

Presidenza del Consiglio dei Ministri



**CARING FOR PERSONS WITH MENTAL ILLNESS:
SOME BIOETHICAL ISSUES**

21 September 2017

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Presentation

Within the complex and differentiated context of mental illness, the opinion intends to examine from the bioethical point of view the persistent critical issues in psychiatric care within the territory, as well as the prospects offered by the recent closure of Judicial Psychiatric Hospitals (OPG),

The bioethical perspective underlying the analysis is the treatment of those suffering from mental illness through the integration of “*cure*” that is centred on the neurobiological components at the basis of the disease, and “*care*”, which deals with the suffering, subjectivity and needs of the actual person.

This involves calling into question both the principles of clinical bioethics and social responsibility towards the enduring phenomenon of stigma and discrimination, insufficient inclusion, lack of full recognition of fundamental human rights.

In the wake of the paradigm shift, with the closure of mental asylums, from the custodial to the therapeutic model, the opinion emphasises the bioethical tension towards the treatment of those affected by mental illness oriented to the maintaining, as far as possible, of independence: a tension already present in the earlier opinions of the NBC dedicated to the topic of mental health, and which is repeated here in the light of relevant international documents, such as the Helsinki Declaration on Mental Health in 2005 and the UN Convention on the Rights of Persons with Disabilities 2007, but also in the light of analysis, comments and resolutions that, at international level, highlight the criticalities in the concrete realization of enshrined rights.

There is still a distance to be bridged between the ideal model of treatment of persons affected by mental illness that emerges in all its centrality, even from the Health Action Plans for mental health proposed by the World Health Organization at various levels, and the concreteness of the practice.

The opinion focuses on the one and the other level: on the theoretical level, the references, declarations, conventions and international plans are accompanied by an analysis of the legal protection measures that our legal system provides for the protection of persons affected by mental illness; on the practical level, it analyzes the studies carried out in Italy on the mental health system, both as regards the services for acutely ill patients, as well as on residential facilities and district units.

These analyzes, the comparison between theory and practice, as well as the voices of Patient and Family Associations, have given rise to a list of priorities for a more effective healthcare system which respects the rights of persons with mental illness by:

- overcoming the existing variability in the approach of services;
- increasing the capacity of residential facilities to discharge patients and let them return home;
- identifying service quality indices;
- bridging the shortage of social interventions. which constitute one of the most important barriers to reintegration

- increasing research;
- verifying the appropriateness of pharmacological intervention;
- giving effect to the right of patients to timely diagnosis and increasing the taking into care of growing children and adolescents.

Regarding the closure of Judicial Psychiatric Hospitals and the new system of treatment - provided for by Law 81 of 2014 - for offenders deemed to be of unsound mind at the time of committing the offence and therefore acquitted, the opinion expresses appreciation for the principles underlying the new system and the establishment of REMS. (Residences for the Execution of Security Measures).

In particular, it is recommended that the inspiration behind the law providing for individual rehabilitation projects within the territory for the acquitted, should be respected, as a rule the execution of the custodial measure in REMS is to be considered the exception to be resorted to when no valid alternatives provide adequate therapeutic perspectives.

This requires the strong commitment of the territorial services for the taking into care of those acquitted.

As regards the persistence of delays, shortcomings in assistance, stigma and discrimination, the NBC, in order to improve the living conditions of persons affected by mental illness, makