their role may be central in helping the daughter or child to eat meals, as is provided by the FBT, or support to apply some treatment procedures, as envisaged by CBT-E. In any case, regardless of the therapy model implemented, it is recommended that parents help to avoid reactions characterized by a high level of expressed emotion, such as critical comments, hostility and emotional hyper-involvement, and increase those characterized by low expressed emotion, such as positive comments, because the high emotion expressed is associated with an increase in the drop-out rate and a worse response to treatment.

2.5 Intensive outpatient therapy or day centre or day hospital

Intensive outpatient therapy, which can also be administered in a day center or day hospital, is a treatment for patients who do not respond to conventional outpatient treatment.

Treatment is indicated for patients who have difficulty changing their eating habits with standard outpatient therapy. Examples include underweight patients who cannot recover weight or patients who are not underweight with high frequency of binge eating and self-induced vomiting who are unable to change eating habits after a few weeks of treatment. In rare cases the treatment can be indicated as the first form of treatment. Examples include patients with long duration of the eating disorder who have not responded to numerous well-conducted outpatient treatments; underweight adolescent patients who cannot receive parental support during meals; patients who openly affirm

during diagnostic assessment meetings that they will not be able to cope with meals without assistance.

Intensive outpatient therapy is contraindicated in patients with moderate-to-severe physical risk, who make improper use of continuous substances, with major depression associated with suicidal risk and acute psychosis.

Unlike rehabilitative hospitalization, which aims to achieve weight normalization and maximum change in specific psychopathology (e.g. normalize weight and decrease excessive evaluation of body weight and shape), intensive outpatient therapy it should be used to address specific obstacles to standard outpatient treatment (e.g. inability to address caloric dietary restriction and weight recovery or to reduce the frequency of bulimic episodes, self-induced vomiting and excessive and compulsive exercise). Once these obstacles have been successfully addressed, treatment can continue with standard outpatient therapy.

Outpatient therapy should preferably be administered in a specialized outpatient centre for the treatment of eating disorders. An outpatient setting is preferable to the day-hospital hospital setting for lower management costs and to create an unmedicated environment that helps patients feel at ease, like at home. The centre should be equipped with clinics for psychotherapy and medical examinations, a kitchen (with gas stove, microwave oven, refrigerator with a large freezer and a dishwasher), a dining room to implement assisted feeding (which can be the same kitchen), a recreation room with TV, computer, internet access and furniture to study.

Intensive outpatient therapy is administered by a multidisciplinary team composed of doctors, psychologists and dietitians. The dietician prepares and assists patients during the meals consumed in the clinic and helps patients plan the weekend and review

the problems encountered in meals consumed outside the clinic. The psychologist administers psychotherapy and the doctor manages the possible medical and psychiatric comorbidity.

The general organization of the treatment is well defined. It can last up to a maximum of 12 weeks but can end much earlier if the patient successfully addresses the key factors responsible for poor progress with standard outpatient therapy. In order to maximize opportunities to implement assisted feeding, patients should attend the surgery during weekdays from 1:00 pm to 8:00 pm and treatment should include a similar combination of the following procedures that are adapted based on resources available locally:

- Three meals a day (lunch, snack and dinner). The food served depends on the resources available. However, modern technology allows the use of frozen or pre-packaged food that does not need to be manipulated. This food can also be provided to the patient for meals to be consumed outside the clinic. To help the patient expose himself to foods of uncertain calorie content and to situations involving social nutrition, it can be useful to accompany and assist the patient to eat the meal in a pizzeria, fast-food restaurant or restaurant during certain meals during the week;
- Two sessions of individual psychotherapy per week;
- Two sessions with the dietician the week;
- A medical visit a week;
- Meetings with significant others (if the adult patient consents - always with adolescents) - to discuss how to create a home environment that facilitates the patient's efforts to keep food changes out of the clinic.

In the final stages of intensive outpatient therapy, the patient should be encouraged to consume more and more meals out of the clinic and treatment gradually evolves into standard outpatient therapy.

Intensive outpatient therapy has some potential advantages over rehabilitative hospitalization for theoretical and economic reasons. The intervention structure and assisted meals can help patients overcome certain obstacles that prevent them from improving with standard outpatient therapy. The high relapse rate that occurs after admission is probably due in part to the fact that changes occur while the patient is in a protected hospital environment and partly due to treatment interruption that typically occurs after discharge. Neither of these two problems affects intensive outpatient therapy because the change occurs while the patient lives in his own home and the sessions continue with the same therapists when the treatment evolves into standard outpatient therapy.

To minimize the possible risk of deterioration, however, patients should gradually consume more and more meals and snacks outside the center. Finally, the costs of intensive outpatient treatment are significantly lower than admission. However, the treatment is not suitable for patients who are unable to adequately consume meals at home during the weekend.

2.6 Hospitalization for intensive rehabilitation

The rehabilitation of eating disorders is intensive, as the extensive rehabilitation used for other areas (e.g. geriatric, orthopaedic...) does not allow the necessary multidisciplinary approach and intensity of care (at least 180 minutes / day). Intensive rehabilitation

can be provided in a day-hospital regime where feasible from the logistic point and if the general conditions of the patient allow it, or under intensive hospital rehabilitation.

Intensive rehabilitation is indicated when:

- The level of severity and comorbidity is high.
- The impact on disability and quality of life of the patient is heavy.
- The interventions to be implemented become numerous and it is opportune - for both clinical and economic reasons - to concentrate them relatively quickly according to a coordinated project (case management) (Guidelines of the Ministry of Health for Rehabilitation activities - Official Journal of 30 May 1998, n ° 124).
- Previous pathways of lesser intensity have not yielded the desired results and the risk for the patient's state of health tends to increase.

Specifically, there are four situations that indicate the need for hospital rehabilitation: (I) failure to respond to outpatient treatment conducted according to current guidelines; (II) the presence of physical risk that makes outpatient treatment inappropriate; (III) the presence of psychiatric risk that makes outpatient treatment inappropriate; (IV) the presence of psychosocial difficulties that make outpatient treatment inappropriate.

Intensive rehabilitation is contraindicated in patients with high physical risk conditions, improper use of continuous substances, major depression with suicidal risk and acute psychosis.

Intensive hospital rehabilitation must be carried out in a department specializing in the treatment of eating disorders that can provide the patient with a rehabilitation program that integrates nutritional,

physical, psychological and psychiatric rehabilitation. In Italy these facilities have been developed both in intensive nutritional rehabilitation departments and in psychiatric rehabilitation departments. The ward should be “open” to allow the patient to be exposed to environmental stimuli that contribute to maintaining his eating disorder.

The treatment should be administered by a multidisciplinary team made up of doctors (internists, clinical nutritionists, psychiatrists), psychologists, dieticians, physiotherapists, educators, nurses and socio-cultural operators.

The hospital rehabilitation treatment must last long enough to allow the normalization of body weight, the improvement of the specific psychopathology of the eating disorder and any associated general psychopathology. These goals are generally achieved in around 90 days. It is useful to follow the rehabilitation hospitalization with a period of day-hospital to allow patients to experience exposure to environmental stressors, to gradually consume meals outside the ward and at the same time continue to have the support of an intensive care.

The diagnostic evaluation of patients admitted to intensive hospital rehabilitation departments must be multidimensional and include the assessment of the nature and severity of the psychopathology of the eating disorder, of general psychopathology and of physical distress.

The objectives and procedures of the rehabilitative hospital treatment must be set on the basis of the multidimensional diagnostic evaluation carried out upon entry and the drafting of the individual rehabilitation project.

The following could be an example of an individual rehabilitation project for patients suffering from eating disorders:

-*Current situation* (summary of the salient elements related to pathology, impairments and disability);
-*Overall outcome* (overall results expected in the long term, beyond the end of admission):

- Reaching remission from eating disorder;
- Achieve a clinical condition associated with minimal physical and psychosocial damage.

-*Functional outcome* (expected outcome at the end of admission, related to the complete set of parameters covered by the treatments provided during admission):

- To achieve an improvement in the clinical severity and related eating disorders that enable the patient's social, work / school reintegration and outpatient therapy.

- *Specific outcomes* (expected results in the short and medium term, relating to smaller or more discrete sets of parameters, for example referred to the recovery of a function):

- Achieve a Body Mass Index greater than 19 (in underweight patients). Maintain weight in the 3 kg range (in normal weight patients);
- Improve the specific psychopathology of the eating disorder (10% reduction to the Human Disorder Examination);
- Improve the clinical severity of the eating disorder (10% reduction in the Clinical Impairment Assessment).

- *Specific area of intervention:*

- Individual psychotherapy;
- List of objectives in order of priority. Increase awareness of eating disorders and tackle the main factors of maintenance of eating disorders;

- Two individual sessions the 50-minute week;
- Psychotherapist psychologists;
- Group psychotherapy;
- List of objectives in order of priority. Tackling the events and emotions that influence nutrition, addressing the excessive evaluation of body weight and shape.
- Two groups the 60-minute week;
- Psychotherapist psychologists;
- Psychoeducational groups;
- List of objectives in order of priority. Acquire knowledge on eating disorders, mechanisms to maintain the disorder and strategies to deal with them;
- Two groups the 60-minute week;
- Educators;
- Nutritional rehabilitation;
- List of objectives in order of priority. Address caloric and cognitive dietary restriction. Normalize body weight;
- Four meals a day;
- Dieters;
- Physical rehabilitation;
- List of objectives in order of priority. Optimize the recovery of lean mass;
- Medical gymnastics 30 minutes twice a week;
- Rehabilitation therapists;
- Management of medical / psychiatric complications;
- List of objectives in order of priority. Manage the medical / psychiatric complications associated with eating disorders;
- Daily medical tour. Pharmacological therapy;

- Internist-nutritionist doctors, psychiatrists.[46]

One of the most delicate circumstances after the therapy, is the relapse. Relapse after discharge is one of the main problems associated with residential rehabilitative treatment of eating disorders. This is due to numerous reasons including the nature of the hospitalization (which does not expose the patient to environmental stimuli to maintain the eating disorder), the persistent nature of the psychopathology of the eating disorder and the poor preparation of the patient for post-hospitalization.

As regards this last point, the research data indicate that the relapse rate after hospitalization is more likely to occur if the patient does not receive treatment after discharge, if post-hospitalization is conceptually very different from that received by the patient during hospitalization and if no major changes occur in the environment where the patient lives. These data indicate as a priority to organize a planned passage from the therapy carried out in the rehabilitation unit to post-hospital outpatient therapy in the referring referral centre. To this end, the rehabilitation unit must contact the referring referral ambulatory centre so that the patient can have the first appointment for an outpatient visit in the week following the date of discharge.

Since the research data indicate that the highest frequency of post-hospitalization relapses occurs in the first and second month after discharge, the referring referral outpatient centre, if its resources allow, must schedule bi-weekly visits in the first month after discharge or at least a weekly visit and a telephone or email contact between a weekly visit and the other.

[46] R. Dalla Grave, *Un modello di gestione clinica dei disturbi dell'alimentazione*, AIDAP, Associazione Italiana dell'alimentazione e del peso, 2017.

Adolescents (aged <18 years) should stay in rooms separated from adults and during exit permits, if authorized by their parents, must always be accompanied by an adult. For the entire day-hospital period, if they do not live in their family home, they must stay in private rooms or apartments with at least one parent or relative designated by their parents.

Adolescent treatment, in addition to the therapeutic procedures described for adult patients, should always include three additional procedures: family therapy, adolescent group and hospital school.

A controlled and randomized study conducted at Villa Garda, on 80 consecutive patients admitted with anorexia nervosa who had not responded to outpatient treatment, treated with intensive hospital rehabilitation based on CBT-E showed that about 90% of patients completed the treatment and more than 85% reached a normal weight level (BMI> 18.5) and over 50% the normalization of the specific psychopathology of the eating disorder assessed with the EDE interview.

At intent-to-treat analysis, the BMI increased from 4.3 (SD 1.7) to 18.9 (DS 1.5). The average BMI decreased to 17.8 (DS 2.2) at six months but stabilized at 12 months. [47]Weight loss, however, was limited only to adult patients and 73.9% of adolescents had normal weight 12 months after discharge. The improvement in the specific psychopathology of eating disorders and general psychopathology was maintained at six and 12 months of follow-up. These results indicate that intensive hospital rehabilitation is well accepted by patients suffering from severe forms of anorexia nervosa who have not responded to well intensive treatments and is effective in producing weight normalization and improving the psychopathology of eating

[47] R. Dalla Grave, *Un modello di gestione clinica dei disturbi dell'alimentazione,* AIDAP, Associazione Italiana dell'alimentazione e del peso, 2017.

disorders at the end of treatment in 85% of patients. After discharge there is a slight average weight loss, but this is confined only to adult patients.

2.7 Ordinary and emergency hospitalization

Ordinary hospitalization can be implemented in internist departments, for the medical stabilization and treatment of severe malnutrition, or in psychiatric wards, for the management of suicidal risk or psychiatric comorbidity and mandatory health treatments (TSO).

The ordinary hospitalization of medical stabilization is indicated in case the patient presents one or more "alert" parameters, while it must be evaluated case by case by the multidisciplinary team that has him in charge, when one or more parameters of "concern" are present. If possible, the patient should be hospitalized in internal divisions where beds are reserved for the management of feeding disorders, or where staff specialized in treating eating disorders are present.

Physicians and nurses working in these departments should receive specific training to manage both medical complications (eg refeeding syndrome) and some expressions of specific psychopathology of eating disorders (eg caloric restriction, excessive exercise and compulsive, elimination behaviors). Hospitalization in psychiatric diagnosis and treatment services should be limited to cases of extreme severity and to those where mandatory health treatment (TSO) is required. Even in these departments, operators should receive specific training to deal with food psychopathology and have close

contact with internist colleagues to manage any medical comorbidities present.

In ordinary or emergency hospitalization, if the patient refuses oral feeding or is unable to reach a nutritional goal adequate to overcome the phase of medical instability, an artificial feeding intervention of limited duration is indicated, aimed at stabilizing the conditions clinics. In these cases the informed consent of the patient or his delegate is required, according to the rules of the code of ethics. Enteral nutrition with a nasogastric tube is the first choice because, compared to parenteral nutrition, it is more physiological, safer, easier to manage.

However, along with enteral nutrition, a path of nutritional rehabilitation with natural foods is always proposed and encouraged.[48]

2.8 Implementation of the network of reference centers

In Italy, specific services for treating eating disorders are few and are not present in all health care companies and only a few regions have implemented a network of reference centers.

The regional network should include a regional coordination center that has the following functions:

- Regional epidemiological observatory on eating disorders. The observatory should assess the prevalence and incidence of eating disorders in the region in order to establish changes over time, provide reliable data to plan the programming of facilities dedicated to their treatment and assess the presence

[48] Ministero della Salute, *Appropriatezza clinica, strutturale e operativa nella prevenzione, diagnosi e terapia dei disturbi dell'alimentazione: Quaderni del Ministero della Salute* 17/22, 2013.

of potential factors environmental risks on which to intervene.

- Programming, coordination and evaluation of universal, selective and targeted prevention interventions. The center should plan and coordinate prevention interventions through relationships with schools, teachers and general practitioners;
- Coordination with basic medicine, specialist outpatient units, intensive rehabilitation units and ordinary hospitalization wards. The center should establish protocols shared with the various levels of care they include:
    - diagnostic evaluation tools to evaluate the psychopathology of the eating disorder, the associated general psychopathology, the degree of clinical damage and the outcome of the interventions;
    - implementation of evidence-based treatments in specialist outpatient units with the planning of training courses and periodic supervision of clinical cases.
    - indications and contraindications for treatment at various levels of care;
    - how to send to the structures of intensive rehabilitation and discharge from these facilities for continued treatment on an outpatient basis;
    - schedule regular meetings to optimize the functioning of the regional network.
- Coordination with family associations. Coordination should include sharing up-to-date information on eating disorders, their potential causes, available effective sharing treatments,

dissemination of information material, and management of contacts with the press and other media (television, internet);

- Research. The center should implement and coordinate research projects in the field of eating disorders.

The regional coordination center should also be a promoter of coordinating the network so that the principles and procedures of clinical governance are adopted, in which the various health organizations belonging to the network should be responsible for the continuous improvement of the quality of their services and the safeguarding of high standards of assistance through the creation of an environment in which excellence in health care can develop.

The dual objectives of clinical governance are the integrated promotion of quality care and efficiency, in relation to economic sustainability which should be achieved using the following tools:

- *Evidence-Based Practice (EBP).* It spreads the use of therapies with the best evidence of efficacy; integrates evidence into clinical care decisions;
- *Information and Data Management*. Improve the interaction and communication between the various company information systems, developing specific clinical databases;
- *Guidelines and Career Paths*. Develops methodologies for the local adaptation of guidelines and the construction of care pathways;
- *Health Technology Assessment*. It promotes the use of international models and reports to reorganize the management methods of health technology;
- *Clinical Audit*. Identifies the inadequacies and results resulting from the change process, in terms of process and outcome;

- *Risk Management*. Consider the error as a "defect of the system" and not of the individual professional and implement corporate clinical risk management programs;
- *Continuous training, professional accreditation*. Consolidates the culture of continuous training among health professionals, understood as an integral part of professional practice;
- *Research and Development*. It spreads the culture and tools of clinical research and health services among professionals, with particular emphasis on the development of independent research. Governing the methods of involvement of the Company and professionals in sponsored research, in order to guarantee their social utility, methodology, ethics and integrity;
- *Staff management*. It defines the management strategies of the teams to enhance human resources, in relation to the attitudes, knowledge and skills of each individual professional;
- *User participation*. Involve citizens in the evaluation and in the methods of providing services and health services.[49]

2.9 Problems to be addressed

The problems to be faced in Italy to be able to offer patients the guarantee of being treated with the best treatments currently available are many.

First, the clinical centers are distributed in Italy like a leopard, with some regions able to provide patients with all levels of care coordinated according to a network model of centers of references,

[49] https://www.aidap.org/2017/la-gestione-clinica-dei-disturbi-dellalimentazione/.

while in many others they are missing above all the most intensive care levels.

Secondly, the treatment options offered to patients suffering from eating disorders in existing clinical services depend on the resources available and the training received from clinicians. Although evidence-based psychological treatments are available, such as CBT-E, IPT and FBT, they are rarely given to patients or, when they are, therapists often deviate from the recommended protocol and forget to use some procedures, or omit them from purpose or introducing unexpected procedures In most cases eclectic treatments are administered in which generic psychotherapies of different nature are combined, not always coherently, with prescriptive and psychopharmacological nutritional interventions, mainly dictated by the training received from the various operators and not by a common theoretical model specific to the treatment of eating disorders.

Thirdly, in some clinical services there is an excessive emphasis on hospitalization, and it is common for patients to receive completely different treatments, both in terms of theory and content, when they pass from a less intensive form of care (e.g.. outpatient treatment) and a more intensive one (e.g. hospital rehabilitation treatment) and vice versa. This creates discontinuity in the care pathway and understandably confuses patients about the strategies and procedures to be used to deal with the eating disorder. Some shelter centres also have excessively long waiting lists.[50]

Finally, few clinical centres collect data on the outcome of short and long-term treatments. There is no single solution to these problems. An increase in resources dedicated to the treatment of eating disorders

[50] G. Waller, *Treatment Protocols for Eating Disorders: Clinicians' Attitudes, Concerns, Adherence and Difficulties Delivering Evidence-Based Psychological Interventions*. Curr. Psychiatry Rep, 2016.

could help. But perhaps a better use of those available could be an even more effective strategy. The primary objective to improve the current situation should be to be able to offer most patients well-administered treatment based on scientific evidence as soon as possible. Evidence-based therapies are inexpensive, because they are administered by a "single" therapist (CBT, IPT) or by two therapists (FBT) in 20-40 sessions, and determine, in 2/3 of the patients who complete the treatment (about 80%), a lasting remission from eating disorders. The advantages of these treatments, which include high levels of effectiveness and low costs, are, however, feasible only if the therapists have received adequate training, otherwise the response rates are drastically reduced.

In Italy, unfortunately, even therapists who specialize in treating eating disorders rarely receive training on evidence-based psychotherapies. For this reason, it is necessary to develop new training methods, such as, for example, post-university courses specifically designed to train therapists and get them the skills necessary to use these forms of psychotherapy. The courses should include the methods commonly used to train clinicians in controlled studies, such as the availability of a manual, the use of an interactive teaching approach, the observation of sessions carried out by experts and the practice of role-playing.

Patients who do not respond to outpatient interventions based on scientific evidence should be offered more intensive treatments such as day hospital or hospitalization in highly specialized referral centres. In these centres, a broad range of medical, psychiatric, psychological and educational procedures are generally offered which are not always consistent with each other and sometimes contradictory messages are provided to patients. To cope with this problem, it is desirable that even in intensive care centres patients are offered a coherent and non-

contradictory approach and that therapists, while maintaining their specific professional roles, share the same philosophy and adopt evidence-based interventions. These skills should be acquired through specific training programs that are added to the basic training path of the individual professional in his / her pertinent discipline.

After discharge, it is also indispensable, in order to limit the relapse rate that affects intensive treatments, to provide patients with an outpatient treatment that is not in contradiction with what was done during hospitalization.

Patients who do not respond to more well-administered outpatient and intensive treatments may consider administering interventions that have the primary objective of improving quality of life, rather than reducing symptoms. This decision must, however, be taken with caution, because patients, even with a long duration of the eating disorder, if actively engaged in the treatment can achieve remission or in any case a significant improvement in their psychopathologies and their nutritional status.

Finally, it is desirable to be able to devote more resources to research to develop more powerful and effective treatments for all eating disorders than those currently available.

Chapter 3
Prevention:
at what level is it possible?

2.1 When prevention is effective

Eating disorders scholars have asked themselves whether prevention of food behavior disorders is possible. There are many questions about the possibility of prevention and the answers are not unambiguous. Despite the numerous and in-depth studies in the field of Food Behavior Disorders and possible causes what is known is that there is no single cause and that multiple factors combine to predispose, precipitate/trigger and then perpetuate the disorder.

Is prevention effective in case of eating disorders?

Some authors believe that giving information about eating disorders can even be counterproductive and harmful. The risk may be to indicate to those children who are experiencing difficulties or discomfort the “way out”, a way that is followed through processes of imitation and identification since, in effect, that for some people anorexia and, in less bulimia, are idealized conditions. Hence, it is good to be wary of preventive programs based only on information regarding these disorders.

On the contrary, many studies have instead found that interventions that stimulate discussion and the development of a greater critical sense towards mass-media messages can be useful.

These types of interventions do not deal exclusively with Anorexia and Bulimia, but also include different adolescent problems (especially problems with the body, self-esteem and interpersonal difficulties) and are concerned with identifying and eventually modifying wrong notions and beliefs, often rooted in young people. It is important to evaluate the effectiveness of preventive programs. Only recently have some prevention programs been developed whose effectiveness is not yet established.

These programs are generally carried out at school level and generally involve the discussion of problems related to food and their consequences or, more generally, problems related to growth and adolescence. Secondary prevention There is also another type of prevention, called "secondary", which aims to identify the cases as soon as possible with respect to the onset of the disorder, since it has been established, at the clinical level, that a treatment undertaken in the early stages of the disease is much more effective. Not always, however, especially in the early stages of illness, the adolescent with a feeding problem admits that he needs help. At this level too, environmental awareness is important: starting with the young people themselves, families and school staff.

In Italy, prevention is applied and regulated through the National Prevention Plan. The areas in which the Ministry of Health intends to apply greater prevention policies are described in the Plan, and it is generally divided into periods of 3 or 5 years.

3.2 The experience of previous National Prevention Plans

The National Prevention Plan (NPP), adopted for the three-year period 2005-2007, with Intesa between the Ministry of Health, Regions and Autonomous Provinces signed on March 23rd, 2005, and then

extended to 2008 and 2009, represented a turning point in the health planning of our country for at least three reasons: the first is linked to the strategic choice of the regions to declare that they want to invest further in the area of prevention to achieve greater health results.

The second is connected to the decision to test a shared governance line, which led the Ministry to better exploit the coordination potential of the centre for disease control, the Regions to profitably implement a series of common operational lines in their planning and health agencies to use this additional tool to help reduce the burden of disease and disability. Finally, the third reason relates to the decision to subordinate programming to available knowledge.

The 2005 Agreement provided for:

- operational lines (relating to cardiovascular risk, recurrent cardiovascular accidents, diabetes complications, obesity, cancer screening, vaccinations, road accidents, accidents at work and domestic accidents);
- a specific financing (overall , 440 million, of which 240 as a "usage restriction" on the share of the CIPE division destined to achieve the objectives of the National Health Plan - pursuant to Article 1, paragraph 34, of the Law of 27 December 1992, No. 662 -e remaining 200 deriving from the indistinct share of the regional health fund);
- a mechanism to verify the achievement of the objectives of the Plan.

Consequently, each Region reported each year on the progress of its work and the CCM has certified the results obtained. A review of this first experience has highlighted some relevant aspects:

- The Plan has interpreted prevention as a strategic resource of the health system, identifying effective interventions to be implemented throughout the national territory and defining a

central coordination function, a regional planning and monitoring, a local implementation and management. Plan, the health system has been called to face the challenge of intersectionality or to provide answers to problems (e.g. the fight against obesity or the prevention of accidents) which, despite having a strong impact in terms of health and partner costs - economic, they were relatively new or not entirely shared in the strategies and in the availability of scientific evidences in support of the action or they required a leap in quality in the integration of skills and structures (e.g. oncological screening programs).

- In the early years, the major commitment, central and regional, was aimed at laying the foundations for "evolutionary" planning and evaluation, that is, not only functional to the Entente's certification obligations, but also preparatory to achieving, keeping them in the time, effective interventions.
- Some structural conditions represented levers for the good progress of the regional Plans: the programmatic involvement of the interlocutors; the activation of cross-regional intra-regional regulations, the search for synergies and networks, if not for the entire Plan, at least for some operational Lines; the growth of the skills of the professional resources deployed; operational integration at company level; the punctual reporting of the results achieved.

In the face of this investment, the implementation of the Plans has encountered some critical issues that have turned out to be the junctions on which to base a better re-proposal of the Plan.

First, the quality of planning has been highly variable between Regions and between areas of intervention and often inadequate, both in the

definition of objectives and expected results, and, often, in the identification of monitoring and evaluation criteria and methods.
Secondly, the use of data and information for the identification of priorities, the definition of objectives, monitoring, the evaluation and improvement of the interventions has often proved deficient or unsystematic.

Thirdly, the Regional Plans have often been interpreted more as a set of "vertical" projects and interventions than as an organic design, capable of identifying the overall picture, in which to place, in a transversal approach to the health problems, the individual initiatives. Fourthly, the architecture designed in 2005 (provision of resources aimed at achieving equally targeted prevention objectives) left unanswered the question concerning the channelling of the activities envisaged by the Plan in the ordinary business work and therefore to the necessary transition from a perspective of interventions deriving from sectorial projects to a logic of paths linked to systematized institutional activities and, among them, coherent.

Finally the lack of some key themes of prevention, first of all that of the relationship between health and the environment, was strident compared to the current epidemiological scenario, bringing to the attention the need to think of prevention as a 360-degree horizon and involve in its processes all the organizational health areas and not only the disciplines more properly (and traditionally) pertaining to the prevention departments.

3.3 National Prevention Plan 2010 – 2013

With the agreement signed on 29 April 2010, the 2010-2012 NPP was approved (extended to 2013 by the State-Regions Agreement 7 February 2013). The Agreement provides, at the ordinal level: the formal responsibility of the Ministry in the coordination and evaluation of the NPP so as to ensure national cohesion. At a financial level, as for the previous Plan, 200.000.000 euros deriving from the Regions own financing and 240.000.000 euros taken from the resources provided for in the Agreements for the realization of the objectives of the National Health Plan, pursuant to the law 662/1996, and subsequent additions, as a rewarding quota. Also the 2010-2012 NPP is configured as the document on the basis of which the Regions have developed their own Prevention Plans and the Ministry in turn, and this is an element of novelty with respect to the past, it has issued its Plan (adopted with Ministerial Decree 10 November 2011 entitled "Operational document for the implementation of central support lines to the NPP").

The NPP 2010-2013 has identified four thematic areas (Macro areas): predictive medicine, universal prevention, prevention in the population at risk, prevention of complications and recurrences of the disease. For each Area one or more General lines of intervention are defined, and, for each Line, the general health objective is stated.

Another fundamental element is the fact that for the achievement of each objective the roles of the institutions of the health system have been defined and therefore the following are specified: the regional lines of intervention, entrusted precisely to regional planning through regional plans; the central support lines, under the direct responsibility of the Ministry.

On this architecture, the Regions have been called to formally adopt their specific Plan, identifying (from the analysis of the needs of their own territory) precise and measurable objectives, recipients of the

interventions and useful indicators for monitoring the degree of approach to the expected results.

The Ministry was instead given the task of accompanying the regional path through the expression of a series of extremely heterogeneous functions, supporting the regional planning and implementation, which, through a process of reflection and operation shared between the central level and Regions, have been brought back and classified on the basis of the governance model known as stewardship (Ministerial Decree 10th November 2010 "Executive project for the implementation of the central Support Lines for the National Prevention Plan 2010-2011") and then declined in the Actions priority power stations (ACP) supporting the NPP (Ministerial Decree 4th August 2011, "Adoption of the executive document for the implementation of the central support lines to the national prevention plan 2010-2012. Priority central actions").

Compared to the previous year, the 2010-2012 NPP was innovative in several respects:

- The principles. The need to base action on evidence of efficacy as data and measurement of results (process and outcome assessment) is stressed, but also the importance of generating knowledge through the dissemination and implementation of registers, surveillance and information systems. The commitment to the person was made explicit, promoting a cultural vision in which at the center there is no self-referentiality of the services but the citizen (healthy or ill) with his expectations and needs, in a logic of continuity and path;

- The governance structure and model. The structure of the Plan was articulated in such a way as to express the concurrence of central and regional governments in the pursuit of established health objectives,

coherently with the institutional scenario, following the reform of Title V of the Constitution. Through the identification of the central Actions, the Plan has in fact proposed an application of the governance model known as a stewardship, implemented by Italy with the Tallin Charter (it is a policy document for the best (most effective and most efficient) management of health systems that identifies, among others, the commitment to assume the governance model of stewardship) and therefore induced a reflection and an impact on the system structures as having addressed the issue of their respective responsibilities (between the regional central government level) as a respective contribution to health objectives. Another example is the assiduous, non-formalistic, comparison with the Regions, first of all with the technical table of the Coordination of Prevention or having together, but in compliance with their respective responsibilities, defined the implementation path both of the programming itself (regional plans and central actions) and of certification.[51]

- The role of evaluation. The Plan reaffirms the importance and need to be able to have (as well as produce) "evidences" in three main moments of the action: tests of theoretical effectiveness (efficacy); monitoring and evaluation of interventions; outcome measure on outcome (effectiveness).

To this end, the Plan has promoted on the one hand the development, at an intra-regional level, of quality planning, developing various tools and activities to support this objective, and on the other, it has also supported culture and use. evaluation, both by supporting the implementation and use of surveillance systems, and by monitoring the

[51] http://www.euro.who.int/en/media-centre/events/events/2008/06/who-european-ministerial-conference-on-health-systems/documentation/conference-documents/the-tallinn-charter-health-systems-for-health-and-wealth

progress of planned interventions, and by promoting the construction of an integrated system for assessing the impact of prevention.

3.4 Planning and planning support activities

At the central level but above all at the regional and local level, the planning of the Plans has, in many cases, proved to be a real opportunity both for the cultural growth of many professionals, who have approached in a systematic manner the themes and methods of planning, both to give visibility to prevention activities within the LHA.

From an operational point of view in the Regions where prevention activities date back to a longer time, they are more consolidated, have a more developed and functional support structure, are implemented at LHA level in a more organized way and integrated with the rest of the activities of Companies, the Prevention Plan has produced (and in some cases activated) an improvement in the collaboration between the Region and the Companies and many poorly structured interventions have been re-planned and methodologically structured in programs or projects, in particular those of health promotion.

Many companies have also developed the idea that prevention activities are not only the prerogative and responsibility of the Prevention Department but of the whole Company, in this favoring a multidisciplinary approach and promoting a culture of prevention.

On the contrary, in the Regions where prevention activities are less consolidated and integrated, the RPP was, experienced as an opportunity to activate and finance “non institutional” project activities, otherwise not feasible or to obtain financing for pre-existing

interventions but no longer sustainable. Finally, in various realities the RPP had a character of “extraordinary” rather than an ability to bring back and harmonize all the prevention activities, and in fact did not systematically change the framework and structure of institutional prevention activities already in place.

The 2010-2013 NPP, in identifying the areas of action, read them based on the target populations (for example, interventions aimed at the universal population or at-risk population groups, etc.) with a clear reed managerial effect. Some of the macro-areas thus identified (e.g. predictive medicine) have not, however, found a correspondence with the organization of the regional (and corporate) system and in practice have been found to be more difficult to implement. The further subdivision of the macro areas into the intervention lines, within which the specific objectives (over 100) had to be placed, created the conditions for a “vertical” design at the expense of planning for “programs” which instead is the most adequate (and perhaps most efficient) way to implement prevention actions.

In the NPP 2010-2013, the dispersion in an excessive number of program lines and specific objectives has created the conditions, in many realities, to shift the focus of regional planning on individual “projects” that have in fact become the basic element of the structure of the Plan (as well as the object of the evaluation / certification). This choice has led to the proliferation of projects, too often not in line with the principles of the Plan (e.g. basing actions on evidence), causing fragmentation and a strong tightening of regional planning in the definition of often fragmented actions perceived, at the local level, not as the result of a harmonious prevention strategy but rather as interventions, often separated from each other, which risk “adding” to the current activities of the services.

3.5 Principles of the National Prevention Plan 2010 – 2013

Consistent with the vision of health recognized and shared worldwide (health in all policies), the 2010-2013 Plan has taken up the challenge of intersectionality and has invested not only in the traditional areas of prevention (universal, selective, secondary) but also in health promotion or in that process oriented not to prevent one or a limited number of pathological conditions but to create in the community and in its members a level of competence (empowerment) that maintains or improves health control.

The Plan has instead marginally addressed the issue of health inequalities. It is better not to adopt an effective and systematic approach against inequalities (both in principles and in operational tools), thus risking creating or augment them as an effect of RPP projects.

The central actions were identified as chronologically functional to the objectives of the NPP 2010–2013 and therefore schedulable in the same time schedule, as a central component of health actions articulated also in the RPPs. Not all, however, have developed in this sense and the expected support for PRPs has not been achieved or perceived sufficiently.

Although they represent an aspect of extreme importance and innovation, the monitoring and evaluation of the 2010-2013 NPP present several critical issues. For example, the monitoring of RPPs has not always adopted a formal structure, with standardized instruments and therefore comparable between the Regions; the indicators used to measure, also for certification purposes, the state of progress in the realization of the Plans are extremely heterogeneous.

They often derive from ad hoc data collections and not from current flows, and in general are not anchored to a measure of the results achieved with respect to the set objectives. This is partly due to the "limits" of the evaluation of the impact of prevention activities consequent to the fact that the expected outcomes are generally very delayed compared to the definition of the policies. There are also further difficulties in identifying solid descriptive variables of the investigated phenomena and related actions. They are much easier, for example, for screening coverage, but less easy for a health promotion activity, for which is added the difficulty in setting standards for indicators. A further limit is represented by the substantial scarcity and fragmentation of the current information flows for prevention.

3.6 The 2014-2018 National Prevention Plan

From the comparison and the critical analysis that accompanied the entire journey and the experience of the previous Plans, highlighting their strengths and critical points, the supporting elements that significantly contributed to defining the new NPP system emerged. To maintain what turned out to be the "good practice" of planning, the Plan, at central, regional and local level, is characterized by the adoption of methodologically shared paths, in order to favor the quality of programming, the comparability of products and results and the growth of culture and expertise of all levels of responsibility involved in the development and implementation of the Plans.

A further element of evolution, arising from previous experiences, is the choice of setting a few objectives common to the State and Regions and leaving to the programming included in the various regional contexts the definition of the target populations and the

management of actions functional to the achievement of these objectives.

Basically, a “high” National Plan perspective is envisaged with respect to which a “re-modulation” of the actions undertaken for their greater effectiveness in achieving common objectives is expected from the outset. The desired result is an improvement not only in terms of cogency in the relationship between determinants / strategies / objectives / interventions / results, but also in terms of integration and transversally of the interventions planned by the Regions with respect to the various population groups, conditions that favor the effectiveness of the interventions themselves.

An indisputable point with respect to the path taken up to now is the role of evaluation, which still represents an indispensable component of the Plan. It has the dual function of measuring the impact that the Plan produces both in the processes, in the health outcomes, and in the system, at central, regional and local level and in the verification of the LEA compliance (essential levels of assistance). The Plan must therefore be accompanied by an adequate assessment structure, anchored to the objectives to be pursued at all levels. It must be based on a shared approach that leads not only to the development of common and rigorous methods and / or procedures for monitoring and evaluation, but also to the creation of the necessary conditions for the use of the evaluation results for the improvement of the effectiveness and sustainability of the interventions and processes underway and for the production of the expected changes. Furthermore, the use of information and surveillance systems is instrumental in the evaluation, which the Plan promotes and enhances for the necessary and correct execution of all the functions deriving from such use, for example of knowledge, action, governance, empowerment.

3.7 Vision in the field of human health promotion and prevention

This Plan intends to respond to a vision whose elements are:

- Affirming the crucial role of health promotion and prevention as factors in the development of society and welfare sustainability, particularly in light of the demographic dynamics that characterize it;
- Adopting a public health approach that guarantees fairness and combating inequalities;
- Expressing the cultural vision in the values, objectives and methods of public health (also gained through the experiences of the two previous NPPs) of a "prevention, promotion and protection of health" which places populations and individuals at the center of interventions with the aim to achieve the highest level of health attainable;
- Basing prevention, promotion and health protection interventions on the best evidence of effectiveness, implemented in an equitable manner and that are programmed to reduce inequalities;
- Accepting and managing the challenge of cost-effectiveness of interventions, innovation, governance;
- Pursuing the development of skills for the appropriate and responsible use of available resources for professionals, the population and individuals.

3.8 Principles of the National Prevention Plan 2014 – 2018

1. The 2014-2018 Plan intends to be a "Plan" for health promotion and prevention implemented through actions that unfold within a five-year strategic framework, providing for the possibility, for the Regions, of fractional operational programming (e.g. in two periods temporal) and, for the central and regional level, periodic assessment of the state of implementation of the interventions.
2. The Plan sets priority common objectives supported by evidence-based strategies and actions, capable in the medium-long term of producing an impact both on health and on the system. Therefore, to be realized through sustainable and "ordinary" interventions; the applicability of this approach is favored (for example in identifying the actions) by the involvement of the Evidence Based Prevention network, implemented on the basis of what is already provided for by the central priority Actions pursuant to the Ministerial Decree of 4th August 2011.
3. The Plan defines a limited number of measurable (macro) health objectives and intends to evaluate the results achieved through early-outcome or output outcome indicators of health processes for which a relationship between output and outcome can be demonstrated.
4. The Plan incorporates the objectives subscribed at an international level and incorporates the objectives already decided within the national plans for the promotion, prevention and protection of health, as well as the obligations provided by the regulatory framework. In doing so, on the one hand it intends to promote the harmonization of the objectives formalized in these acts guaranteeing a comprehensive approach to public health; on the other, it considers regional and local contexts for

the purposes of declination and implementation of macro objectives.

5. The Plan guarantees the transversality of the interventions: it must be strongly pursued also in terms of integration (formal and operational), in order to achieve the objectives of the NPP, between different sectors, institutions, services, organizational areas. Therefore, in defining strategies and actions, it ponders both the function of the NHS directly delivering the interventions, and the role of NHS steward towards other actors and stakeholders.
6. The Plan recognizes the fundamental importance of the genesis and use of knowledge and therefore recognizes the establishment of registers and surveillance as indispensable infrastructural elements for the achievement of health objectives.

3.9 Intervention priorities and criteria for defining macro objectives

The macro objectives of this Plan have been identified based on the following priorities:

- Reduce the burden of disease. As is evident also from the reasons of the choices made in this sense at the level of the WHO, it is a question of lifting our country system from a preventable burden of morbid and deadly events, strengthening the contribution of the health service to the welfare system and making this is more sustainable, also in relation to the demographic trends typical of our country. This is particularly

true of the goal of reducing premature mortality from chronic non-communicable diseases. But the objectives on the reduction of accidents and occupational diseases and the promotion of active aging (including the prevention of dementia) are also exploitable in this sense.

- Investing in the well-being of young people. It is a choice with a strong educational and empowerment content that intends, in a holistic approach as much as possible, for what will be the active (working and managerial) class in the society of the near future, promoting responsible and conscious growth through the adoption of healthy lifestyles and behaviours of refusal towards any form of dependence in a logic of search for a psychophysical and emotional well-being.
- Strengthen and confirm the common heritage of preventive practices. It is about investing in a cultural heritage of great social importance and that over the years, also in relation to the national planning acts and the consequent efforts made by the institutions and professionals of the health system, has led our country to consider as well common the practice of preventive interventions such as those to safeguard the health of workers, those relating to cancer prevention and vaccination.
- Strengthen and systemize attention to fragile groups. This choice is implemented both as a fight against inequalities and as a system of interventions (perhaps already offered unequally) for the prevention of disability.
- Consider the individual and populations in relation to their environment. It is a question of promoting a healthy relationship between health and the environment by contributing to the reduction of diseases (chronically non-communicable) but also

developing all the potential of an inter-institutional approach of the health service.

Nevertheless, in defining the macro objectives, strategic value criteria were also considered. First, *relevance*. It is a relevance evaluated primarily as a burden of disease for the entire Italian population, but also a relevance in terms of development for social groups particularly at risk of fragility or inequality, as well as an ethical and social cohesion relevance. Secondly, *consistency.* The predominant criterion in this sense is that referred to in the principle of application of international and / or national commitments, as consistency with the policies adopted.

Moreover, the search, perhaps slavish, of the coherence between the macro objectives and rather of a methodologically coherent approach was not pursued, applying for each of the macro-objectives the same logical structure. We have, then, *governance*. This is the overall governance of the national health system that also takes into account all the actors and stakeholders and expresses the way in which those that are recognized as the needs of the country and its population are summarized in an overall approach (in its various articulations), in light of the commitments undertaken in the international organizations in which the country participates.

This Plan, as a tool of strategic value, adopts the public health vision functional to the necessary harmonization of the numerous sector interventions as a tool of governance. *Stewardship*. The application of this role involves the promotion of the improvement of the system, the efficiency and effectiveness of the health system's governance action. *Development*. Opportunity of a development perspective of prevention as a whole, particularly in those areas of "health and / or organizational" for which the need for a qualitative leap is recognized, as for example

with regard to the use of evidence scientific and to measure the impact of interventions.

This NPP identifies few macro objectives with high strategic value, which can be pursued simultaneously by all the Regions, through the development of plans and programs which, starting from specific local contexts as well as focusing on an approach that is as cross-sectoral and systematic as possible, make it possible to reach the expected results.

3.10 Vision and principles in the field of prevention in food safety and veterinary public health

In the field of prevention, it is good to recall the activities aimed at guaranteeing food safety and veterinary health, which oversee food and feed hygiene and safety, animal health and welfare, and that promote nutritional safety.

It is a branch of Prevention that carries out a set of specific activities, such as: the control of pathogens, contaminants, allergens, residues of dangerous substances and all those factors that can enter the food chain and cause damage to human health; the promotion of nutritional health in the population, aimed at reducing the frequency of diseases related to deficiencies of micronutrients fundamental to human health; the prevention and management of a remarkable list of animal diseases transmissible to humans, as well as of animal diseases that must be checked for the damage they cause to livestock production and for their implications related to the entry of drug residues into the food chain and for the enormous damage that can cause our food products to be exported, prized and appreciated throughout the world; attention to animal welfare, an important element of civilization, which is also the basic condition for reducing the need to resort to treatments therapeutic,

thus reducing the risk to the food they produce; the guarantee of fair commercial practices for feed and food to protect consumers' interests, including feed and food labeling and other forms of information.

These prevention objectives are pursued through the establishment of rules, actions, procedures capable of being acted on large territorial and population areas, through legislative/regulatory instruments, b. the maintenance of a high standard of official control along the entire food chain, c.la prevention, elimination or reduction to "acceptable" levels of risks for human beings and animals, through the definition of interventions to protect health that are effective, proportionate, targeted and transparent and that increase the level of trust of consumers and commercial operators; Attention to food safety prevention and veterinary health has a historical legacy in Italy, and is a cultural and scientific achievement for medicine, with the development of veterinary medicine: "One Health, A Health". It is a conception today as timely as ever, which expresses the scientific awareness of the need for a multidisciplinary collaborative approach that considers health as the product of an interaction between people, animals and the environment.

In Italy, in fact, the increasing attention paid to food and veterinary safety since the beginning of the 1900s by the governments of that time, continued in 1945, with the transfer of these skills from the Ministry of the Interior to the newly established High Commissioner for Hygiene and Health, incardinated in the Presidency of the Council, and in 1958 subsequently to the Ministry of Health, established in 1958, and therefore naturally in the national health service established in 1978.

In Italy, veterinary public health and food safety consists of a real "system", which involves a set of eleven institutions, bodies, laboratories, connected to each other through structured forms of

coordination and multidisciplinary cooperation. The system is set up around three levels of competent authority (Legislative Decree No. 193/07)[52]: The Ministry of Health, the Regions and Autonomous Provinces of Trento and Bolzano and the local health agencies. These three competent authorities are functionally related to each other, and interact with the other actors of official control, such as the Carabinieri Command for Health Protection (NAS) and other police bodies to which specific control areas are assigned, as well as the peripheral offices of border inspection, of maritime health and for the Community obligations of the Health Ministry, as well as the network of public laboratories specifically dedicated to the sector, ensuring a widespread presence on the national territory.

The cultural achievements of the EU health policy in the field of veterinary public health and food security, with the evolution of the problems linked to globalization, and therefore to the exchange of goods and people between countries and continents, have become an integral part of a political strategy of international level.

A strategy that responds to rules and standards issued internationally by some reference bodies, such as: the WHO, the Codex Alimentarius, a joint initiative of FAO and WHO that since 1963 has been developing harmonized international standards, guidelines and codes of practice to protect the health of consumers and ensure fair practices in international trade; the OIE (World Organization for Animal Health), in the field of animal infectious disease prophylaxis for international trade, the WTO (World Trade Organization), an international organization created to ensure the implementation of agreements and relations multilateral trade agreements. This strategy

[52] https://www.camera.it/parlam/leggi/deleghe/07193dl.htm

can be summarized in the summary adopted by the OIE: “One Health, One World”.

In the international scenario among the main factors of change that influence the sector, with the consequent need to adapt prevention measures, climate change, the globalization of trade flows, migration flows and economic crises must be considered. In fact, economic crises tend to push, in general, towards lower quality food consumption and, precisely for this reason, certain attention becomes necessary to the essential role of Prevention.

In reality, in times of crisis there is inevitably also a reduction in the capacity for public spending, and it is therefore difficult to ensure the maintenance of numerically adequate staff, dedicated to the prevention sector, which today sees a progressive aging and depletion of human resources in our country dedicated, due to the hiring stoppage. Maintaining a capacity for prevention with adequate human, laboratory and organizational resources is therefore an objective that must involve all countries, given the ever-present risk of global repercussions resulting from episodes in which, locally, prevention is lacking.

In terms of effectiveness and appropriateness, in compliance with EC Regulation 882/2004, the Ministry of Health, in agreement with the Regions, defined the Integrated National Control Plan 2011-2014, completely developed in a web environment, defined a “standard for the functioning of the competent Authorities”, approved with the agreement of the State Regions of 7 February 2013.

Moreover, work groups are in progress for the elaboration of guidelines on some organizational aspects and the regular performance of audits is guaranteed to verify the achievement by the competent authorities of the set objectives. All this guarantees the coherence and quality of food safety and veterinary health prevention activities

throughout the national territory. It is a prevention activity that in Italy engages about 3% of the National Health Fund (FSN).

Furthermore, a substantial part of its operating costs is also covered by taxes paid by operators in the sector as a tribute for carrying out official controls, according to the rules imposed by the European Union.

The analysis of the cost-benefit ratio cannot ignore a careful evaluation of the value of the prevention activities:

- each year in the EU territory more than 320,000 cases of human foodborne illness and zoonoses are recorded, but the real number it is probably much higher;[53]
- in industrialized countries the percentage of the population that suffers from foodborne illnesses reaches up to 30% a year. In the United States of America, for example, it is estimated that approximately 76 million cases of food-borne illnesses occur every year, with a hospitalization of 325,000 people and 5,000 deaths;[54]
- A study conducted in the United Kingdom in 2006 has shown how food-related illnesses are responsible for about 10% of morbidity and mortality in the United Kingdom and costs the related NHS approximately 7.5 billion euros. The same study concluded that the weight of health-related illnesses measured in terms of mortality and morbidity is similar to the ones attributable to smoking. The cost for the British National Health Service has been found to be twice the amount attributable to car, train, and other means of transport, and more than double

[53] http://www.efsa.europa.eu/en/topics/topic/foodbornezoonoticdiseases.htm
[54] http://www.who.int/mediacentre/factsheets/fs237/en/

> that attributable to smoking, and that most of the cargo is attributable to a poor diet, rather than foodborne illnesses.[55]

The exercise of this prevention activity therefore appears to be all the most effective for human and livestock health, as it reduces the costs that the NHS has to bear in order to face the treatment of food and animal diseases downstream.

The related economic and social repercussions, and the more it succeeds in providing its own contribution to the qualification of Italian food production on international markets.

While the evaluation of the evidence of effectiveness is proper to the competent authorities in proportion to the pertinent decisional level and to the territorial area of competence. For example, the evaluation of the effectiveness of certain activities established by European standards and the consequent corrective measures is the responsibility of the European institutions (Commission, Council, Parliament), similarly to what can happen for the national or regional level.

Besides, the critical elements emerging during the planning and implementation of official controls should be solved by the competent Authority that implements them or referred to the competent offices at institutional level, as mentioned above, in order to guarantee the necessary feedback for the next cycle of programming.

With the legislative decree 112 of 1998[56], a significant part of the competences in food safety and veterinary public health were conferred to the Regions, preserving to the State the tasks of international

[55] M. Rayner, P. Scarborough, British Heart Foundation Health Promotion Research Group, *ANNUAL REPORT*, Department of Public Health, University of Oxford, UK, 2006.

[56]https://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=1998-0521&atto.codiceRedazionale=098A4235&elenco30giorni

veterinary prophylaxis, of adoption of norms, guidelines and technical prescriptions and the verification functions for national aspects. Furthermore, with the subsequent reform of Title V of the Constitution, the health legislation has become a competing subject, confirming the state competence in matters of international prophylaxis. The EC regulation 882/2004 has provided, in article 4, paragraph 3, that

> *"if a Member State confers the competence to carry out official controls to another authority or to other authorities that are not the central competent authority, in particularly those at regional or local level, effective and efficient coordination must be ensured between all relevant competent authorities"*[57]

It also establishes the obligation for the competent authorities to carry out audits to verify the achievement of the objectives of the same regulation and further verification methods have been established with the State Regions Agreement of 23 March 2005. [58]

3.11 Macro Objectives of the 2014-2018 National Prevention Plan

The first macro objective of the 2014 – 2018 National Prevention Plan is the *reduction of the predictable and avoidable*

[57] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32004R0882.
[58] http://www.trovanorme.salute.gov.it/normsan-pdf/2005/23771_1.pdf.

burden of morbidity, mortality and disability of non-communicable diseases.

Chronic non-communicable diseases - cardiovascular diseases, tumors, chronic respiratory diseases and diabetes - are, worldwide, the main public health problem. They are, in fact, the first cause of morbidity, disability and mortality and their impact causes high human, social and economic damage.[59]

The World Health Organization has developed a comprehensive Action Plan for the prevention and control of non-communicable diseases for the period 2013-2020 which it provides to all Member States and to the other stakeholders a roadmap a series of policy options, in order to undertake coordinated and coherent actions to achieve the nine global voluntary objectives, including that of the relative reduction of 25% of early mortality due to cardiovascular diseases, tumors, diabetes or chronic respiratory diseases by 2025.

The WHO European Region has the highest CNCD burden worldwide. Two groups of diseases, cardiovascular diseases and cancer, cause nearly three quarters of mortality in the Region and three main groups of diseases, cardiovascular diseases, cancer and mental disorders, constitute more than half of the disease burden measured in "DALYs" (years of life lived in conditions of disability or lost due to an illness). Furthermore, many early deaths are preventable: estimates indicate that at least 80% of all cases of heart disease, stroke and type 2 diabetes and at least one third of cancer cases can be prevented. The inequalities in the burden of non-communicable diseases, then, within countries and between countries show that the potential for improvement in terms of health is still enormous.[60]

[59] http://www.euro.who.int/en/health-topics/health-policy/health-2020-the-european-policy-for-health-and-well-being
[60] http://www.salute.gov.it/imgs/C_17_pubblicazioni_2087_allegato.pdf

In addition to the current significant epidemiological, social and economic weight of chronic diseases, the increase in the coming years linked to the increase in the average age of the population and the increase in the global population must be added. It is estimated that in 2050 the number of people over the age of 60 will be around 2 billion globally. The aging of the population is rapidly progressing not only in high-income countries, but also in medium and low-income ones. A negative effect of this phenomenon is the increase in disability related to chronic non-communicable diseases and the number of subjects with reduced autonomy, poor social inclusion and lower participation in active life.

Additionally, as the age increases, the number of people with dementia grows exponentially. The progressive aging of the population therefore forces the governments of industrialized countries to implement appropriate and innovative strategies to mitigate the negative effects on the social and economic system, as well as on an individual level. The promotion of active aging is the strategy shared in this sense at international level.

For what concerns the main CNCDs, among cardiovascular diseases, which include all the diseases affecting the heart and blood vessels, the most frequent are those of arteriosclerotic origin. Among these, the most relevant epidemiologically are ischemic diseases of the heart and central nervous system, as myocardial infarction and stroke. Also, in our country the diseases of the circulatory system are the main cause of death. In 2010 (last mortality data available), a total of 220.539 deaths occurred due to diseases of the circulatory system (95.952 in men and 124.587 in women); of these, 72.023 deaths were attributed to ischemic heart disease (36.742 in men and 35.281 in women) and

60.586 to cerebrovascular diseases (23.991 in men and 36.595 in women).[61]

The weight of CVD on hospital admissions is increasing. Hospital discharge data indicate that more than half of CVD hospitalizations are due to chronic evolution and complications of acute events, among the most frequent heart failure, rhythm disturbances, late effects of stroke, as well as complications of hypertension arterial and diabetes.

3.12 Risk factors and determinants: environment, society, culture, politics

Starting from the principles of the Ottawa Charter [62]and from the strategies for "Health in All Policies", the environment and the context have taken on the meaning of a global, social and political process that influences or, better, say, determines health. Global factors such as globalization and urbanization, associated with an aging population, interact with social, cultural and economic health determinants (education, housing, work) in predisposing individuals to behavioral health factors, such as tobacco use, incorrect habits food, inadequate physical activity, harmful consumption of alcohol.

They can determine metabolic and biological alterations (increase in blood pressure, overweight and obesity, increase in blood sugar and fat in the blood) such as to cause CNCDs. Associated with globalization, for example, the so-called "nutritional transition" is

[61] http://www.salute.gov.it/imgs/C_17_pubblicazioni_2087_allegato.pdf.
[62]http://www.euro.who.int/__data/assets/pdf_file/0004/129532/Ottawa_Charter.pdf.

spreading, that is the transition to high-energy food regimes, a phenomenon that is favored by the parallel increase, on the supply side, of food production, promotion and sale ready and of foods rich in fat, salt and sugar and by the significant reduction, also due to urbanization, in the levels of physical activity in the population.

Even environmental policies are among the distal determinants of chronic diseases, often referred to as "causes of causes".[63]

The burden of deaths, illness and disability related to the main diseases could be effectively reduced each year through an adequate environmental policy and intersectoral policies aimed at reducing environmental health exposures, as highlighted in the report "Preventing disease through healthy environments: towards an estimate of the environmental burden of disease".[64]

The report indicates four main areas on which to intervene: 1) climate change and sustainable development; 2) exposure to the main environmental risk factors: air pollution (indoor and outdoor), noise pollution, chemicals, radiation, inadequate working or living conditions; 3) information on environmental health and risk communication; 4) management of natural resources (including water and sanitation).

Finally, if it is true that reducing the negative influence of behavioral risk factors, we act by decreasing the presence of biological and metabolic factors that are directly called Cause for CNCDs, it is also true that behavioral factors are the expression of social and economic factors (underlying drivers) that must be kept in mind when

[63] http://www.euro.who.int/en/health-topics/noncommunicable-diseases/cancer/publications/2012/action-plan-for-implementation-of-the-european-strategy-for-the-prevention-and-control-of-noncommunicable-diseases-20122016.

[64] A. Prüss-Ustün, J. Wolf, C. Corvalán, R. Bos, M. Neira, *Preventing disease through healthy environments A global assessment of the burden of disease from environmental risks*, World Health Organization, 2016.

defining health promotion strategies because they influence the distribution of the main risk and protection factors for health and therefore offer a good basis for prevention interventions centered on the collaboration of the health system with other sectors of the political and economic-social life of the context of belonging, both locally and nationally.[65]

3.13 Accountability of prevention organization and sustainability

The importance of recognizing the type of healthcare organization as one of the determinants of the quality and effectiveness of health system interventions has emerged for some years.

Although the primary literature essentially concerns the level of care and assistance, the principles and the culture that derive from these acquisitions are valid for all the structures of the health system; to this is added specific evidences at least for some secondary prevention interventions.

Even at the policy level, for years health systems have been urged to restructure in the optic of continuous quality improvement, including, in particular, the cost-effectiveness of the services and interventions offered. [66]

Attention to organizational models as determinants of more effective and/or higher quality interventions becomes, therefore, an essential element also for planning in prevention. This consideration of general order acquires additional depth if they are observed both the provision of prevention interventions following the 2005-13 NPP, which determined an increase in the complexity (both of the

[65] http://www.euro.who.int/__data/assets/pdf_file/0008/346328/NCD-ActionPlan-GB.pdf?ua=1.

[66] http://www.euro.who.int/__data/assets/pdf_file/0010/113302/E55363.pdf?ua=1

interventions and of the organization) compared to the structuring originally envisaged in Legislative Decree 502/92 and 517/93;[67] and the general dynamics of the allocation of resources and, in this dimension, the number of regions on the recovery plan.

The attention to the quality of the organization as well as to its cost-effectiveness becomes therefore a priority element both for the quality/effectiveness of the planned interventions, and for the sustainability of the prevention.

Although it is difficult to quantify the cost of a low-cost effective organization, such cases they can however contribute to the more general evidence of the existence of widespread wastes, often correlated with significant qualitative and quantitative deficiencies in the services provided. Another problem arises from, ultimately, poor availability of cost-effectiveness assessments of interventions, particularly in prevention.[68]

However, there are significant cases in which certain interventions have been evaluated as more cost-effective than others and, sometimes, cases of inefficiency in achieving the expected performance volumes. All this must be seen in the context of the reform of Title V of the Constitution and therefore in the context of the autonomy of the Regions in defining their respective organizations. In this sense, therefore, it is not a question of setting a specific organizational structure as the objective of the NPP, but rather of focusing the problem of effectiveness on the attention of organizational choices and therefore identifying the strategies and objectives that safeguard it, in a context of national cohesion, the effectiveness and efficiency of planned interventions.

[67] http://www.anaao.it/userfiles/DLgs_502_92.pdf
[68] http://www.ceistorvergata.it/area.asp?a=445

It is possible and necessary, ultimately, to recognize the need to proactively address the possible criticality of an effect of protection of health and/or promotion and/or prevention less than what can be obtained due to organizational or not optimal performance decisions.

This condition must be addressed - both in its definition and in the consequent specific objectives and monitoring and evaluation systems - with respect to two essential functions, different even if synergistic, for the regional health services:

- Intervention delivery function: deals with all interventions for promotion, prevention and protection of health defined by regulatory structures and planning documents;
- Governance function: this is the coordination and governance approach of all the players that contribute to achieving the objectives of prevention, promotion and protection of the health. The stewardship model adopted, precisely because of its motivations and methodologies, is a strategic element of inspiration and orientation also for the intra-regional prevention government.
- The evident complexity of the objectives set by this plan and the size of the stakeholders to be involved risk nullifying well-articulated interventions that are not coordinated with a single reference center. Indeed, a relevant part of these interventions is in fact related to styles of life that require strong assiduousness of action to be able to be modified in the desired sense.
- Based on the above, it appears, therefore, necessary that the "prevention departments" assume (if this has not already been done), within the LHA, this directing role is the functions of direct provision of benefits, and governance of interventions not delivered directly. This can be done by building and developing

> a network of links between institutional and non-institutional stakeholders that connects the territory to the regional and national government.

In this sense, the NPP represents the strategic framework of prevention policies and the reference of governance at central and regional level. Its declination in regional contexts aimed at achieving all the objectives set in respect of the single realities and territorial differences, directs not only the policy and planning choices of the interventions, but also on the system aspects. Particularly, the direction of close interaction and organizational, functional and operational integration. Moreover, it guarantees a coordinated use, under the guidance of the prevention department, of all the internal and external resources to the system.

Compared to the first "delivery" function, the quantification of this lower health gain can be measured only in specific contexts: e.g. the Atlas of avoidable mortality provides estimates, quite usable for this purpose, for a single LHA.

A similar local dimension is provided by performance evaluations and the analysis of possible quality problems in services, analysis that has its own detection and intervention systems established in national and regional / company regulations.

Precisely the attention to the effectiveness of the interventions as determined (also) by the organizational models, leads to the identification of some specific elements that can be interpreted as determinants of a less effective promotion and protection of health with the same resources or of less health gain obtainable from the prevention interventions.

3.14 Prevention and contrast of overweight and obesity

As seen, the Italian Ministry of Health did not develop, so far, a prevention policy regarding anorexia; the focus on a prevention strategy concerning an eating disorder was about obesity. A working group for the prevention and contrast of overweight and obesity was established on 6 June 2019, established by Ministerial Decree of 18th January 2019 and subsequent additions to the Directorate General for Prevention health.[69]

The objective is to draw up a guideline document for the prevention and contrast of overweight and obesity, especially that of children, shared with the Regions and Autonomous Provinces. The high prevalence of overweight and obesity is a worldwide public health problem. Obesity is an important risk factor for chronic diseases and, if present in children, it is associated with an earlier onset of diseases typical of adulthood. No country, to date, has reversed its obesity epidemic, although there are some signs of positive change. However, even where progress has been made, there remain strong inequalities in the prevalence of obesity.

The national and local prevention strategies are based on the principles of "Health in all policies" and aim at developing synergies between all sectors and subjects that have the ability to affect health, to act on individual behavior, but above all on environmental factors and on the socio-economic determinants that condition them, promoting interventions throughout the course of life.

The spread of overweight and obesity, however, makes necessary to strengthen the prevention and contrast actions of a

[69]http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=3784

phenomenon that has epidemic dimensions, in the context of an overall strategic design, through the identification of roles and responsibilities of all the actors involved and avoiding sectoral interventions and fragmented, also for the purpose of ensuring the early acceptance of overweight and/or obese individuals and delaying or avoiding the use of pharmacological or surgical therapies. All the general conditions are based on the EU Action Plan on Childhood Obesity 2014-2020, drafted on 24th February 2014.[70]

Therefore, the decision group, the Table, in addition to the presence of representatives of the competent Directorates General of the Ministry of Health, the Regions, the Ministry of Education, and the Istituto Superiore di Sanità, provides for a broad multidisciplinary representation, in order to address all the complex aspects of effective prevention and management. The guidance document that will be defined aims to be a tool available to health and non-health operators, decision makers and various stakeholders, also in order to favor the achievement of the related objectives of the National Prevention Plan and to guarantee greater homogeneity of action at national level.

[70]https://ec.europa.eu/health/sites/health/files/nutrition_physical_activity/docs/childhoodobesity_actionplan_2014_2020_en.pdf

Chapter 4
Italian Healthcare System Costs

4.1 What are DRGs?

In 1995, following the reorganization of the National Health Service (NHS) (Legislative Decree 502/1992 and subsequent amendments and additions), a prospective type of hospital remuneration system was introduced in Italy, based on the classification of "Diagnosis Related Groups" (DRG), in Italian ROD (Raggruppamento Omogeneo Diagnosi), fully introduced by the USA experience. Until then, the hospital activity was described in terms of admissions volumes and hospitalization days provided and was financed based on a retrospective assessment of the costs incurred.

In particular, in 1994 with the Decree of the Minister of Health (Ministerial Decree, April 15th) the criteria for determining the rates of health services and for the related updating at least every three years are established, including hospital ones, defined as episodes of admission classified with the version 10 of the Health Care Financing Administration (HCFA) DRG. On December, 23rd of the same year, with the financial law for 1995 (Law 724/1994), it is therefore sanctioned that starting from 1st January 1995 all public and private hospitals already affiliated with the NHS will be financed for their activities of hospitalization for acute cases with all-inclusive and predetermined rates for hospitalization, classified by complexity and expected costs of assistance, as measured by the DRG and differentiated by type (ordinary, day-time).

However, after its introduction, this system was subjected to irregular maintenance, at national level, with the adoption of the

subsequent 19 and 24 DRG versions of the Centers for Medicare and Medicaid Services (CMS), respectively in 2006 and 2009 and only two updates of national tariffs, in 1997 and 2012; at the regional level, system updates, especially with regard to tariffs, were generally more frequent, but very variable between regions.

In 2011 the It.DRG Project starts, coordinated by the DGProg of the Ministry of Health and by the Emilia-Romagna Region, as leader. The main idea of the It.DRG is represented by the development of a new classification and enhancement system for acute hospital admissions. It is representative and specific of the Italian reality that allows a better and sustainable access to innovation, also providing information tools suitable for its continuous management and maintenance.

The DRG is a system that groups, classifies and measures the characteristics of hospital admissions based on the type of organ involved, procedures performed and age. The groups are more than 500, are numbered with three digits corresponding to a specific description, an attribution to the medical or surgical partition and a relative weight. In particular, version 24 of the CMS-DRG Classification in use in the USA for hospital discharge between October 1st, 2006 and September 30th, 2007.

When researchers at Yale University devoted themselves to developing DRGs (Diagnosis Related Groups) during the 1970s, the intent was to define a tool for management. it had to be able, on the one hand to provide a measure of the activity carried out in the hospital, and on the other hand to support the choices for the management of the management.[71]

The development of DRGs, in fact, follows the introduction of key concepts, which still guide the organization and management of

[71] R.B. Fetter, J.L. Freeman, *Diagnosis related groups: product line management within hospitals.* Academy of Management Review, 1986.

care, including importance assumed by the type of patient, the hospital product, the treatment episode.[72]

In this sense, the DRG system constitutes the natural evolution of the finalized studies "at providing decision makers in hospital planning and administration with a tool for generating useful information in the design and operation of a progressive patient care facility".[73]

The application of the DRGs to the financing of assistance provided in hospitals occurred only subsequently, in this instrument, the possibility of controlling costs and at the same time improving the transparency of hospital activities.[74] The first large-scale experiment was carried out in the State of New Jersey in 1980,[75] then, with the comfort of the results obtained, even the United States federal government, in 1983, adopted the DRGs as a basis for financing prospective hospital admission regime for the Medicare program.

In the early nineties, in the presence of an increasingly restrictive economic constraint, even our National Health Service (NHS) is facing a process of profound transformation. In particular, the hospital sector presents a series of critical issues: a widespread excess of production capacity in terms of volume of hospitalizations for acute cases, otherwise distributed over the territory; generally excessive hospital stays, especially in private facilities, compared to progress in the clinical field; a general and widespread inefficiency in the use of the

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[72] M. Nonis, *La diffusione del sistema DRG nei Paesidell'Unione Europea: riflessioni e prospettive dal documento HOPE*, in E. Guzzanti, *L'assistenza ospedaliera in Italia dalla retta giornaliera di degenza all'esperienza dei DRG considerazioni e proposte*. Organizzazione sanitaria, 2007.

[73] R.B. Fetter, J.D. Thompson, *A decision model for the design and operation of a progressive patient care hospital*, Medical Care, 1969.

[74] A.D. Spiegel, F. Kavaler, *Cost Containment and DRGs -A Guide to Prospective Payment*. *Owings Mill (MD*), National Health Publishing, 1986.

[75] J.K. Iglehart, *New Jersey's experiment with DRG-based hospital reimbursement*, NEJM, 1982;

huge volumes of resources absorbed by the hospital system and a generally unsatisfactory level of quality of care.[76]

In fact, the activity of the hospitals was evaluated as a whole and remunerated simply by repaying the costs incurred or based on the days of hospitalization provided. However, the costs are not homogeneous and dependent on the simple occupation of the bed, but on the differentiated activities to which hospitalized patients are subjected[77]. Thus, was born the need to define a measure of the hospital product, assess its variability and operational efficiency. Following the innumerable health reforms in the field of New Public Management.

The NPM explains a style of public sector management. It aims to integrate the administrative law and traditional management practices of a public body with a more result-oriented methodology. It spreads, especially in the Anglo-Saxon countries starting from elaborations and revisions of the tradition of US business administration, subsequently spread also in Europe. NPM introduces new methods of work organization in Public Administrations, with the aim of obtaining better management performance.[78] In Italy starting in 1995 we assist a radical change in acute care hospital care. Especially, we move from a repayment system at the foot of the list to a prospective payment system imported from the USA, based on DRG tariffs related to a single episode of hospitalization.[79].

The fee for DRGs introduces for the first time the idea of an economic value associated with each hospitalization, different from any

[76] L. Lorenzoni, *La ricerca dell'efficienza*, Drg-Press, 1994; N. Falcitelli, T. Langiano, *La remunerazione delle attività sanitarie. Caratteristiche attuali e ipotesi evolutive*, Bologna, Il Mulino, 2006.
[77] J.D. Thompson, R.F. Averill, R.B. Fetter, *Planning, Budgeting, and Controlling-One Look at the Future: Case-Mix Cost Accounting*, Health Services Research, 1979.
[78] O.E. Hughes, *Public management and administration: An introduction*, New York, Palgrave Macmillan, 2012.
[79] https://www.gazzettaufficiale.it/eli/id/1994/12/30/094G0760/sg.

other, by type of pathology, patient characteristics, services provided, etc.[80]. In fact, this system allows for a more accurate measurement in terms of evaluating the performance of a hospital than the universe to which it belongs and thus obtaining significant feedback, the comparison standards.

From the analysis of the legislation it emerges as from the moment in which Italy has implemented the new mechanism for reimbursement of benefits, replacing the expense mechanism at the foot of the list, to date, there have been three Italian editions of the ICD-9 manual CM, respectively 1997, 2004, 2008.

As for the DRG system, instead, after the introduction with the HCFA-10 version, the CMS-19 (2006) and CMS-24 (2009) versions followed.

A similar criticality in the use of the system concerns the slow maintenance at national level of the tariff system, which has contributed to the expansion of the interregional variability of the tariff systems in force, both in relation to the tariffs (with reference to the amount, the determination methods, the provision of extra tariff reimbursements for prostheses and / or drugs and the provision of tariff classes), both in relation to the associated systems of volume and expense regulation.[81] For example, an analysis by the National Agency for Regional Health Services - AGENAS[82] shows that the tariffs in force in 2008, consistent with the 19th version of the DRGs, were determined by the Regions in different ways. That is, based on a cost analysis, based on the maximum rates pursuant to Ministerial Decree 12/09/2006, based on the

[80] F. Taroni, *DRG/ROD e nuovo sistema di finanziamento degli ospedali*, Roma, Il Pensiero Scientifico, 1996.

[81] L. Arcangeli, *La remunerazione delle prestazion,* In: C. De Vincenti, R. Finocchi Ghersi, A. Tardiola, *La sanità in Italia: governo pubblico, regolazione, mercato*, Bologna, Il Mulino, 2010.

[82] I. Morandi, L. Arcangeli, *Le tariffe nazionali e regionali nelle prestazioni ospedaliere*, in: *L'attività ospedaliera: dati e riflessioni*, Roma, AGENAS, 2009.

Ministerial Decree 30/06/1997, based on the Single Tariff for Interregional Compensation (TUC) using mixed forms of calculation.

Only with much delay, the Ministerial Decree of 18th October 2012, issued following the rules on the so-called spending review, updated the maximum ministerial tariffs for the remuneration of hospital services (the validity of which was however limited to 31st December 2016).

The adoption of the new national tariffs by numerous regions, as well as the compensation of interregional mobility, from 2014 has led to a reduction in the heterogeneity of the rates for the remuneration of acute hospital care. During 2013, twelve regions adopted ministerial tariffs, and, at the same time, no region has approved a new tariff based on the costs of its healthcare facilities. However, from 2012 to the present, national tariffs have not been updated, a requirement that is still more binding considering the issuance of the Prime Minister's Decree on the new LEA (Essential Assistance Levels).

A further criticality of the Italian system in force is represented by the simple and straightforward importation of US DRG systems, including the case-mix costing model used nationally and in different regions to define the costs underlying the relative weight systems and rates, associated with DRGs.[83] In fact, although they have been based on analysis of activity and cost data observed in samples of Italian hospitals, the official valuations of acute hospitalizations have been affected by the characteristics of the care and cost profiles typical of the

[83] N. GoldfielD, *L'evoluzione dei Diagnosis related groups (Drg)*, in: N. Falcitelli, T. Langiano, M. Trabucchi, *I Drg in Italia: un successo o un'occasione perduta*?, Bologna, Il Mulino, 2010.

American reality dated. Specifically, the parameters for defining the DRG costs v. 24 are based on 2004 data.[84]

Nevertheless, with the adoption of the DRG system for the classification and remuneration of admissions a standardized and meaningful definition was made in clinical and economic terms of the hospital product,[85] allowing assessments and progressively more detailed analyzes, both retrospective and prospective, on a regional, national and international scale. [86]

In this sense, the DRG has undoubtedly been recognized, also in the Italian reality, as a valid tool in redefining the relations between producers and paying entities, [87]in allowing a more rigorous regional planning and, finally, in making available to professionals and managers a new unified and recognized evaluation language. [88]

The main advances in Italy, following the use of the DRGs, can be summarized as follows:

- Qualitative and quantitative improvement of information assets;
- Increased monitoring and control capacity for health expenditure;

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[84] M. Nonis, A.M. Lerario, *DRG: valutazione e finanziamento degli ospedali. Esperienze internazionali e politiche delle Regioni in Italia*, Roma, Il Pensiero Scientifico, 2003.

[85] L. Arcangeli, N. Falcitelli, T. Langiano, *I primi dieci anni dei Drg in Italia*, Politiche Sanitarie, 2004.

[86] M. Casas, M, Wiley, *Diagnosis Related Groups in Europe: uses and perspectives*, New York, Springer Verlag, 1993; J.R. Kimberly, G. De Pouverville, *The migration of managerial innovation. Diagnostic-related groups and health-care administration in Western Europe*, San Francisco, Jossey Bass, 1993; F. Gilardi, K. Füglister, S. Luyet, *Learning from others: the diffusion of hospital financing reforms in OECD countries*, Comparative Political Studies, 2009.

[87] E. Guzzanti, Prefazione in: F. Taroni, *DRG/ROD e sistemi di pagamento degli ospedali*, Roma, Il Pensiero Scientifico, 1996.

[88] F. Taroni, L. Arcangeli, *Il sistema dei DRG fra politiche sanitarie e politiche economiche: storia, situazione attuale e prospettive future*, Arco di Giano, 2011.

- Greater appropriateness in the use of the hospital with transfer of casuistry to levels of care more consistent with the needs of patients.

4.2 It.DRG project: Genesis

In order to better understand the origin of the It.DRG Project, it is appropriate to put forward a quick description of the "Mattoni" event, which is the main preparatory experience for the It.DRG Project.

The Mattoni Project,[89] approved in December 2003, arises from the need to accompany the reorganization of the new shared information source [90] with a parallel and complementary generation or updating project, in order to identify uniformity of expression in terms of data collected and methods of reading / measurement, by defining methodologies, classifications and homogeneous codifications at national level, thus developing a "common language".

The Project involved numerous professionals engaged in 15 different project lines or Bricks (*mattoni*):

1. Structure classification;
2. Classification of outpatient services;
3. Evolution of the national DRG system;
4. Reference Hospitals;
5. Minimum standard of quantity of services;
6. Waiting times;
7. Measurement of appropriateness;

[89] www.mattoni.salute.gov.it.
[90] www.nsis.salute.gov.it.

8. Measurement of the Outcome;
9. Realization of the Patient File;
10. Pharmaceutical performance;
11. Emergency rescue and system 118;
12. Residential and semi-residential assistance;
13. Primary care and home care;
14. Measurement of SSN costs;
15. Collective health care.[91]

At the head of each project line there were two regions ("leader" and "associate"), which coordinated the activities of other regions and bodies, while the general coordination was handled by the NSIS Director's Cabin, established by the State-Regions Conference.

The Project was also linked to the feasibility studies of the NSIS through the preliminary steps of the integration system of individual health information, the monitoring of the LEAs and the appropriateness, the monitoring of waiting times (ex-post), the monitoring of costs and performance enhancement.

Thus, on the information of the hospital activities detected over the years, the comments and suggestions of the users of the information flow of the SDO, as well as of the stakeholders and based on lessons from international experiences, originate the need to prepare an Italian model for the classification of admissions hospital, which is consolidated in the organizational sphere of the NHS.

In the years following the closure of the Mattoni Project, the Ministry of Health started collaborations with some regions already involved in the mentioned Bricks and therefore more endowed with expertise, as well as with the Organization for Economic Cooperation

[91] www.mattoni.salute.gov.it.

and Development (OECD) to guarantee a broad informative-training support regarding similar foreign experiences,[92] to undertake the shared elaboration of a strategic project aimed at the development of an Italian system for the measurement and enhancement of hospital products.

In March 2015, the DGProgs of the Ministry of Health, together with the Emilia-Romagna region and with the collaboration of the Friuli Venezia Giulia and Lombardy regions and AGENAS, officially presented the "National project for the development and testing of a new system of measurement and enhancement of the products of hospital structures It.DRG Project". Furthermore, starting from the agreement stipulated with the Ministry of Health in September 2017 (Agreement It.DRG) the ISS is included in the It.DRG Project. This agreement had the objective of completing the closure of the experimental phase of the Project, ending the 31st December 2017.

4.3 Project organization and stakeholders

For the management of the It.DRG Project, in the experimental phase (Mattone It.DRG) a functional organization was mapped, through the activation of:

- Four working groups (WG), dedicated to the implementation of the Project Work Plan, each assigned to the responsibility of a region or of the Ministry of Health;
- Technical Coordination of WGs;
- General Coordination of the Project;
- Project Scientific Committee;

[92] L. Lorenzoni, M. Pearson, *Description of alternative approaches to measure and place a value on hospital products in seven Oecd countries*, Paris, OECD Health Working Papers, 2011.

- Strategic Project Committee;
- Technical Secretariat of the Project.

In particular, the priority reference principle for the definition of the WG was the guarantee of authority, pursued by choosing the components based on their recognized competence and professionalism in the subjects covered by the specific activities of each WG.

The *Technical Coordination of the WGs* ensures the constant shared monitoring of the progress of the activities in each WG and their alignment with the objectives pursued (both specific for WG and transversal) and the relative scheduled timing, as indicated in the Project Work Plan and in the Operational Plans. The participants are four referees of the WG together with the AGENAS representative who plan and coordinate seminar meetings.

The *General Coordination of the Project* supported by the DGProgS of the Ministry of Health, in collaboration with the Emilia-Romagna Region head of the project, calls upon and calls the Scientific and Strategic Committees of the Project and collects indications and opinions / assessments. It also addresses the activities of the working groups, convenes meetings to present the results of the activities carried out within each Group; formulates the definition of the components of the system for measuring and enhancing the products of hospitals, analytical tools and information tools, based on the final products of the WG and the assessments of the Scientific Committee proposing it to the evaluation of the strategic Committee.

The *Project's Scientific Committee*, composed of authoritative international national experts, guides and supervises the methodological approach of the activity lines / WG and assesses the products with respect to the criteria provided. The main functions of the

Scientific Committee are the methodological orientation and general supervision of the complex of activities envisaged for the pursuit of Project objectives by the WGs in charge of developing the specific lines of activity; the systematic evaluation of the methodological documents prepared by the working groups, of the respective intermediate and final products.

The *Project Strategic Committee* composed of representatives of the Ministry of Health, some Italian regions and AGENAS, guides the activities of the WGs and defines the final objectives of the project for satisfying the information needs to support the governance of the NHS. Furthermore, it establishes the procedures for the adoption and use within the NHS, as well as for the subsequent periodic updating, of the components of the new classification system proposed by the General Coordination of the Project.

The *Technical Secretariat of the Project*, managed by the Office VI of the DGProgS of the Ministry of Health, is responsible for managing the Project. In particular, the Technical Secretariat provides support for the activities of the General Coordination of the Project and for the Technical Coordination of the working groups.

The methodological path for the development of the Project takes place in a scenario of continuity with respect to the tools, the logic and the methods currently used in the NHS. It is articulated in a short-medium term scenario, consistent with the deadlines set by current legislation, according to a logic of gradual development. Moreover, it develops not only and exclusively on the classification systems, but above all on the product weighing system, for the purpose of measuring them useful also for valorization purposes. It allows for the measurement systems of the different areas / types of hospital activities consistent with each other, with which to be able to weigh the entire activity provided by a hospital in its various components, using results

produced both in other national projects and in experiences foreign companies acquired in countries with similar paths. Finally, it offers accessible, transparent, comprehensive and regularly updated tools.

4.4 Preliminary Analysis

The start-up phase of the It.DRG Project aimed to contribute to identifying reference methodological criteria to specify the operational paths of the activity lines, through the performance of preliminary, quantitative and qualitative analyzes.

The subjects involved in this phase of the Project, starting from January 2011, were initially the DGProgS of the Ministry of Health and AGENAS, with the fundamental support of the Organization for Cooperation and Economic Development (Directorate for Employment, Labor and Social Affairs), of the Department of Statistical Sciences of the Sapienza University of Rome and of the University Hospital Policlinico Umberto I of Rome. The Emilia-Romagna Regions, leader and co-coordinator of the Project with the DGProgS. In parallel, Friuli Venezia Giulia and Lombardy have started collaboration with the Ministry of Health and AGENAS for sharing and deepening the objectives, contents and operating methods of the Project, in preparation for the subsequent experimental phase, producing the documents methodological, organizational and operational.

The contents of the main preliminary analysis carried out and the main results obtained, in terms of methodological criteria proposed to implement in the experimental phase the work paths of the work groups with reference, in particular to the processing of data available

on acute hospital admissions (SDO archives) for the purpose of assessing the limits of the classifications available in describing and measuring the Italian hospital casuistry and the production of information supporting the process of reviewing the classifications, in particular of hospital products (DRG). Furthermore, another fundamental element is the recognition of the characteristics of the hospital information systems present in the NHS hospitals, carried out in support of the selection path of the pilot hospitals of the experimental phase of the Project.

Instead, the results of the preliminary analysis carried out with specific reference to the passage from the ICD-9-CM classification to the ICD-10-IM for the coding of the diagnoses, to the improvement and adaptation to the Italian hospital context of the ICD-9-CM classification for the codification of procedures and interventions, the development of an Italian version of the DRG system and the definition of an Italian model for measuring the costs of admissions associated with the new It.DRG classification.

Very briefly, the results of the descriptive analyzes carried out have shown that the following types of admissions are relatively more critical in terms of variability of the length of stay within the groups:

- Surgical admissions with respect to medical admissions;
- Hospitalizations related to areas attributable to Major Diagnostic Categories: MDC 3 - diseases and disorders of the ear, nose, mouth and throat; MDC 5 - diseases and disorders of the cardiovascular system; MDC 8 - diseases and disorders of the musculoskeletal system and connective tissue; MDC 9 - diseases and disorders of the skin, sub-cutaneous tissue and breast.

The results of the regressive analyzes carried out, only on some diagnostic aggregates and of procedures selected to test the model, lead to estimates of the impact of the different variables as the ACC changes.

However, some regularities seem to emerge in the effect of the variables considered. In particular, when there is at least one of the comorbidity classes defined by the Elixhauser index, an increase in the duration of hospitalization is observed in all the cases analyzed, confirming the positive link expected between length of stay and complexity of the case, approximated by the presence of complications. Similarly, the modalities of the type of hospitalization seem to have a coherent effect as the aggregate changes. This means that when the effect of ordinary hospitalization is set at 1, the effect of the urgent hospitalization mode induces an increase in the length of hospitalization, while the programmed hospitalization appears to be on average linked to a shorter hospital stay than the others. the effect of the age group does not seem, however, unambiguous. The middle classes ([35, 39] and [49, 65]) seem similar in duration of hospitalization, but the extreme classes do not always have the same behavior in terms of estimated effects on the length of hospitalization. The selected grouping variable, that is, the region to which the hospital belongs, seems to have a limited role, as shown by the intra-class correlation coefficient, often less than 0.1, regardless of whether the individual variables are included in the model or also the structural ones. Finally, all the structural characteristics produced very variable effects as the aggregate considered varied, limiting the interpretation.

The recognition of information systems in use in Italian hospitals, carried out by the DGProgS of the Ministry of Health and the Emilia-Romagna region, had the dual objective of first, gathering information useful for the purposes of selection, based on objective criteria and documented pilot hospitals to be involved in surveys, including those with information systems sufficiently developed to be able to guarantee the collection of the information necessary for the

purposes of the Project; second, to better know the hospital context in which the Project products will be introduced.

4.4.1 Hospitals involved.

Considering the objectives of the survey, it was decided not to involve the entire universe of NHS hospitals, but to limit themselves to those that can guarantee volumes and range of the cases treated suitable for the purposes of the Project. To this end, on the basis of data from the national SDO archive, accredited public and private hospitals have been identified, with acute ordinary admissions volume and number of treated DRGs higher than the 80th percentile of national distribution (equal, respectively to 9,700 discharges / year and 388 DRG treated / year).

A check was therefore carried out on the distribution of the selected hospitals, both in terms of size (number of beds) and by region, with respect to the overall regional hospital offer; moreover, the inclusion of hospitals with a large number of cases was verified, in particular, in two priority areas for the review of classifications (neonatal and cardiovascular), in order to integrate hospitals with relevant case studies that may not be included. Thus 246 hospitals were selected, equal to 16% of all NHS hospitals, whose wide variability in terms of size, complexity of the treated case history and operating efficiency (number of beds for acute cases, number of acute discharges in ordinary hospitalization, average weight, standardized average hospital stay for the case-mix, Case-Mix Index, Comparative Performance Index).

The questionnaire was administered through the regional managers of health information systems, invited to involve other hospitals in their region, possibly excluded from the list of pre-selected

but deemed suitable for the purposes of the Project. There were 106 hospitals that completed and sent the questionnaire (7 of which were private), distributed over 15 regions, equal to a 43% response rate.

4.5 Setting up the icd-10 Italian clinical change for the purpose of diagnosis classification

The national clinical modifications of the international classification of diseases are admitted by the WHO for certain needs of a country. In general, they constitute expansions of the WHO classification by introducing new codes at a detailed hierarchical level, in order to be able to classify particular nosological entities separately.

Authorized by the WHO, national clinical changes to an international standard should fully respect the WHO hierarchical tree to allow a coherent international comparison. For this reason, at national level it is not possible to introduce new categories with three characters, nor to delete any category (three or four characters) present in the WHO classification. In the national clinical modifications the objective pursued by the expansions of the WHO codes mainly concerns the use of the same in the financing of services (in particular, reimbursement of hospital admissions), the detection of epidemiological data relating to pathological conditions of regional importance and timely adaptation to the state of the art.

In the first case some OMS concepts are disjointed due to the different absorption of resources that the same pathological condition can entail depending on the site concerned, the etiology, the clinical conditions (course, complications, etc.) or other relevant factors. Specifically, the US clinical modification of ICD-9-WHO has on one

hand introduced classification levels with expansions up to the fifth character and on the other hand has not always respected the hierarchical tree WHO, inserting new categories with three characters and eliminating others in three or four characters.

By using the Italian adaptation of ICD-10-WHO in the new classification of admissions, called classification It.DRG, it was taken into account that each pathology code, when present in the main diagnosis, can determine one and one only MDC (Major Diagnostic Category). This required verification of compliance with the criterion of mutual exclusivity of each main diagnosis codified both within the MDC itself and between all the MDCs. In the event of non-compliance, the ICD-10-WHO codes concerned have been modified. In summary, the Italian modification of ICD-10-WHO had to be different from that of other countries (e.g. containing the number of modifications), able to understand and improve the current classification of pathological conditions and simplify their use by the health workers. The work to be done could only go through the tenth revision of ICD-10-WHO, operating first a fine transcoding from ICD-9-CMa ICD-10-WHO, and then a real clinical modification aimed also at the needs of use of the classification in the new Italian DRGs, to arrive at an Italian version of ICD-10. The different structure and the different level of detail of ICD-9-CMe of ICD-10-WHO has involved a meticulous work, although in the tenth revision of ICD there are some concepts present in the ICD-9-CM tree.

The classification is divided into 22 chapters. The first character of the ICD-10-OMS code is a letter. A particular chapter is associated with each letter, with some exceptions: the letter D is used in Chapter II, Tumors, and in Chapter III, Diseases of the blood and blood-forming organs and some disorders of the immune system; the letter H, is used in Chapter VII, Diseases of the eye and ocular adnexa, and in Chapter

VIII, Diseases of the ear and mastoid apophysis; four chapters (I, II, XIX and XX) use more than one letter as the first character of the respective codes. Each chapter contains several three-character categories sufficient to represent its content. Chapters I-XVII refer to diseases and other pathological conditions, Chapter XIX classifies traumatisms, poisonings and some other consequences of external causes. Chapter XVIII deals with symptoms, signs and abnormal findings, both clinical and laboratory. Chapter XX, "Causes External morbidity and mortality", was traditionally used to classify causes of trauma and poisoning, but from the ninth revision also refers to external causes of diseases and other pathological conditions. Finally, Chapter XXI, Factors influencing the state of health and the use of health services, codifies information that explains the reasons for resorting to health services of people without ongoing illnesses, or the circumstances in which the patient is receiving health care in that particular moment, or, again, information that has some relevance to the health care of a given person. Chapter XXII contains codes for special purposes.

The chapters are divided into homogeneous blocks of categories with three characters. In Chapter I the titles of the blocks reflect two axes of classification: modes of transmission and grouping of infecting organisms. In Chapter II the first axis is the behavior of the tumor and, within the behavior, the axis is mainly per seat, although some categories with three characters refer to relevant morphological types (e.g. leukemia, lymphoma, melanoma, mesothelioma, Kaposi's sarcoma). The set of categories to which a single block refers is indicated in brackets after the title.

Within each block, some three-character categories classify individual pathological conditions since they are very frequent, severe or susceptible to public health interventions, while other categories

refer to groups of diseases with some common characteristics. There are also usually categories to classify “other” pathological conditions that are different from each other, but rarer, and “unspecified” pathological conditions.

Although it is not mandatory to use them to provide data internationally, most three-character categories are divided up to ten sub-categories, by adding a fourth numeric character after the decimal point. If the three-character category concerns only one disease, the four-character sub-categories are used to identify different anatomical sites or variants. If the three-character category refers to a group of diseases, the sub-categories identify individual diseases. The fourth character .8 is generally used for other pathological conditions belonging to the three-character category, while the “.9” is mainly used to provide the same meaning as the three-character category title, without adding further information. When the same four-character subdivisions concern a group of three-character categories, they are reported only once at the beginning of this group. A note on each affected category indicates where to find the details. For example, categories O03-O06, related to different types of abortion, have fourth common characters concerning associated complications.

4.6 Online consultation on the Italian portal of health classifications

On the Italian Health Classification Portal, managed by the CCIOMS, it is possible to browse the 2014 version of ICD-10-WHO, based on ICD-10-IM. It is also possible to consult the TransIT transcoding support software and consult the ICD-10-IM experimental

version 31.12.2017. ICD-10-WHO navigation online and consultation of the ICD-10-IM software and file are allowed only to registered users of the Portal and authorized for consultation in the context of the It.DRG Project.

TransIT is a web application written in PHP that allows you to suggest how to transcode ICD-9-CM codes into ICD-10-IM codes, based on the transcoding table. It will be up to the encoder to choose, based on the available clinical information, which ICD-10 codes to use, verifying inclusions and exclusions in the list of inclusions and the four-character subcategories of paper Volume 1 or in the browser of ICD-10-OMS version 2014, available on the Italian portal of health classifications. TransIT is available at the following address: *www.reteclassificazioni.it/transit/.*

The interface is also optimized for mobile devices. TransIT has been developed to allow access to ICD-9-CM mappings to ICD-10-IM in two ways: manually, interacting with the web interface; through web service: it is possible to query the system through Application Programming Interface Representational State Transfer (API REST), obtaining answers in JSON format. The REST interface is available at: *Https://www.reteclassificazioni.it/transit/api/.*

The use of web services makes it possible to support interoperability between different computers through a network, or in a distributed context. TransIT provides the available mappings through a REST API that supports the JSON format. Through this interface, it is possible to obtain transcoding within any other software, always receiving the most up-to-date official transcoding. The JSON format of the result is currently the most used for web services and can be easily interpreted in any programming language.

4.7 Adaptation to the state of the art of the classification of relevant pathologies

It would be advisable to take the opportunity of setting up an Italian clinical modification of ICD-10-OMS to overcome the basic WHO version, incorporating in ICD-10-IM the most up-to-date classification settings of some relevant pathologies, such as diabetes mellitus and lymphomas. In particular, as regards diabetes mellitus, a proposal has already been formulated, in relation to the fact that over the years the classification of diabetes is much changed, and the classifications proposed by ICD-9-CMe ICD-10-OMS they are largely outdated. Specifically, the classification indicated in the document "AMD-SID - Italian standards for the treatment of diabetes mellitus 2016" produced on 20.06.2016 by the two main Italian Scientific Societies as well as that recently proposed by the American Diabetes Association are substantially aligned with ICD-11-WHO.

The CCIOMS (which, we recall, is the Italian Collaborating Center of the WHO for the Family of Classifications, Central Health Directorate, Social and Health Integration, Social Policies and Family, Friuli Venezia Giulia Region) on the basis of a formal agreement with WHO signed at the end of 2015, he prepared the Italian translation of the three volumes of ICD-10, fifth edition, 2016 version which proceeded to publish with own funds and for institutional purposes. The translation and publication rights of this version are from the Central Health Management, social and health integration, social policies and families of the Autonomous Region of Friuli Venezia Giulia, in its capacity as CCIOMS[93]. This activity was not part of the IT Project work

[93] L. Frattura, Nota introduttiva all'edizione italiana in: L. Frattura, G. Bassi, V. Della Mea, C. Morassutto, F. Munari, A. Simoncello, F. Talin, S. Terreni, I. Tomainu, P. Tonel, C. Zavaroni, *Classificazione internazionale delle malattie e dei problemi*

plan .DRG, but in fact it would allow to lay the foundations for two important decisions for Italy: on the one hand, that of formally adopting ICD-10-WHO version 2016 as a standard of codification of morbidity; on the other hand, to update the experimental version of ICD-10-IM, formally agreeing with the WHO on ICD-10-IM. The new Italian edition of ICD-10-WHO differs from the previous one in addition to the contents, which are updated to 2016, also for translation.

At the same time, the CCIOMS, since 2012, has been carrying out the Secretariat activity of the international ICD updating process, supporting the WHO in its maintenance.[94] This activity allows you to be at the forefront of the classification update process and puts Italy in a position to have the latest ICD-10-WHO updates available completed in 2017 and with the last year of formal implementation 2019. Their translation by the CCIOMS will make it possible to update the same version 2016. To underline the fact that in some Italian regions the CCIOMS has supported training activities on the use of ICD-10-WHO in the codification of morbidity in particular clinical settings, a sign of interest by clinicians and decision-makers in the need to use updated versions of ICD and to be trained to do so.[95]

The system of reimbursement through Diagnosis Related Group (DRG), since its first introduction has played a fundamental role in the mechanism of regulation of the health model of Lombardy. In fact, in this region a clear separation had been defined between buyer and provider that was not found in the other regional models (Regional Law

sanitari correlati, Bassa Friulana-Isontina Palmanova, OGV Officine Grafiche Visentin, 2017.

[94] J. Hargreaves, L. Frattura, P. Tonel, *Update and Revision Committee (URC)Annual Report. WHO-FIC Annual Meeting Booklet*, Mexico City, 16-21 October 2017, WHO, 2017.

[95] L. Frattura, L. Bruno, *ICD-10 use in children psychiatry between old approaches and ICD-11,* WHO-FIC Annual Meeting Booklet, Tokyo, 8-12 October 2016, WHO, 2016.

31/1996). The reorganization that had led to the distinction between "production companies" (previously Hospital Organizations now Local Healthcare Authorities) and "territorial health planning and management companies" (first Local Health Offices now Territorial Health Agencies) equalized the structures private accredited to public structures in the methods of accreditation and contracting of production budgets at territorial level. There are about 100 private hospital facilities accredited in Lombardy and these provide about 30% of regional hospital production. It is not just small care homes but also nationally important hospitals, which over time have been organized in hospital groups, operating in several territories, where they have often assumed a prominent position also on the crucial issues of investment in technology and training.

In this condition, the prospective payment system immediately became an operational tool (for financing) and was then used as a programming and management tool. The measurement tool, almost inevitably, as it happens to all the tools when they are used, has also become an object to be studied and modified in order to manage a growing complexity of the system. The DRG system, imported from the United States where it was used to finance the Medicare program, was immediately accepted as an important innovation if only for the urgency of having a system for measuring and weighing hospital treatments. It cannot be forgotten that the novelty introduced also raised bitter polemics over the monetization of health and the introduction into the hospitals of company and production logics. Overall, however, the instrument was not rejected even though there were plenty of opportunities to report compatibility and comparability problems since the attribution and weighting logics were essentially transferred without corrections between very different systems.

The doubts concerned the differences in the mix supplied, the different delivery sets, the possible differences in weighing and the specificity of the codes. These were not doubting of a general nature but rather of specific doubts and specific objections. Did it make sense to reimburse the rehabilitation of spinal cord injuries at the same rate as the rehabilitation of neuropathies given that they are in the same MDC10, (where the MDC, the Major Diagnostic Category or Major Diagnostic Category is an aggregation of DRG used in the admissions classification system to distinguish the cases on the basis of a clinical-anatomical criterion. There are 25 categories: the first 13 describe an anatomical system, from the central nervous system to the reproductive system, while the remaining 11 categories describe areas of a clinical nature. Each DRG is included in a single and specific MDC)? Why did the DRG 114 have such a high weight (1.2)? Was a natural birth cost more (with more assistance in observation, preparation and delivery but less in days of hospitalization) or was it more expensive for a caesarean section (with more days and less effort in the observation phase)? Why was the weight of pediatric hospitalizations so low compared to the costs recorded? So many contradictions in the system were gradually brought into focus by clinicians gradually trained also on managerial issues and by administrators (gradually entwined with clinical problems).

The objections were often raised not in terms of radical opposition to the system but rather as a request for adaptation and these questions then sought an institutional forum available to listen to them. These requests have often found in the General Directorate for Health (now Welfare) of the Lombardy Region a point of listening and a commitment to deepen and therefore to find possible solutions.

Over the course of 20 years, the Regional Council, based on a regular analytical survey of production costs, has repeatedly resolved

changes to the rates in force. Based on the evidence gathered, it proposed changes to the tariff system, threshold values and even tariff distinctions within the same final group. However, not being able to adopt systems different from the one envisaged at national level, the Region has progressively introduced coding rules, additional fields in the track and new tracks to be able to identify the expected differentiations in the final groups. These adaptations served to recognize a greater economic value for the use of procedures and devices not yet listed in the official codes, supplementing the rates of the less valued specialties (pediatrics, obstetrics, psychiatry), increased the reimbursements for one-day surgery, they modified the mechanisms of attribution to groups with complications and introduced new values in the calculation of hospitalization duration thresholds.

Corrections and adaptations took place progressively and without following a defined theoretical model. The circumstantial nature of the corrective actions, functional only to the achievement of specific supply stimulation and management objectives, made the system lose its unity and partly canceled the meaning of relative weight. Yet these choices have made the Lombard regional system an advanced laboratory where the tariffs can be supplemented by the partial reimbursement of the devices and where the high-cost procedures find a partial additional economic recognition. With the tariffs we have tried to discourage opportunistic behaviors (e.g. cesarean section, arthroscopy, "upcoding") but we have also tried to stimulate the growth of many "undervalued" areas (e.g. palliative care and spinal units). Other regions have also felt the need to change the ministerial tariff rate over time. Although different methods have been adopted and different choices have been made, it can be said that in many regions the same tensions to change were present to overcome the static nature of the system.

A testimony of this general condition is represented by the Single Conventional Tariff (TUC) 11: the TUC tariff (agreed between the Regions to standardize the compensation of patient mobility between regions and used for this purpose between 2007 and 2013) represents the synthesis of these different needs obviously not contemplated within the ministerial tariff. Almost all the tariffs existing in the national tariff were modified within the TUC based on lists and conditions agreed between the Regions. These "corrective" interventions are on the one hand the clear signal of a need to govern the system by means of tariffs, on the other a sign of powerlessness of the system which, bound to the "imported" attribution logic, is not able to intervene on the attribution mechanism since it is not the owner.

The outcome of these tensions is that in these years the Regions, relying also on profoundly different logics, have progressively and mutually distanced themselves from a unitary and national model considered too static. The It.DRG Project represents therefore the opportunity to reduce this divergence and for the first time creating a national weighing system that can be built, fed and maintained regularly. Within this project, the Directorate General for Welfare of the Lombardy Region has taken on the task of proposing an updated version of the coding of the procedures and in the course of its realization the attempt to bring back the experiences lived and to try to systematize them was inevitable. combining them with a renewed desire to learn about the evolution of systems in the rest of the world.[96]

The TUC modifies and integrates the value of ministerial tariffs in various points, highlighting the existence of different types of admissions that are not adequately recorded and remunerated. In particular, the interregional compensation of health mobility was

[96] www.salute.gov.it/portale/documentazione/p6_2_2_1.jsp?lingua=italiano&id=2454.

initially regulated by notes from the Ministry of Health (100 / scps / 4.4583 of March 23rd, 1994) as a result of which regional tariffs were applied from 1995 to 2002. In June 2003, the Conference of Presidents and Health Councilors of the Regions and Autonomous Provinces approved the Consolidated Text for the Interregional Compensation of Health Mobility. Technical changes introduced by the regional referents for the year of activity 2001 and later. From July 1st, 2003 the TUC is introduced, updated and approved every year. From 2012 with the Ministerial Decree of October 18th, which introduced new tariffs, the TUC 2012, already extended for 2013, could no longer be applied and the Conference established that healthcare mobility would be offset with the rates published therein.[97]

The "Project of a new system of measurement and enhancement of the products of hospital structures" represents today the most advanced Italian attempt to equip itself with a national system to enhance hospital services. This attempt is in line with a current trend which sees the spread of payment systems by case treaty very similar to DRGs in logic, but autonomous in development and different in form from the original model. Having imported the system of attribution of the cases to the DRGs from the American Medicare system, it is possible that in the transfer, without modification, purposes and application areas that were not coherent with those present in the Italian hospital reality were implicitly accepted.

Hence, the need to equip oneself with a system of their own (more closely related to the strategies of the National Healthcare System), also starting a virtuous path that passes through a new design of the hospital accounting model, also an investment in the accurate detection and timely delivery of data. In this very complex process the

[97] http://www.regioni.it/newsletter/n-1793/del-10-05-2011/mobilit-sanitaria-compensazione-interregionale-testo-unico-4400/.

subject of diagnosis and procedure classifications is perhaps part of an already better defined riverbed, or rather in the need to have uniform and comparable data (an objective in which the WHO plays a leading role), from which the need to find a balance between legitimate needs for autonomy and localization and the need to align with international standards to guarantee maximum comparability.

4.7.1. New technologies

In flat-rate payment systems, new technologies are one of the most critical factors and often become the main trading ground between hospitals insurance / funds that use the DRG system as a reference model. In the context of the NHS, where the updating of the classifications has assumed less and less frequent cadences, each Region has pushed forward in an attempt to govern the phenomenon. Since there is no connection between the authorization process for the introduction of new devices and the updating of the classifications, the list of procedures is destined to be perpetually incomplete. The absence of a detection method, regardless of the activation of reimbursement mechanisms, prevents us from estimating outcomes and the economic impact of the innovation introduced. For those who have invested, the new technology turns out to be a “boomerang”, while the structures less prone to innovation, which do not immediately invest in new technologies, could even receive a benefit when the failure to re-proportion the weights spreads the resources on the whole system, in proportion to the surveys of previous periods.

All this information has now been included in the list of procedures, verifying the correspondence of the classification with the products in the National Classification of Devices (CND), the founding instrument of a possible price observatory for the NHS. It is possible that, in the new experimental software of attribution to It.DRG, these elements can be used to create final groups or to weigh differently end groups left homogeneous. However, there are not only implantable devices. In recent years, all those devices that allow a minimally invasive approach have become particularly important. The percutaneous, endoscopic or laparoscopic approach (especially if it is robot-assisted) generates an increase in variable costs (due to the use of disposable materials) without, however, modifying revenues. Years after the introduction of these techniques there are still no specific rates for endoscopic treatments (considered, wrongly, not "operating room") and there are no differentiations for laparoscopic or percutaneous surgery.

The experimental phase of the It.DRG Project was in fact the first Italian experience in the definition of "regionalized" classification systems, with the consequent limitations linked to the need to build the necessary operational and methodological know-how. In this context, the choice was made to initiate a gradual review of the measurement system of hospital facility products currently in use in Italy, since a more drastic and radical intervention could have generated serious problems. Another limiting element was represented by the lack of analytical information on the cost data per case treated, which would have returned a surely more reliable result with respect to hospitalization durations, unsatisfactory in reading the consumption of resources as often found in international literature.[98]

[98] F. Cots, X. Castells Oliveres, A. Garcia Altes, M. Saez Zafra, *Relation of direct hospitalization costs with length of stay*, Relación Sanitaria, 1997.

One of the key methodological components for the future is in fact represented by the systematic use of evidence on resource absorption data (cost per case treated) as the main driver for the development and finishing of the structure of the classification logic of the IT.DRG, therefore using objective data, quantifiable and coming from reliable sources.

4.8 Italian approach to the definition of costs of hospitalization of hospitals for acute related to new It.drg: the model It.cost

Developing an "Italian system for the identification, measurement and enhancement of acute care admissions", primarily aimed at governing the system and improving the level of value-for-money in the remuneration of NHS providers, presupposed the availability of a standard evaluation model economic of hospital products, fueled by detailed information on the care pathways provided and on the costs incurred.

With respect to the distribution of NHS government levels of competencies in the definition of hospital remuneration systems, the objectives therefore refer to the preparation of the tools necessary to establish levels and payment methods for hospital services as measured by the new It.DRG system. The determination of a tariff system was not included in the objectives, but only of "methodological indications" to allow its preparation and use, at various levels, based on the set of instruments produced by the Project.

The system of relative weights associated with It.DRG, in fact, reflects the existing proportionality between the cost levels of admissions attributed to the individual diagnostic classes. In fact, the measurements on Italian casuistry are similar, starting from the resource / cost absorption profiles observed retrospectively in a sample of NHS hospitals.

This system of relativity of average costs per class therefore constitutes a basic tool for uniformly estimating, for evaluative as well as predictive purposes, the value of hospital admissions for acute care, taking into account their composition in terms of case history (at national, regional level, corporate, operating unit, etc.).

The corrective factors of the relative weights envisaged by the It.DRG system, similarly measured on the Italian casuistry starting from the observed data, constitute the tool to refine the predictive capacity of the levels of consumption of resources / costs associated with the cases dealt with, according to the presence of those characteristics that involve specific consumption and / or care commitment levels that are significantly different, compared to the set of cases attributed to the "basic" IT.DRG.

In the so-called It.Cost Model, adaptation concerns the location of the two crucial elements:

- Cost categories, i.e. the aggregations of hospital costs with respect to which the composition of the average costs associated with the hospitalization classes is established, redefined according to the organizational-managerial characteristics of the Italian hospitals, in order to be fed with the data produced by the existing systems of Accounting, General (CoGe) and Analytical (CoAn);
- Allocation statistics, i.e. the absorption rates of the direct costs included in the individual cost categories, used for the respective distribution between the classes of admissions, redefined to reflect the

care pathways adopted in the Italian hospital context. In this case the adaptation is made even more necessary by the need to adapt also to the new It.DRG classes.

In addressing the path of localization of the system for measuring and evaluating hospitalizations in the Italian context, the basic decision concerned the purposes assigned to the new system. The analysis of foreign experiences on the subject of classification systems clearly indicates how the criterion that guides them is fundamentally constituted by the priority role or weight attributed to the clinical significance or to the representativeness of the costs of admissions.[99]

While in the first case, in fact, the system tends to multiply the number of classes in order to improve the descriptive capacity of the classification in prevalently clinical terms, of severity levels of cases, in the second case the system can contain the number of classes, sacrificing adherence to clinical descriptive needs and giving preference to the system's ability to reflect the variability of service delivery costs.

The analysis of the Italian context existing at the time when it was decided to start the localization path highlighted the following main functions attributed to the DRG system, which are still valid:

1. The allocation of financial resources between providers of the National Healthcare System, for a volume overall higher than 40% of the total financing of the Service;
2. The priority contribution to the definition of standard costs of the levels of assistance guaranteed by the NHS, in consideration of the share of costs absorbed by hospital assistance;

[99] L. Lorenzoni, A.Belloni, F.Sassi, *Health-care expenditure and health policy in the USA versus other high-spending*, The Lancelet, 2011.

3. The priority contribution to monitoring the guarantee of Essential Levels of Assistance (LEA), in consideration of the relative level of robustness of the hospital discharge (SDO) flow compared to other information flows on the NHS activities;
4. The regulation of inter and intra-regional mobility;
5. The description of the clinical characteristics of the casuistry treated in the single NHS hospital facilities, in internal management reporting, in evaluative and comparative studies of hospital and regional performance, etc.

This evidence was based on the identification of the aims of the new hospital admissions classification system pursued by the Project: making the information elements necessary for the governance of the Italian hospital system available to the NHS policy makers, also contributing to a remuneration model aimed at encouraging both best practices, in terms of quality and appropriateness of care provided by hospitals, and efficiency in their internal management.

The project document approved in February 2012 by the Scientific Committee of the Project[100], therefore, in limiting the priority area of localization of the admissions classification system to the acute area, it also established its orientation in the sense of tendentially keeping the classification of products stable over time and mainly acting on factors of adjustment of relative weights to guarantee their refinement and updating of the measurement and, therefore, of valorization.

It is therefore through the adjustment factors of the relative weights per product that the improvement of the specification level of the classification system would take place. In fact, what is proposed is a two-level system:

[100] (Ministry of Health, 2012)

I. the first related to the clinical / epidemiological description of the activities produced, in terms of basic diagnosis / procedure categories, to which are associated the expressive relative weights of the level of consumption of basic / average resources;
II. the second related to the measurement of resource consumption associated with the activities produced, in terms of adjustment factors of the relative weights of the basic categories.

The expected advantages of the system mainly concern their effect in:

- limiting the need for frequent significant updates of the classification and measurement systems of hospital products;
- avoid tending the system towards a detailed classification, with a very high number of final classes containing few procedures, similar to a fee-for-service system;
- facilitate the temporal analysis of production, also guaranteeing a limited number of categories / DRGs at risk of remaining empty or with a low number of cases;
- limit the phenomenon of "forcing" the system (so-called "DRG creep") in order to increase the share of more complex admissions, since the reporting of secondary diagnoses that complicate a DRG is used downstream of the allocation of basic categories and does not represent the only factor in the adjustment of resource consumption (and therefore of the associated remuneration level).

4.9 Ongoing activities and future developments: implementation, management and maintenance

From the beginning of 2018, following the closure of the first experimental phase of the Project and the continuation of the collaboration between ISS and the Ministry of Health, have begun the activities to proceed with the planned experimentation of the products of the 4 work groups, starting from the shared definition and programming of the contributions of the national and regional Bodies involved, in continuity with what was developed in the previous phase. In a nutshell, the experiments are intended to verify and fine-tune the localized versions of the components of the new Italian system for measuring and enhancing hospital products. Therefore, they concern the new classification and coding systems of diagnoses and procedures / interventions, the It.DRG classes and the algorithms for their attribution, and, above all, the new surveys and processing of hospital activity and cost data. "Model It.Cost" for the calculation of the system of relative weights and correction factors. To this end, a group of pilot hospitals will be involved, selected ad hoc.

We therefore started to work collegially (ISS, Ministry of Health and the Emilia-Romagna Region) for the definition of the sample for experiments, in terms of list of pilot hospitals, to be involved in the trials, and numerosity and composition of the sample of hospitalization episodes on which to proceed with the experiments, in order to be able to deduce significant information for the purposes of verifying the revisions of the classifications produced and the expected impact assessments of their adoption at national level, also in economic terms.

4.9.1 Final considerations

The It.DRG Project therefore constitutes a significant intervention of national importance and, in the wake of the "Mattoni" experience, follows unitary, organic, and integrated management methods that through a series of actions converge towards a common development objective in support of the NHS. This objective translates into a modality of concrete approach to the concept of value.

Defined by Michael Porter for the first time, as the return in terms of health of resources invested in healthcare, the value results from the relationship between relevant health outcomes for the patient (favorable outcomes - adverse effects) and costs incurred by the system, and can be estimated both at the level of the entire care pathway, and at the level of the individual health service (drug, diagnostic test, surgery, etc.)

The value in healthcare embraces the concepts of continuous measurement of health outcomes and costs incurred.[101] One of the main exponents of the Evidence-based Medicine movement, Muir Gray, believes that value must also support the way in which resources are distributed to the population (allocative value), the appropriateness of their use for specific needs of health (technical value), as well as the alignment between health results and patient expectations (personal value).[102]

According to Ricciardi, the creation of value-based health services presupposes:

- a reorganization of the assistance on the patient's conditions, favoring the integration of specialties and professionals, abolishing the organization in silos;

[101] M.E. Porter, E.O. Teisberg, *Redefining health care: creating value-based competition on results*, Boston, Harvard Business School Press, 2006.
[102] J.A. Muir Gray, *Evidence-based healthcare: how to make health policy and management decisions*, London, Churchill Livingstone, 1997.

- measurement of outcome and costs for each patient;
- the definition of repayment models for the provision based on value and specific to the condition such as the so-called bundled-payments;
- the creation of care pathways through different settings
welfare;
- sharing best practices with a view to producing and guiding excellence;
- the creation of telematic platforms capable of recording all the data collected and allowing their use for monitoring purposes.

All this would allow us to respect the maintenance of universal, fair, supportive, typical and characteristic coverage of our NHS.[103] In this perspective, in fact, with the more analytical measurement of results and costs for each hospitalization, the results of the It.DRG Project can also contribute to the reformulation of a system of financing aimed at remunerating more equitably and appropriately the services provided in the patient's integrated care path, defining an adequate financial requirement to support the course itself and to remunerate the outcome and therefore the value offered to the patient rather than the health service provided. Starting from the Project we believe that we can take a step forward towards an important change, not only in management and organization, but also cultural, among health professionals, which can push them to actively collaborate as an organization oriented to achieving the best results of health.

4.10 Italian case of anorexia treatment

[103] M.E. Porter, *What is value in health care?*, N. J. Engl, Med, 2010.

Therefore, as can be seen, the models for the evaluation of the costs of pathologies in Italy have been multiple, applied with more or less success to the universally recognized pathologies to which departments are destined. But what happens if a condition that is not yet recognized as such must be treated, as in the case of specific eating disorders as anorexia?

The doctors Abbate Daga, Facchini, Delsedime, De Bacco, Leone and Fassino have tried, successfully, daring an answer to this question through an experiment carried out in the Piedmont region. [104]

Their study is aimed to: a) calculate operative costs of hospitalization and assume if DRG reimbursements are plenty – stating to approximations of the Piedmont Region; b) articulate an examination of cost-effectiveness via valuations achieved with QALYs (Quality Adjusted Life Years, i.e. 1 QALY = 1 year in good health); c) establish if the cost of an hospitalization is acceptable, as linked to clinical advancement and inpatient outcome.

The weight of the costs that the public, private or family patient's health care system must support, often at a pre-operative age, is probably more significant than the expenses for treatment in a hospitalization regime: although the duration of an "adequate cure" includes in average 45 days of stay in the ward and 50 sessions of psychotherapy, the economic loss in terms of productivity caused by the death of a patient or the damages on her social work function largely compensate for the resources used in the treatment.

In this perspective it is essential to identify the criteria for evaluating an intervention both for clinical results and for improving the quality of life. In fact, an advanced evaluation of a health intervention in psychiatry is not only based on efficacy and costs

[104] https://www.jpsychopathol.it/wp-content/uploads/2015/07/11abbate1.pdf.

incurred, but also on how and how the treatment makes the patient's life "better", and therefore her quality of life. The usefulness of considering the psychopathological aspects and those concerning the quality of life separately was also discussed.

The most common unit of measurement in this type of analysis is the QALY (quality adjusted life year: life year gained weighted for quality of life), which assesses not so much the number of years of life gained as the relationship between years and quality of life. The QALY was born with the aim of comparing the years of life spent with different states of illness with those lived in complete health. The basic idea is that the social preferences on the result of the use of resources can be expressed in numerical terms. The preference for each state of health is "weighted" according to the average evaluation calculated on a collective, indicating the patient's choice on a scale that goes from a minimum of zero (death) to a maximum of one (perfect health): utility score.

There are also negative values calculated in the case of clinical conditions of severe disability.[105] It is difficult to assess in terms of quality a year of life of a patient in psychiatry, and to date there is no uniformity of calculation. However recently the cost utility analysis has been applied on psychosis[106] and personality disorders of cluster B.[107] Some authors have attributed a QALY value of 0.222 to a year of life spent with a mean anxiety and depressive symptomatology, another[108] have attributed a QALY value of 0.55 to a year of life of a patient

[105] C. Philips, G. Thompson, *What is QALY?,* Harvard Medical Communication, 2001.
[106] P. McCrone, T.K. Craig, P. Power, et al., *Cost-effectiveness of an early intervention service for people with psychosis*, Br J Psychiatry, 2010.
[107]D.I. Soeteman, R. Verheul, J. Delimon, et al. *Cost-effectiveness of psychotherapy for cluster B personality disorders*, Br J Psychiatry, 2010.
[108] S. Gilbody, P. Bower, P. Whitty, *Costs and consequences of enhanced primary care for depression: systematic re-view of randomised economic evaluations*, Br J Psychiatry, 2006.

suffering from major depression episode. There is no agreement in the literature on the determination of the "cost of a QALY", the most cited estimates vary from a minimum of $ 26,900 to a maximum of $ 165,000 (in 2002 dollars).[109] The most widespread value, and probably the first appeared, is the one proposed in the early 1980s as a standard for dialysis in the Medicare program, in the US, amounting to $ 93,500 (in 2002 dollars).[110] In 2000 the World Health Organization proposed GDP per capita as a threshold value for a year of life associated with a health program: very cost-effective if lower than the per capita GDP (€ 21,550 in 2006; International Monetary Fund, World Economic and Financial Surveys, October 2007), cost-effective if included between one and three times GDP per capita, and not cost effective if it is more than three times per capita GDP (WHO 2000). Finally, the NICE indicates an acceptable expenditure in the range of £ 20,000-30,000. Few researches have been applied in the study of eating disorders in terms of cost and quality of interventions,[111] despite the high cost of this mental disorder and the need for intensive and protracted care that patients with severe eating disorders require.[112]

The research project has set the following objectives:

• Quantify the actual costs of a hospitalization for DCA and determine whether the reimbursement by DRG is appropriate, using the Piedmont Region as a reference for the calculations;

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[109] R.A. Hirth, M.E. Chernew, E. Miller, et al., *Willingness to pay for a quality-adjusted life year: in search of a standard*, Med Decis Making, 2000.

[110] M.C. Weinstein, *From cost-effectiveness ratios to resource al-location: where to draw the line*? In: F.A. Sloan, *Valuating health care: cost, benefits and effectiveness of pharmaceuticals and other medical technologies*, Cambrigde, MA, Cambridge University Press, 1995.

[111] V. Pohjolainen, P. Räsänen, R.P. Roine, et al., *Cost-utility of treat-ment of bulimia nervosa.* Int J Eat Disorder, 2010.

[112]E.L. Harvey, A.M. Glenny, S.F. Kirk, et al., *An updated systematic review of interventions to improve health professionals' management of obesity*. Obes. Rev., 2002.

• Create an ad hoc tool to evaluate 1 QALY in the context of hospital admissions for food addicts;
• Set up a cost / effectiveness analysis through an assessment using QALY;
• Determine if the cost of hospitalization is adequate in relation to the clinical progress and outcome of hospitalized patients.

The working hypothesis is that the severity of the clinical picture (psychiatric and internist) and the complex follow-up of patients admitted to a hospital ward for DCA, imply the need for a highly specialized intervention that requires a higher financial expenditure than that provided for in the repayments established by the DRG. This expenditure would in any case be justified by the increased quality of life of the patients after admission, assessed through an "intervention / non-intervention" relationship favorable to the intervention.

4.10.1 Casuistry

The sample consists of 101 female subjects, divided into the following diagnostic groups: Restorter anorexia nervosa (ANR 53 cases, 53%), Binge Purging anorexia nervosa (ANBP 13 cases, 12.7%), bulimia nervosa (BN 35 cases, 34.3%).

The patients had a mean age of 28.87 years (± 10.08), on average with a long history of disorder (years of illness 9.87 ± 8.65) and of previous admissions (number of hospitalizations in media performed prior the admission taken into consideration by the study: 1.39 ± 1.28). These patients were admitted to the inpatient ward of the SCDU CPR for DCA at the San Giovanni Battista hospital in Turin in the period 01/2006 - 01/2008.

In the hospital setting, patients were subjected to nutritional interventions (also with the use of parenteral or enteral nutrition), diagnostic investigations, motivational psychotherapy and supportive daily interviews, psychopharmaceutical therapy. During admission, a suitable treatment project was also prepared for each patient, based on the psychodynamic formulation of the individual case.[113] The psychodiagnostics tests and evaluation of the intervention were administered at the entrance and at the discharge of the first admission, it was also given an evaluation based on physical and psychiatric parameters six months after discharge: patients were then divided into patients with good or poor outcome. During the two years of the study it was observed if the patient needed a new hospitalization (relapse); the path taken by the patients after admission was also considered, divided between the Outpatient department (psychiatric check-ups and psychotherapy), Psychiatric-Nutritional DH, Community for DCA or Drop-out.

4.10.2 Economic benefits

Some of the most used tools in the cost utility analysis such as the EuroQol 5D (EQ 5D).[114] They make it possible to identify the state of health in which to place each patient through dimensions such as movement capacity, personal care, habitual activities, pain and discomfort, anxiety or depression. Other models use a scale graded from 0 to 100 (Visual Analogue Scale, VAS) on which the subject

[113]S. Fassino, G. Abbate Daga, P. Leombruni, *Manuale di Psichiatria biopsicosociale*, Torino, CSE, 2007.
[114] A. Oreopoulos, R. Padwal, F.A. McAlister, et al., *Association between obesity and health-related quality of life in patients with coronary artery disease*, Int J Obes. 2010;

indicates his or her perceived health status.[115] The EQ-5D is designed to give a self-assessment on the quality of the intervention, the authors have developed a version addressed to relatives or health professionals.

According to Gunther,[116] the CGI scale (Clinical Global Impression Scale) succeeds in giving an evaluation in terms of quality, reliable and comparable to that attributed by VAS and EQ-5D administered by the operators, two of the most commonly used scales in the QALY model. During this first phase of the intervention we evaluated the quality of the intervention through the medical impression of the specialist correlated with what emerged through the CGI disease severity scale, following a CGI correspondence model = 1 with QALY = 0.9 until at CGI = 7 with QALY = 0.3.

Four scales were introduced on the EQ-5D model adapted by the group to be more easily used on DCA: anxiety, depression, severity of the blood chemistry (blood count, electrolytes), severity of food symptoms. An intensity value was assigned to each subscale and a QALY score was assigned, according to this scheme: slight = 0.01 QALY; average = 0.02 QALY; severe = 0.03 QALY. The CGI / QALY and EQ-5D / QALY scores were recorded at each patient's entry and discharge, then added together. Thus, for example, a patient with CGI of 7 and maximum severity in all subscales resulted with a QALY value of 0.18. This value, found in the most serious cases of hospitalization due to severe anorexia, with important internal and orthopedic complications, is comparable to other assessments attributed in hospitalizations due to highly debilitating oncological diseases: in fact,

[115] H.M. Wang, M. Beyer, J. Gensichen, et al., *Health-related quality of life among general practice patients with differing chronic diseases in Germany: cross sectional survey*. BMC, Public Health, 2008.
[116] O.H. Günther, C. Roick, M.C. Angermeyer, et al., *The respon-siveness of EQ-5D utility scores in patients with depression: a comparison with instruments measuring quality of life, psychopathology and social functioning*, J Affect Disorder, 2008.

a score of 0.079 is assigned to "an incapable patient to carry out normal daily activities, high anxiety, deflected mood".[117]

In assigning the DRG value to each hospitalization, the ClinGrouper software was consulted online at www.drg.it. The values emerged through the computer analysis were equated with the Tariff for the Piedmont Region Public Institutions 2006. The amount of actual departmental expenses for each hospitalization, which corresponds to € 422,000, was extracted from the hospital reports for the year 2007 for the University Hospital "S. Giovanni Battista" of Turin.

4.10.3 Results: Average cost of a hospitalization, cost of a day of hospitalization, DRG

The average days of hospitalization were 23.68 (± 7.48). The total cost of staff and medical equipment for the year 2007 divided by the number of days of hospitalization in 2007 (1,082 days) gives an average cost per day of hospitalization of € 390,00. The average cost per day multiplied by the number of average days of hospitalization gives the cost of an admission on average, that is € 9.235. An admission for anorexia has a DRG value of 428, a threshold value of 51 days and a weight equal to 0.7242. The amount calculated for a hospitalization within the threshold value is € 2,231.85 (Amount calculated based on the Piedmont rates - Public Institutions of 01/01/2006), while if above the threshold value the amount corresponds to € 3,894.96.

[117] J. Hutton, R. Brown, M. Borowitz, et al., *A new decision model for cost-utility comparisons of chemotherapy in recurrent metastatic breast cancer*, Pharmacoeconomics, 1996; J. Nielsen, N.E. Jeppesen, K.T. Brixen, et al., *Severe anorexia nervosa: five fatal cases*. Ugeskr, Laeger, 2008.

A hospitalization for bulimia has a DRG value of 432, a threshold value of 25 days and a weight of 0.71. The amount calculated for a hospitalization within the threshold value is € 1,959.64 (Amount calculated on the basis of the Piedmont rates - Public Institutions of 01/01/2006), while if above the threshold value the amount corresponds to € 2824.49.

The average cost of an "outline day", i.e. beyond the threshold value, according to the DRG calculation is € 178.

4.10.4 The cost of care

The cost of admission to the specialized psychiatric ward for eating disorders is about € 9500, or € 390 per hospital day. This value is higher than that assessed according to the ClinGrouper software which is the basis for the calculation of the DRG, which corresponds to € 2231.00 for anorexia and € 1959.00 for bulimia, or about € 178.00 per day of hospitalization.

The "weight" calculated for a hospitalization for DCA (about 0.7) is practically the same as that calculated for a hospitalization with a diagnosis of bronchitis (0.74 points) or a routine intervention for appendectomy (0.72 points) (Italian Tariff 2003). In the case of hospitalization in a structure specialized in the treatment of DCA, the treatment is multimodal and requires the cost of intervention of various medical and paramedical figures, in addition to a marked specialization and aptitude for the care of these patients. absorption of resources must take into account additional variables in addition to those that specifically define the disease (ICD-9 or ICD-9-CM codes) that refer to

the presence of active comorbidity and functional independence, conditions that are particularly evident in patients admitted to a department for DCA.[118]

Furthermore, the care of patients with eating disorders who require hospitalization requires a protracted stay in order to be effective for at least three reasons: a) it takes time to gain confidence and build a genuine working alliance with patients so ambivalent and resistant to treatment as patients suffering from severe anorexia nervosa; b) re-nutrition in the case of weak patients must be carried out with precaution to avoid refeeding syndrome; c) even partial weight recovery requires a few weeks to respect the patient's biological and psychological times.

In fact, it is proved that a limited intervention in time and a late management are predictors of bad outcome in the treatment of eating disorders.[119]

4.10.5 Conclusions

Healthcare costs, particularly in psychiatry, are the result of a complex interaction that involves both the clinician and the patient. A cost problem is also given by the waste of resources in inadequate care. In fact, in the treatment of DCA: "to increase savings through care policies aimed at the economy, reduces hospitalization time, therefore a quick discharge at a lower body weight, therefore greater probability

[118] A. Wagner, H. Aizenstein, V.K. Venkatraman, et al., *Altered reward processing in women recovered from anorexia nervos*a, Am J Psychiatry, 2007.; J.W. Coughlin, R. Edwards, L. Buenaver, et al., *Pain, catastrophizing, and depressive symptomatology in eating disorders*. Clin J Pain,2008.

[119] W. Vandereycken, *The place of inpatient care in the treatment of anorexia nervosa: questions to be answered*, Int J Eat Disorder, 2003.

of a second hospitalization, therefore the increase in costs". [120] In difficult cases, not curing or "curing little" due to scarcity of resources, skills or burn-out stress, costs more than cure.

As we observed in this study, an adequate intervention on a patient suffering from DCA appears to be economically advantageous in terms of cost-effectiveness even considering the early age of onset and the high risk of mortality. The problem of effective care and the importance of having trained therapists for such a specific intervention is therefore outlined.[121] The gain in terms of QALY, however, appears decidedly underestimated by the current system of reimbursement in Italy. Paradoxically, it is economically disadvantageous to deal with the admission of ED in Italy to the National Health System. It is no coincidence that Private Accredited Structures paid per day or much more than in the Public Service proliferate.

The DRG system, based on isoresources, appears to be ineffective in clinical application as it tends to equate very different interventions between them (for example bronchitis and anorexia). On the other hand, an evaluation based on QALYs at the present time has not yet been applied in the context of the DCAs. This model for assessing the quality of the intervention took into account the clinical variability as observed by the therapist through a questionnaire drawn from standardized assessment scales (EQ-5D): this tool was also useful in identifying patients who leave the cures, which fall and those suitable for an intensive DH course.

[120] *Ibidem*.
[121] S. Fassino, G. Abbate Daga, *Percorso formativo psicodinamico per lo psichiatra nell'era delle neuroscienze*, Minerva Psichiatrica, 2006.

Chapter 5

The excellence Italian centre

5.1 The case of Gioia Center

As already seen in the second chapter of this paper, are unequivocally well explained, in Italy, the general directives and settings regarding the cure for eating disorders. The question is: *where* it is possible to cure them?

During the past, several hospitals to cure patients affected by eating disorders, especially in the case of anorexia, in psychiatric and/or gastroenterological wards. Starting from the 00's years, it began usual the idea of of creating specific treatment centers for eating disorders. One of the examples of public centers of Italian excellence is the Gioia Center for the behavior of eating disorders, in Chiaromonte (PZ), Basilicata.

In 1998, the "Study Commission of the Ministry of Health for the assistance of patients suffering from anorexia and bulimia nervosa" had published some specific indications regarding the treatment of these disorders. They conceived the therapy of eating disorders in interdisciplinary and integrated terms. However, care structures were necessary, in which different professional figures systematically

collaborated, privileging, without ever excluding the other, the somatic or psychic verse according to the phases of the illness.

The same Commission hypothesized a technical organizational model according to a network of assistance divided into four treatment levels, based on the severity and characteristics of the patient: the outpatient clinic as the first filter and in any case the most appropriate therapy in most cases; day hospital as a more intensive level of intervention with the possibility of assisted meals; hospitalization in urgency if the clinic conditions were critical and unstable; the rehabilitation hospitalization in an out-of-hospital environment for periods of three to five months, and then imagining a living space where this path can be taken.

Since then the Italian regions have moved, not all and not all with the same pace. But in about ten years no one has been involved in knowing what evolution public health has had in the sector, no monitoring has been done to verify the concrete translation of those lines on the territories. This in the face of a disorder with psychopathological bases that obsessively spreads and dominates the actions of many young people. The discrepancies between the region and the region are very high and there are entire regions, especially in the south of Italy, where no level of assistance is guaranteed.

The realization, therefore, of the care center in Chiaromonte in Basilicata has had a double meaning: on the one hand, to cover a welfare gap in a strategic position easily accessible for all the regions of the South, on the other hand to build a center of excellence in the System National Health, as an example of good health.

The scientific significance and at the same time of appropriate health policy in the structuring of Chiaromonte services was evident; since 2008 it has become the regional reference center and since the same year it has been included among the five centers of excellence for

the multicentric research of the Minister of Health “The Good Care Practices in the Treatment and Prevention of Eating Behavior Disorders”, that had as objectives, in the 2008-2010 biennial activity of monitoring and monitoring the pathology in Italy, to develop a map of the services dedicated to the treatment of these pathologies, to update the national guidelines of 1998.

5.2 The origins

The city of Chiaromonte, with two thousand inhabitants, was mobilized through administrators, operators, the figure of the then mayor Luigi Viola, but also ordinary people, who perceived how revolutionary this project would be. One of the goals was that the place should not be isolated from the community. The assignment of the patients, in fact, also had to be able to have a protective frame for the relatives, thus emphasizing how rehabilitation as a process that involves the opening of negotiating spaces for the patient is fundamental. The Giovanni Gioia treatment center is the first treatment center in the South, and the second in Italy after the experience of the twin center Palazzo Francisci, in the city of Todi in Umbria.

The human and professional experience that took place at the Chiaromonte Center, established on August 2, 2006, allowed for an effective and focused reflection on the complexity and promises of truly decisive interventions specifically for eating disorders (eating disorders) by the creators of the structure, Laura Dalla Ragione, Rosa Trabace, Federico Lapentina and Mario Marra.

They have undoubtedly operated in line with the basic and methodological assumptions and with a view to integrating therapeutic practices, also recognizing that such profound and personal discomfort

requires a complete revisitation and reconstruction of the personality. Therapeutic treatment, therefore, can realize where a realistic and concrete dose of optimism, determination and passion in taking care of the other prevails.

They have translated the intentions of treatment into pragmatic operations and enriched the methodology by enhancing the experiences and contributions of individual professionals, finalizing the methods applied and inspired by already consolidated experiences in the sector, such as those applied to the reality of Todi, to coherence and congestion. As illustrated in their essay, "Emotional Awakenings and Nutritional Ties. An integrated and interactive pathway for DCA care in the center of Chiaromonte"[122], their etymological equation wanted to highlight the essence of a curative purpose aimed at globally taking care of the other in its evolutionary process. in fact, eating disorders are in substance, albeit in a specific and elective symptomatologic structuring, an early interruption or defect of the bio-psychological acquisition of development, which, as such, takes on an acute configuration that reverberates over the entire identity and on the system of socio-parental relations. Therefore, the nutritional process appears feasible in the light of a treatment proposal that restructures the missed imprints and / or attachments and the shackled ties so as to realize the recovery and the possible fulfillment of the compromised evolutionary process. Ultimately, this is the therapeutic purpose of Centre Gioia: to create the conditions so that mechanisms that lead to a desirability of life and consequently awaken nutritional appetite, overcoming the instinctual need denied.

[122] F. Lapentina, R. Trabace, *Risvegli emozionali e legami nutritivi. Un percorso di cure integrate ed interattive dei DCA nel centro di Chiaromonte*, Franco Angeli, Milano, 2009.

A crucial stage for this process to be aimed at autonomy and release is therefore to dissolve in a deeply structured "pathological nucleus" in the unconscious personality of unresolved symbiotic dependence which becomes a nutritional pathological dependence.

It is responsible for treating patients with DCA (Anorexia, Bulimia, Bed) where outpatient treatment is ineffective. It is a treatment area, alternative to the hospital, where girls and boys can live an intensive psycho-nutritional therapy experience, accompanied by a rich and welcoming life experience. It has 20 beds in a residential regime and 10 beds in a semi-residential regime; double rooms and spacious living spaces. It represents the therapeutic continuation in a protected environment of a hospital stay or the alternative to hospitalization itself. The duration of the residential program varies from 3 to 5 months and is such as to allow a weight recovery and the construction of an awareness of the disease that can be accepted by the patient.

It is established by the team and takes place on the proposal of the attending physician, local services and / or directly at the request of the patient. Patients from all over the country are welcomed. Residential treatment and organization of activities in the residency rehabilitation program has characteristics of high specialization and care intensity. The organization of the day is extremely structured, both in the careful management of meals, and in activities aimed at making patients regain proper nutritional behavior. The program includes various phases of assistance both from a psychological and nutritional point of view.

The internal monitoring that takes place once a week (blood and chemical tests) is guaranteed by the services and / or departments of the Chiaromonte Hospital. Family members of resident guests meet every 15 days with nutritionists, dietitians and psychotherapists; there are also parent self-help groups.

5.3 The approach to treatment: from method to education

Each individual is unique, consisting of a biochemical, somatic, behavioral, emotional and reactive uniqueness. Everyone responds individually to events, external stimuli, emotions, food and drugs. The subject, therefore, must be placed at the center of observation, in its entirety and complexity. In a holistic view, the disorder or disease is not only the expression of a sick organ or apparatus, but the manifestation of a breakdown of a mind-body balance.

According to the principles of complementary medicines, every disorder, and therefore also those of eating behavior, are an expression of general discomfort that affects man in his integrity.

Treating the methodological aspect of education inevitably means bringing a reflection about the educational relationship in their multiple implications which, in this context of care, can be defined as a helping relationship. it is a topic of importance as it is supported by the neurobiological perspective that reaffirms the existence of a direct relationship between brain and mind, believing that interpersonal relationships of significant importance have a decisive influence on the development of brain functions. It follows that the influence and determined by the transmission and sharing of emotions play a decisive role in the processes of integration of the various mental functions.

The interaction process requires some fundamental elements: - the predisposition to listening, -the comprehension of verbal, non-verbal and para verbal messages; - the acceptance of the perspective of

others and the consequent satisfaction of needs. Listening should not be understood as a passive process or rather an active process.

The technique proposed in the Gioia treatment centre intends to create a reflective moment of the listener who in this way sends feedback to the other subject of the relationship, according to what is supported by the theory of classical communication which, starting from a coded source, translates a message to be decoded to the receiver thus creating a feedback of communicational return. Particular attention deserves the silence understood not simply as the time between one sentence and the other, rather what Plato defined a silent dialogue of the soul with itself. It becomes, moreover, the ability to be led by the word of the other where the word leads. What has been said underlines the development between the two members of the relationship of an empathic relationship, that is, sharing the emotional state of the other also in relation to the corporality, "I rather put myself in the shoes of the other".

In the educational profession it is, therefore, indispensable developing a particular sensitivity to the body and to the messages that it refers to, precisely since empathy passes through gestures that cannot be considered mere paraverbal actions, but as motor movements of emotional manifestations as it is essential to grasp meta communications and translate them into direct and non-violent communications. Implementing empathetic listening means both avoiding excessive emotional involvement and excessive detachment. in this regard, a reflection on the autonomy / dependence dichotomy is developed. problematizing the concept of autonomy in relation to the idea of dependence means facing an aspect that in the field of education can generate contradiction.

Although not forgetting that autonomy is based on dependence, for the specific purpose of the structure, it should be emphasized that in

the field of eating disorders this dichotomy is resolved as an element aimed at structuring autonomy. The identification of dependence is intended as a negative category and produces the relative assumption of autonomy in an asymmetrical relationship educating / educator.

The relationship, therefore, characterizes the educational method that is determined as an educational style, only when it becomes personal appropriation. The educational styles of reference and their consequences are:

1. Authoritative educational style, where the behaviours of the educator are characterized by the proposal of few rules; by sharing rules that are motivated and respected by all; the rules develop security, but do not escape obstacles, prohibitions or failures; the exception of the rule and part of the style; even transgressions are clear and motivated. These have consequences for the patient who affirms himself in a safe climate; it facilitates the resolution of conflicts and frustrations (problem solving).
2. The second educational style is defined authoritarian: the educator proposes many rules unquestionable; the rules are not motivated; the exception of the rule is not allowed; transgressions involve punishment. The consequences on the patient are affirming himself in a climate of frustration; the reaction and aggression to affirm and defend itself.
3. The third style is permissive or hyper protective: the educator does not propose rules because he is overly concerned with the subject's emotional safety; all requests are met; situations of frustration in tension are avoided as a source of insecurity and emotional distress; the consequences on the patient are the impossibility of developing one's own forces and emotional resources; and

the reaction is one of aggression with respect to the first frustrations.

4. The fourth is the inconsistent educational style: where the rules of the educator depend on the mood of the educator; the educator moves from authoritarian to permissive styles without any predictability of his behaviour; the consequences on the patient are the having no reference point; the development of anxiety, insecurity and aggressive explosions difficult to contain.
5. The fifth educational style is the hyper-anxious: the educator proposes too many rules because he expresses an excessive concern for the patient; the rules limit personal experimentation. The consequences on the patient are the development of the thought dangers are everywhere; the attitude will be of insecurity and shyness aimed at the obsessive search for security.
6. The sixth educational style is the hyper critical one: the educator notes only the negative behaviours of the patient and never the positive ones; the interaction is based on reproaches and criticisms and devaluations; the consequences on the patient are the constant fear of making mistakes; development of low self-esteem.

If the style is such only when there is a personal appropriation of the method with respect to the community, the necessity of a congruity of styles determined by an institutional containment is evident. In other words, the congruity of the relational style is based on a work of identifying the user with whom one comes into contact.

Specifically, in eating disorders, it becomes necessary to adopt a style aimed at favouring social interaction and the development of

self-esteem, which is indispensable for the development of the subject's autonomy and for the resolution of emerging problems in the relationship aimed at positive modification.

This allows us to support an authoritative rather than authoritarian or permissive style, in harmony with the global approach to residential treatment. In the daily practice of educational action, it translates into terms of emotional relationship, care, play, understood in its recreational educational meaning, generating, especially in the relationship with adolescents, the appropriation of maternal and paternal roles with respect to the relative functions. This determines the *social maternage*, which is based on care, education, relationship, authority and recreation, generating positive aspects (such as care, address, emotional exchange, model, creativity) and negative (such as dependency, control, emotional blackmail, up & downs, loss of the role). If *social maternage* is identified, despite its limitations, as a reference model in relation to the adolescent, in interaction with the adult subject it can determine an attitude of care of a welfare type and therefore requires the need for an approach that it is based on peer advocacy, which goes beyond up / down positions to favour the autonomy of the subject.

This model sets the relationship on the enhancement of the other, through a sharing of responsibility between educator and educed, while maintaining diversity and roles. According to this model, the operator must support the user by enhancing full autonomy by virtue of a future posting. The peer advocacy model refers to the peer education model, which is related to the concept of life skills, that is, potentialities present in all individuals that are often hidden. The educational action of the Gioia center tends towards the development of the subject's potential through a multidisciplinary approach.

5.4 The individual educational project

To respond to the criteria for personalizing the intervention, it is essential to use the individual educational project that differs from the general structure project.

The planning intends to give meaning to the daily action, not accidental, rather subject to a process shared by the therapeutic team. In this way, the educator will not take care of the patient who expressly manifests problems but will have a clear understanding of the objectives to be achieved for each subject. This will avoid the onset of misunderstandings, inconsistencies and errors and will neutralize the evaluator's idiosyncrasy, that is, the series of emotional factors that will influence the fairness of the judgment.

The design requires fundamental steps, first of all the definition of the incoming elements, collected in a defined and ample time in relation to the period of permanence. In this phase a “framework project” will be used, sent by other services or to be defined with the contribution of the multidisciplinary team, in which the following are established:

- the general objectives to be achieved;
- The timing of taking charge;
- the definition of responsibilities in the structure of the network nodes.

The use of the individual, family and social anamnesis is also valid, information that will be expanded during the course thanks to subsequent contacts with the family and the sharing of useful information for the continuation of therapeutic treatment between the different professions operating in the Center. It follows that observation, which is the responsibility of the entire team, will become

indispensable. Therefore, *in itinere*, there will be a continuous updating integration of the previous information that will provide an overall picture of the patient. The general objectives can be identified in five macro areas: Autonomy, development of potential, self-esteem and emotional stability, development of appropriate behaviors, relationship skills.

We therefore proceed from the identification of the general objectives to the definition of specific glasses, which allow the development of suitable paths to meet the needs of the individual. The definition of the tools, methods and methods for verifying the intervention implemented will represent the subsequent stages of pedagogical planning. The intervention requires the participation of the interested party who must necessarily be involved in the decision-making process, explicitly. This is an indispensable prerequisite, both with the minor and with the adult, in order to make the intervention feasible and effective.

5.4.1 The communicative process

Communication, as claimed by Consonni, implies an idea of participation and what should be implemented is a conversation or rather an intentional interaction. In continuity with what has been said so far, years can be concluded by focusing on the pragmatic approach of communication, which essentially concerns internal processes as well as their relationship with the reference context. The actions, in this sense, become elements bearing this continuum which unfolds, according to Austyn, in acts:

- *Locutori*: acts of saying something, ie content and form;
- *Illocutori*: acts in saying something, that is, the action of the one who communicates;

- For speakers: in fact, by saying something, the outcome of the communication.

Specifically, the communication process is carried out not only through the action towards the other in need of care, but also as a working method which is Bali, among others, of a valid tool, namely the logbook. It allows the sharing of different elements between operators, including group dynamics, the emotional manifestations of the individual, you have to take action on the educational intervention, episodes of family and social life that the individual reveals.

The risks that arise from educational and community action push the educator to analyze developing new skills, also by virtue of the verified failures. This requires the development of practical knowledge, i.e. decision-making and action-oriented; the development of typological knowledge, that is, that does not proceed conceptually and generalizing cases; the development of articulated strategy of reflections on the action and during the action. It can be concluded by stressing that the development of new skills must necessarily stimulate the communicative and therefore relational process. In the operating reality it is a matter of effectively and sharing this intervention methodology, which also requires the development of a listening and comparison function within the group of educators, as well as accurately detecting the style for being logical and character what a difference the price list. Otherwise one would risk theorizing the importance of the educational role and sacrificing that physiology and spontaneity and authenticity that humanizes it.

5.5 The T-group: criteria of organization and clinical structuring

Residential treatment must be conceived and articulated on field and context situations that always privilege the type of patients rather than the theoretical approaches and, therefore, must take into due consideration the need to make significant permanent changes in a relatively short period of time on different levels of personality.

The typology applied in the Center of Chiaromonte is based on understanding the assortment of groups, their depth and the severity of some evident variables. The most important variables are:

1. The failure to acquire significant primary autonomy and the attachments made or missed during the actual evolution of the individual, since the Psycho-biological imprinting typical of the post-natal weaning process must not be such as to prevent a minimum socialization;

2. The thickness of the defensive and regressive mechanisms and alarm and surveillance systems which are an impediment to the possibility of being in rare relations with each other and among them, in particular, the attitudes of reactive independence and attack or delegating dependence and liabilities;

3. The levels of aggressiveness facing outwards and inwards and the ability to manage the unconscious and vegetative responses attached.

On the clinical evidence level, highly regressive attitudes can cause hysterical blacks that lead to contamination of or highly destructive attitudes of mental paralysis in relationships, considering that the group is highly suggestible and permeable, responds to social pressure conditioning systems and conformism.

In other words, these diagnostic criteria for selection and assortment of groups must appear such as to make the person in the group relationship system treatable ego, otherwise it will be appropriate to proceed to a preliminary or intensive phase of individual

psychotherapy. The person must be put in a position to activate emotional investments in internal relations before external ones in order to effectively modify the typical levels of interdependence, ambivalence and ease of double bonds. In fact, in group relationships the more subtle forms of attack and non-verbalized escape make communication scarcely usable and tend to generate confusion and marked conflict.

For these reasons, a preliminary and good exploration of the personological, experiential and family substrate will allow to implement a sort of prescriptive differential diagnostics for group treatment. On the other hand, the psychodynamic reading of the disorder in terms of missed attachments and unrealized evolutionary processes, provides a key to understanding from a clinical point of view but also such treatment and leads us to understand how important it is to encourage acquisition and emotional passages to the light of an effective modification of the emotional structures of the individual. Precisely for these reasons, the group appears to be an emotional container where the individual first of all feels empowered and then gradually expresses his / her anxieties on condition that the group is perceived as a large therapeutic basket devoid of judgment and resolutive anxiety. Group therapy which must have a prudent analytical and psychodynamic cut is a substantial experiential pragmatic reduction that allows to operate tacitly at an unconscious level and that only in the most favorable situations allows a deep introspective deepening capable of controlling contextualize transparency mechanisms or, in any case, to allow their understanding and processing in a limited time frame.

Inspired by the Foulkesian model[123], it can be said that group therapy situations present peculiar aspects that derive from the way and

[123] S.H. Faulkes, *La Psicoterapia gruppoanalitica*, Astrolabio, Roma, 1976.

from the therapeutic ones. The group is made up of members whose relationships between people can be disturbed and, therefore, discussion and emotional exchange must be fluctuating and free but aimed at the outlet and junction of the blocks that determines the disease. The therapist must represent an active guide who, as a conductor and analyst, must aim to achieve an enough balance between the constructive and destructive indications.

In other words, he must judge to what extent it is possible to proceed with the analytical investigation taking into account the tolerance of individuals and the group as a whole. In essence, communication in the group and gradually to the mental mechanism of annulment and exaltation of the bodily and behavioral manifestations of the disorder is replaced by the occupation of a real emotional space. But for this to happen, the conductor must push communication around the most gratifying resolutive instances and existential expectations.

Considering that the stay in residence can vary from three to five months and that the mobility of patients is unpredictable, it will still be necessary to structure them in terms of groups if you warn me for a total number of 10 or 12 people.

5.6 The diagnostic and therapeutic contribution of medical specialties

In the Gioia care center, the multidisciplinary approach is explicit and made a central part of the care.

It is obvious that eating behavior disorders should be read in a predominantly psychogenic key, but this does not exempt us from an evaluation and it is a careful understanding, referred to us precisely by the clinical evidence of these patients, that many other factors are

related to it, both from a etiopathogenetic point of view that from the functional alterations that derive from it, if not even from the alterations to anatomopathological which structure much more severe organic pictures. The problematic nature of the phenomenon therefore always requires multidisciplinary and integrated interventions which must be wisely initiated, pursued and measured through a sort of longitudinal chronogram of clinical practice. The treatment in order to identify specialized medical tools and methods aimed at rare diagnosis and to practice remedial treatments for emerging and related diseases that would risk invalidating the entire treatment process. Among these, the approach and the psychiatric, endocrinological, paediatric and internist co-operation are essentially analysed, without this being understood as the exclusion of specialized branches of which advice and treatment is required if necessary.

Today, eating behavior disorders can no longer be considered to present a rigorous picture of clinical and phenomenological purity, since we are increasingly seeing an individual historical modification of the problem. In fact, it is frequently characterized by two main aspects: comorbidity and symptomatic migration. For these reasons, the importance of carrying out a diagnostic, psychiatric and psychopathological assessment of the person's overall mental state and an individual differential diagnosis that allows to understand the presence of major and more severe, latent or manifest pathologies, in relation to which the eating disorder proves to be apparent more than substantial.

Precisely for these reasons, if you also want to consider the ease with which you can incur evaluation errors due to the difficulty of measurement and the incidence and depth of other problems, it is appropriate to refer to the updated and contemplated diagnostic criteria and to follow the specific diagnostic criteria. for anorexia nervosa,

bulimia nervosa and eating disorders not otherwise specified. However, it is necessary to consider that the clinical experience, with the scope of the most recurrent and usual charts that are not found in these patients, shows us that this disorder is often accompanied by more or less structured anxious syndromes, reactive depression and obsessive ideational rituality. and varied borderline paintings. Precisely for these reasons, the assessment of the non-opportunity to enter the residential path in Chiaromonte must also be implemented and calibrated on the non-rigid and pre-ordained clinical criteria that duly take into account the motivation, the level of conservation of San and emotional and emotional resources, the ability to adapt to the community environment and, in other words, a substantial personological integrity that allows to contemplate any related pathologies as unmanageable and reversible.

Eating behavior disorders, such as anorexia nervosa, bulimia nervosa, uncontrolled feeding and other unspecified eating disorders, purely medical internists, are of considerable importance due to the many complications that patients affects present. The clinical evaluation of the patient with an eating behavior disorder includes a diagnostic clarification of the disease, an evaluation of other possible causes of weight loss and the consequences of malnutrition, an analysis of the psychological context of the disease and the decision of the treatment plan. Vital signs generally provide good evidence of the degree of malnutrition, since chronic malnutrition is associated with a reduction in blood pressure, a slowing of the heartbeat and also with changes in the electrocardiogram. Other physical changes associated with malnutrition include defined chest and presence of gibbosity for vertebral scoliosis, muscle weakness, hair similar to that seen in babies and reduced reflexes and dry skin.

Most patients with anorexia and bulimia almost normal laboratory tests, although all organs and organs are affected and

compromised by malnutrition. The laboratory anomalies identified in routine tests are generally related to the particular eating habits of individual patients, therefore, in case of chronic malnutrition, there is usually a reduction in the number of white blood cells, sometimes a reduction in the number of platelets and in in some cases a serious anemia the presence of amenorrhea, in fact, would seem to protect the patients, for a certain period, from iron deficiency anemia or iron deficiency.

To make a diagnosis of the eating behavior disorder in its various forms, the evaluation of patients is performed by a group of professionals who, to define the severity of the disorder, the type of treatment to be undertaken, whether outpatient, semi-residential, residential or hospitalization, carries out a series of investigations ranging from general medical check-ups, nutritionists, psychiatrists, to instrumental and laboratory tests.

In this context, the professional profile of the biologist integrates and becomes necessary in the multidisciplinary team of the Gioia Center as it takes care of the guests, monitoring the blood chemistry parameters to evaluate the real state of health and well-being before entering the residence and throughout the rehabilitative and nutritional therapeutic path.

To make patients participate in the usefulness of laboratory tests, they are given technical instructions on how to collect some samples by patients, such as urine culture, or information on the path that their samples or explanations follow regarding the values of the tests performed. All this involves them and facilitates their adherence to a therapeutic path that can give good results. The biologist’s activity at the Giovanni Gioia eating disorders center is divided into several phases ranging from group meetings with guests during which the various topics ranging from how to collect some samples are addressed,

clarified and discussed biological and why they need special attention, the explanation of the normal range of laboratory tests, the explanation of the different terms such as enzymes, electrolytes, hormones, hepatitis, notions about the human body and its organs. In addition, the biologist asks for a weekly meeting with the multidisciplinary team to illustrate the results of the diagnostic tests and thus integrating with the work of the other specialist figures of the center and, moreover, holds individual interviews with the patients focused on all the tests performed individually by each of them, in order to explain why certain dosages are carried out and what their importance is also in relation to the results of each individual patient with respect to the normal range, thus providing them with a detailed comment and clarification on the laboratory reports.

This contact of the biologist with the guests has very positive effects on the guests themselves, as the knowledge of the blood and chemical values stimulates in each of them in various ways, to become aware of the seriousness of the disorder and to become more available for controls. This creates the conditions for a strong motivation to achieve therapeutic goals and adherence to treatment, creating a fundamental therapeutic alliance.[124]

5.7 Rates and concessions

According to the provisions of the regional resolution n. 1454 of 11th October 2011, regarding the adjustment of tariffs to be applied in the regional reference center for eating disorders of the Giovanni Gioia weight based in the hospital of Chiaromonte.

[124] N. La Sala, "*Il contributo diagnostico e terapeutico delle specialità mediche*", in F. Lapentina, R. Trabace, *Risvegli emozionali e legami nutritivi. Un percorso di cure integrate ed interattive dei DCA nel centro di Chiaromonte*, Franco Angeli, Milano, 2009.

The resolution is based on the regional law number 12/1996[125] and subsequent modifications concerning the reform of the regional organization is the resolution of the regional council number 11/1998 with which they have been identified as falling within the general competence of the regional council and according to the regional law number 33 of 31st December 2010 (provisions for the formation of the annual and long-term budget of the Basilicata region financial law 2011), and on the legislative decree of 30th December 1992 on the reform of the national health service followed by the definition the essential levels of assistance of the decree of the Council of Ministers of 29th November 2001.

And given that the resolution of the regional council number 1078 of 20th July 2011 has proven the revision of the tariffs applied at the regional reference center for eating behavior disorders of the weight "Giovanni Gioia" based in the hospital of Chiaromonte and, that others yes the criteria adopted in the aforementioned revision are withdrawals described in attachment number two of the resolution of the regional council number 1078/2011 attributing the burden of the tariff fully charged to the regional health system for the first 90 days of assistance, both in residential cyclic rehabilitation treatment than in semi-residential cyclic rehabilitation treatment (daily 12 hours).

Subsequently, with a note dated 15 September 2011, a reformulation of the aforementioned attachment is proposed so that the total health care of the regional health system is 150 days instead of 90 days. This proposal is aimed at obtaining a real therapeutic efficacy, as it is not possible to activate intensive care and responses until after a significant symptomatic regression of the acute cases and if not after I find myself,

125 https://www.regione.basilicata.it/giunta/files/docs/DOCUMENT_FILE_541617.pdf

the approach with families is a process of overall adaptation, which refer to a minimum standard guarantee period of 150 days.

Afterward, the subsequent note number 304 of 28th September 2011, with which the Stella Maris Mediterraneo foundation, as a qualified subject of excellence for scientific research linked to the IRRCCS Stella Maris of Calambrone (Pisa), once again represents the absolute urgency of modify the attachment of the resolution of the regional council number 1078/2011 to guarantee resolutive therapeutic interventions.

It was found that the aforementioned note confirms the substantial recovery of economic resources by virtue of the significant percentage, attested on an average of 75% of patients from other regions, mainly from the neighbouring Campania, Calabria and Puglia, as already explained in the resolution of the regional council number 1078/2011 and in the related activity data. Following the verification of the requested change, associated with a necessary increase in the cost sharing, equal to 30% already after the 150th day of stay instead of after the 270th day, determine the cyclic residential rehabilitation treatment, the following charges for the regional health system:

Table 5.1 The cyclic residential rehabilitation treatment

Number of days of assistance	Cost in euros, pursuant to D.G.R n. 1078/2011	Cost in euros following the requested amendment	Delta
90	€ 14.400 (€160x90days) 100%	€ 14.400 (€160x90days) 100%	
150	€ 8.160 (€136x60days) 85%	€ 9.600 (€160x60days) 100%	€ 1.440 +
270	€ 16.320 (€136x120days) 85%	€ 13.440 (€112x120days) 70%	€ 2880 -
>270	112/per capita/*pro die* 70%	60/per capita/*pro die* 50%	€ 52 -

Noted that, both in residential and semi-residential conditions, the interruption to 90 days of the therapeutic intervention, and of the dedicated specialist assistance, such as that provided by the Center for Eating Behaviour Disorders in Chiaromonte, could determine the use of hospital assistance by moving, albeit in the presence of only one hospitalization, the delta of increase in expenditure towards the production of DRG and the consequent charges.

It was therefore considered necessary and indispensable to accept what was requested regarding the duration of the residential and semi-residential rehabilitation treatment with consequent modification of the regional tariff. The significant percentage, attested on an average of 75% of patients from other regions, mainly from the neighbouring regions of Campania, Calabria and Puglia and which contributes to the compensation of costs with interregional mobility.

The modifications have been managed as follows:

- Cyclic residential rehabilitation treatment:

  - € 250 per capita/ *pro die*;
  - Adjustment to € 290 per capita / *pro die*;
  - First 150 days for the regional health system. From 150th day to 270th day: 70% paid by the regional health system, 30% by the assisted person, if in need of responsibility by the municipality of origin. From 270º day onwards: 50% to be paid by the regional health system, 50% to be paid by the assisted person, if in need from the municipality of origin.

- Semi-residential rehabilitation cycle treatment (daily 12 hours):

  - € 144 per capita/ *pro die*;
  - Adjustment to € 160 per capita / *pro die*;
  - First 150 days for the regional health system. From the 150th day to the 270th day: 70% to be paid by the regional health system, 30% to be paid by the patient, if in need of responsibility by the municipality of origin. From 270th day onwards: 50% to be paid by the regional health system, 50% to be paid by the assisted person, if in need from the municipality of origin.

- Cyclic daily rehabilitation treatment (six hours):

  - € 80 per capita/ *pro die;*
  - Adjustment to € 92 per capita / *pro die*.

In the cyclical residential rehabilitation treatment and in the cyclical semi-residential rehabilitation treatment (daily 12 hours), the tuition fee is reduced by 30%, in the event of planned temporary absence of the structure for periods but is greater than seven days and the respective rates apply to it of relevance, depending on the period. During the year, entries that restart the acceptance in residential and semi-residential conditions are not possible, with a new entrance paid by the regional health system for 150 days. Entry into the residential or semi-residential regime must be considered continuous for the purpose of counting days of hospitalization. The transition from one treatment regime to another (from residential to semi-residential) is not considered a new entry unless 180 days have passed since the previous discharge. In the case of readmissions that took place within 180 days of the previous discharge, the days of hospitalization, already carried out in a residential or semi-residential regime, are counted for the purpose of determining the cost sharing. Access to the structure is subject to the authorization of payment by the LHS.

CONCLUSIONS

Healthcare costs, particularly in psychiatry, are the result of a complex interaction that involves both the clinician and the patient. A cost problem is also given by the waste of resources in inadequate care. In fact, in the treatment of disorders of eating behavior to increase savings through care policies aimed at the economy, reduces hospitalization time, consequently a quick discharge at a lower body weight, hence greater probability of a second hospitalization then the increase in costs. In difficult cases, not curing or “curing little” due to scarcity of resources, skills or burn-out stress, costs more than cure.

An adequate intervention on a patient suffering from disorders of eating behavior appears to be economically advantageous in terms of cost-effectiveness even considering the early age of onset and the high risk of mortality. The problem of effective care and the importance of having trained therapists for such a specific intervention is therefore outlined. The gain in terms of QALY, however, appears decidedly underestimated by the current system of reimbursement in Italy. It is no coincidence that private accredited structures paid per day or much more than in the Public Service proliferate.

The DRG system, based on isoresources, appears to be ineffective in clinical application as it tends to equate very different interventions between them (for example bronchitis and anorexia). On the other hand, an evaluation based on QALYs at the present time has not yet been applied in the context of the disorders of eating behavior. The problems to be faced in Italy to be able to offer patients the guarantee of being treated with the best treatments currently available are many.

First, the clinical centers are distributed in Italy like a leopard, with some regions able to provide patients with all levels of care coordinated according to a network model of centers of references, while in many others they are missing above all the most intensive care levels.
Secondly, the treatment options offered to patients suffering from eating disorders in existing clinical services depend on the resources available and the training received from clinicians. Although evidence-based psychological treatments are available, such as CBT-E, IPT and FBT, they are rarely given to patients or, when they are, therapists often deviate from the recommended protocol and forget to use some procedures, or omit them from purpose or introducing unexpected procedures In most cases eclectic treatments are administered in which generic psychotherapies of different nature are combined, not always coherently, with prescriptive and psychopharmacological nutritional interventions, mainly dictated by the training received from the various operators and not by a common theoretical model specific to the treatment of eating disorders.

Thirdly, in some clinical services there is an excessive emphasis on hospitalization, and it is common for patients to receive completely different treatments, both in terms of theory and content, when they pass from a less intensive form of care (e.g.. outpatient treatment) and a more intensive one (e.g. hospital rehabilitation treatment) and vice versa. This creates discontinuity in the care pathway and understandably confuses patients about the strategies and procedures to be used to deal with the eating disorder. Some shelter centres also have excessively long waiting lists.

Finally, few clinical centres collect data on the outcome of short and long-term treatments. There is no single solution to these problems. An increase in resources dedicated to the treatment of eating disorders could help. But perhaps a better use of those available could be an even

more effective strategy. The primary objective to improve the current situation should be to be able to offer most patients well-administered treatment based on scientific evidence as soon as possible. Evidence-based therapies are inexpensive, because they are administered by a "single" therapist or by two therapists in 20-40 sessions, and determine, in 2/3 of the patients who complete the treatment (about 80%), a lasting remission from eating disorders. The advantages of these treatments, which include high levels of effectiveness and low costs, are, however, feasible only if the therapists have received adequate training, otherwise the response rates are drastically reduced.

In Italy, unfortunately, even therapists who specialize in treating eating disorders rarely receive training on evidence-based psychotherapies. For this reason, it is necessary to develop new training methods, such as, for example, post-university courses specifically designed to train therapists and get them the skills necessary to use these forms of psychotherapy.

Patients who do not respond to outpatient interventions based on scientific evidence should be offered more intensive treatments such as day hospital or hospitalization in highly specialized referral centres. In these centres, a broad range of medical, psychiatric, psychological and educational procedures are generally offered which are not always consistent with each other and sometimes contradictory messages are provided to patients. To cope with this problem, it is desirable that even in intensive care centres patients are offered a coherent and non-contradictory approach and that therapists, while maintaining their specific professional roles, share the same philosophy and adopt evidence-based interventions. These skills should be acquired through specific training programs that are added to the basic training path of the individual professional in his / her pertinent discipline.

After discharge, it is also indispensable, in order to limit the relapse rate that affects intensive treatments, to provide patients with an outpatient treatment that is not in contradiction with what was done during hospitalization.

Patients who do not respond to more well-administered outpatient and intensive treatments may consider administering interventions that have the primary objective of improving quality of life, rather than reducing symptoms. This decision must, however, be taken with caution, because patients, even with a long duration of the eating disorder, if actively engaged in the treatment can achieve remission or in any case a significant improvement in their psychopathologies and their nutritional status.

Finally, it is desirable to be able to devote more resources to research to develop more powerful and effective treatments for all eating disorders than those currently available.

In conclusion, it is remarkable the conditions which allowed the success and the consequential cost-effectiveness of the policies applied in the Gioia care centre in Chiaromonte.

First, the dimensions of the city. A small town allows the patients not feeling alienated, which would be typical in a large city, creating a sense of protection indispensable to the valuable success of the therapy.

Secondly, the allocated resources from the regional funding, which allowed a continued and efficient care so that even the patients in need would have been sure to receive the best care.

Third, the multidisciplinary équipe, able to cover all the aspect of the care of such a complex pathology.

These are the three indispensable elements to recreate the efficiency of this excellence care centre, in other to develop another useful reality to treat a disease which is still very equivocal and uncertain regarding the rank in the Italian healthcare classification.

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Summary

The intent of this document has been the appraising, discovering and examination of the various quotations to the costs that the medication of anorexia has on the national and on the regional health care system. The five chapters, allocated to give a suitable clarification and drawing of accounting values of anorexia starting from the origins, the effect it has in Italy, the numerous prevention policies applied by the health care system, concluding with a nominee to an exceptional treatment center located in southern Italy.

The historical and cultural social background that has allowed the encouragement and advancement of anorexia in today's society has origins in the pathological contributions related to the lack of deliberation, found many centuries ago: such as the fasting tendency of some Christian saints, which can be reported as in unequivocal examples of anorexic behaviors, or the insatiable hunger present in Greek and Jewish literature. The studies achieved at the beginning of the nineteenth century, which defined the pathology also as anorexia nervosa, it has often been considered a disease, other times it is considered a variant of other pathologies. Starting in the second half of the nineteenth century, several doctors considered anorexia as a result of a hysterical phenomenon. Freud himself, starting from 1895, spoke of a melancholic structure of anorexia by establishing a link between anorexia and depression. Tendentially and cyclically, socio-cultural factors have brilliantly explained and illustrated how some distinct traits are shared throughout history. First, the emergence of a new ideal of lean and tubular beauty that has become above all famous and popular through the media of the West, promoting a psychological edict of ability especially for adolescents, subjected to the judgment of peer

groups. Only recently have these diseases been the subject of research and clinical studies, considered for a very long time a disorder or endocrine I have symptoms or consequences of other pathologies such as hysteria, obsessive neurosis, schizophrenia and mood disorders.

Barely in the last decades of the twentieth century we set out to speak of the so-called “diet industry”, the sponsorship of tools, strategies and programs that could be used for weight loss without taking into account the cost-benefit ratio. According to the latest statistics from the World Health Organization, the incidence (i.e. the number of new cases of a disease, in a defined population, over a given period of time) of anorexia nervosa is estimated to be at least eight new cases percent thousand people among women per year, while between 0.02 and 1.4 new cases percent thousand people among men per year. The age group in which the disease occurs and more often between 15-19 years, some recent clinical observations have reported an increase in onset in pre-adolescent age.

Central question to answer to better scrutinize the efficient results of good policies, is: who is the patient?

The increase in cases in this new society is partially explained by the lower age of the first menarche observed in the last decades, but it could also be connected to an anticipation of the ages in which the adolescent is exposed to social and cultural pressures towards thinness, as the Internet and social media can be. A first approach can also provide a greater risk of permanent damage in addition to naturally malnutrition, particularly if the damage occurs in subjects who have not yet matured the adult body characteristics. In contrast, environmental factors are multiple and can be divided into early - those risk factors that interfere with the early stages of neurodevelopment and with the maturation and programming of stress response systems- and late - childhood abuses, psychosocial stresses.

The premorbid peculiarities of patients with eating disorders are generally similar: timid, submissive, obedient, perfectionist children or adolescents competitive; conscientious and aiming to get the most out of every performance, they have an academic performance that is often above average. At times, on the contrary, we find temperamental characteristics of greater extroversion, with behavioural methods of an oppositional type and with a propensity to compete.

The model for the management of therapy applied for the care of eating disorders it is based on two general principles: multidisciplinary management and the multiplicity of care contexts.

The major advantage of the multidisciplinary approach is the presence of clinicians with multiple skills. They can facilitate the evaluation and management of complicated patients with serious medical and psychiatric problems coexisting with the eating disorder.

The disadvantages can be divided into two main categories of problems: often none of the therapists observes and appreciates the patient's entire clinical picture. Second, facilitates the administration of contradictory information to patients about their disorder and strategies to deal with it. To avoid the insurgence of abysmal consequences, it is essential the clarification of the level of intervention and competences.

In Italy, five levels of intervention are available in the treatment of eating disorders: first level: general practitioner or freely chosen paediatrician; second level: specialist outpatient therapy; third level: intensive outpatient therapy or day centre or day hospital (diagnostic/therapeutic/rehabilitative); fourth level: intensive residential rehabilitation (code 56 or ex art. 26); fifth level: H24 admissions (ordinary and emergency). The role of drugs in the treatment of eating disorders is limited, and however not determined during the evaluation of the instrument's levels. For anorexia nervosa there are no empirically supported pharmacological treatments,

although numerous drugs have been tested, such as antidepressants, antihistamines and recently atypical antipsychotics. However, none has been shown to have a useful clinical effect in improving the psychopathology of eating disorders.

The role of prevention has been very controversial. Some authors believe that giving information about eating disorders can even be counterproductive and harmful. The risk may be to indicate to those litters who are experiencing difficulties or discomfort the “way out”, a system that is followed through processes of imitation and identification since, in effect, for some people anorexia and, in less bulimia, are idealized conditions. However, it is important to evaluate the effectiveness of preventive programs. Only recently have some prevention programs been developed whose effectiveness is not yet established. These programs are generally carried out at school level and normally involve the discussion of problems related to food and their consequences or, more commonly, problems related to growth and adolescence. There is also another type of prevention, called “secondary”, which aims to identify the cases as soon as possible with respect to the onset of the disorder, since it has been established, at the clinical level, that a treatment undertaken in the early stages of the disease is much more effective. Not always, nevertheless, especially in the early stages of illness, the adolescent with a feeding problem admits that he needs help. At this level too, environmental awareness is important: starting with the young people themselves, families and school staff. In Italy, prevention is applied and regulated through the National Prevention Plan. The areas in which the Ministry of Health intends to apply greater prevention policies are described in the Plan, and it is generally divided into periods of 3 or 5 years. The macro objectives of this Plan have been the reduction of the burden of disease, the investment in the well-being of young people, the strengthening and

confirmation of the common heritage of preventive practices, the improvement and the systematization of the attention to fragile groups and, finally, the attention to the individual and populations in relation to their environment. In the field of prevention, it is significant to recall the activities aimed at guaranteeing food safety and veterinary health, which oversee food and feed hygiene and safety, animal health and welfare, and that promote nutritional safety. These prevention objectives are pursued through the establishment of rules, actions, procedures capable of being acted on large territorial and population areas, through legislative/regulatory instruments. The Italian Ministry of Health did not develop, so far, a prevention policy regarding anorexia; the focus on a prevention strategy concerning an eating disorder was about obesity. A working group for the prevention and contrast of overweight and obesity was established on 6th June 2019, established by Ministerial Decree of 18th January 2019 and subsequent additions to the Directorate General for Prevention health.

In 1995, following the reorganization of the National Health Service (NHS) (Legislative Decree 502/1992 and subsequent amendments and additions), a prospective type of hospital remuneration system was introduced in Italy, based on the classification of "Diagnosis Related Groups" (DRG), in Italian ROD (Raggruppamento Omogeneo Diagnosi).

Until then, the hospital activity was described in terms of admissions volumes and hospitalization days provided and was financed based on a retrospective assessment of the costs incurred.

The DRG is a system that groups, classifies and measures the characteristics of hospital admissions based on the type of organ involved, procedures performed and age. In this sense, the DRG system constitutes the natural evolution of the finalized studies "at providing decision makers in hospital planning and administration with a tool for

generating useful information in the design and operation of a progressive patient care facility". Nevertheless, with the adoption of the DRG system for the classification and remuneration of admissions a standardized and meaningful definition was made in clinical and economic terms of the hospital product, allowing assessments and progressively more detailed analyzes, both retrospective and prospective, on a regional, national and international scale.

Currently, the DRG has undoubtedly been recognized, also in the Italian reality, as a valid tool in redefining the relations between producers and paying entities, in allowing a more rigorous regional planning and, finally, in making available to professionals and managers a new unified and recognized evaluation language. The main advances in Italy due to the use of the DRGs are qualitative and quantitative improvement of information assets, an increased monitoring and control capacity for health expenditure and a greater appropriateness in the use of the hospital with transfer of casuistry to levels of care more consistent with the needs of patients. Therefore, as can be seen, the models for the evaluation of the costs of pathologies in Italy have been multiple, applied with more or less success to the universally recognized pathologies to which departments are destined. But what happens if a condition that is not yet recognized as such must be treated, as in the case of specific eating disorders as anorexia? The doctors Abbate Daga, Facchini, Delsedime, De Bacco, Leone and Fassino have tried, successfully, daring an answer to this question through an experiment carried out in the Piedmont region. Their study was aimed to calculate operative costs of hospitalization and assume if DRG reimbursements are plenty – stating to approximations of the Piedmont Region and establish if the cost of a hospitalization is acceptable, as linked to clinical advancement and inpatient outcome. The total cost of staff and medical equipment for the year 2007 divided by the number of days of

hospitalization in 2007 (1,082 days) gives an average cost per day of hospitalization of € 390,00. The average cost per day multiplied by the number of average days of hospitalization gives the cost of an admission on average, that is € 9.235. An admission for anorexia has a DRG value of 428, a threshold value of 51 days and a weight equal to 0.7242. The amount calculated for a hospitalization within the threshold value is € 2,231.85 (Amount calculated based on the Piedmont rates - Public Institutions of 01/01/2006), while if above the threshold value the amount corresponds to € 3,894.96. The cost of admission to the specialized psychiatric ward for eating disorders is about € 9500, or € 390 per hospital day. This value is higher than that assessed according to the ClinGrouper software which is the basis for the calculation of the DRG, which corresponds to € 2231.00 for anorexia and € 1959.00 for bulimia, or about € 178.00 per day of hospitalization.

Healthcare costs, particularly in psychiatry, are the result of a complex interaction that involves both the clinician and the patient. A cost problem is also given by the waste of resources in inadequate care. In fact, in the treatment of disorders of eating behavior to increase savings through care policies aimed at the economy, reduces hospitalization time, consequently a quick discharge at a lower body weight, hence greater probability of a second hospitalization then the increase in costs. In difficult cases, not curing or "curing little" due to scarcity of resources, skills or burn-out stress, costs more than cure.

An adequate intervention on a patient suffering from disorders of eating behavior appears to be economically advantageous in terms of cost-effectiveness even considering the early age of onset and the high risk of mortality. The problem of effective care and the importance of having trained therapists for such a specific intervention is therefore outlined. The gain in terms of QALY, however, appears decidedly underestimated by the current system of reimbursement in Italy. It is no

coincidence that private accredited structures paid per day or much more than in the Public Service proliferate. The DRG system, based on isoresources, appears to be ineffective in clinical application as it tends to equate very different interventions between them (for example bronchitis and anorexia). On the other hand, an evaluation based on QALYs at the present time has not yet been applied in the context of the disorders of eating behavior. The problems to be faced in Italy to be able to offer patients the guarantee of being treated with the best treatments currently available are many.

First, the clinical centers are distributed in Italy like a leopard, with some regions able to provide patients with all levels of care coordinated according to a network model of centers of references, while in many others they are missing above all the most intensive care levels.

Secondly, the treatment options offered to patients suffering from eating disorders in existing clinical services depend on the resources available and the training received from clinicians. Although evidence-based psychological treatments are available, such as CBT-E, IPT and FBT, they are rarely given to patients or, when they are, therapists often deviate from the recommended protocol and forget to use some procedures, or omit them from purpose or introducing unexpected procedures In most cases eclectic treatments are administered in which generic psychotherapies of different nature are combined, not always coherently, with prescriptive and psychopharmacological nutritional interventions, mainly dictated by the training received from the various operators and not by a common theoretical model specific to the treatment of eating disorders.

Thirdly, in some clinical services there is an excessive emphasis on hospitalization, and it is common for patients to receive completely different treatments, both in terms of theory and content, when they pass from a less intensive form of care (e.g.. outpatient treatment) and a more

intensive one (e.g. hospital rehabilitation treatment) and vice versa. This creates discontinuity in the care pathway and understandably confuses patients about the strategies and procedures to be used to deal with the eating disorder. Some shelter centres also have excessively long waiting lists. Finally, few clinical centres collect data on the outcome of short and long-term treatments. There is no single solution to these problems. An increase in resources dedicated to the treatment of eating disorders could help. But perhaps a better use of those available could be an even more effective strategy. The primary objective to improve the current situation should be to be able to offer most patients well-administered treatment based on scientific evidence as soon as possible. Evidence-based therapies are inexpensive, because they are administered by a "single" therapist or by two therapists in 20-40 sessions, and determine, in 2/3 of the patients who complete the treatment (about 80%), a lasting remission from eating disorders. The advantages of these treatments, which include high levels of effectiveness and low costs, are, however, feasible only if the therapists have received adequate training, otherwise the response rates are drastically reduced. In Italy, unfortunately, even therapists who specialize in treating eating disorders rarely receive training on evidence-based psychotherapies. For this reason, it is necessary to develop new training methods, such as, for example, post-university courses specifically designed to train therapists and get them the skills necessary to use these forms of psychotherapy. Patients who do not respond to outpatient interventions based on scientific evidence should be offered more intensive treatments such as day hospital or hospitalization in highly specialized referral centres. In these centres, a broad range of medical, psychiatric, psychological and educational procedures are generally offered which are not always consistent with each other and sometimes contradictory messages are provided to

patients. To cope with this problem, it is desirable that even in intensive care centres patients are offered a coherent and non-contradictory approach and that therapists, while maintaining their specific professional roles, share the same philosophy and adopt evidence-based interventions. These skills should be acquired through specific training programs that are added to the basic training path of the individual professional in his / her pertinent discipline. After discharge, it is also indispensable, in order to limit the relapse rate that affects intensive treatments, to provide patients with an outpatient treatment that is not in contradiction with what was done during hospitalization. Patients who do not respond to more well-administered outpatient and intensive treatments may consider administering interventions that have the primary objective of improving quality of life, rather than reducing symptoms. This decision must, however, be taken with caution, because patients, even with a long duration of the eating disorder, if actively engaged in the treatment can achieve remission or in any case a significant improvement in their psychopathologies and their nutritional status. Finally, it is desirable to be able to devote more resources to research to develop more powerful and effective treatments for all eating disorders than those currently available.

The central question could be: where is it possible to cure the anorexia? The answer is an excellence in the care of eating disorders, the Gioia Centre in Chiaromonte, Basilicata. It is the only public care center in the South, and the second in Italy, with its twin in Todi, Umbria. It is a manifesto regarding the deals of the intentions of treatment into pragmatic operations and enriched the methodology by enhancing the experiences and contributions of individual professionals, finalizing the methods applied and inspired by consolidated experiences in the sector. The therapeutic purpose of Centre Gioia: to create the conditions so that mechanisms that lead to a

desirability of life and consequently awaken nutritional appetite, overcoming the instinctual need denied. It is responsible for treating patients with DCA (Anorexia, Bulimia, Bed) where outpatient treatment is ineffective. It is a treatment area, alternative to the hospital, where girls and boys can live an intensive psycho-nutritional therapy experience, accompanied by a rich and welcoming life experience. It has 20 beds in a residential regime and 10 beds in a semi-residential regime; double rooms and spacious living spaces. It represents the therapeutic continuation in a protected environment of a hospital stay or the alternative to hospitalization itself. The duration of the residential program varies from 3 to 5 months and is such as to allow a weight recovery and the construction of an awareness of the disease that can be accepted by the patient. The account of the study has been based likewise on the interviews to the biologist of the center and to the regional executive secretary of the General Affairs and administrative manager. The first was essential to the explanation on how are organized the several phases of the recovery, ranging from group meetings with guests during which the various topics ranging; the second was essential for the data's recollecting regarding the financing of the Gioia center care, the agreement with the regions of origins of the patients and the consequential affection on the regional healthcare market.

In conclusion, there are the notable conditions which allowed the success and the consequential cost-effectiveness of the policies applied in the Gioia care centre in Chiaromonte. The three indispensable elements to recreate the efficiency of this excellence care centre, in other to develop another useful reality to treat a disease which is still very equivocal and uncertain regarding the rank in the Italian healthcare classification. The dimensions of the city which allows the patients not feeling alienated, the allocated resources from the regional

funding, or the multidisciplinary équipe, able to cover all the aspect of the care of this pathology.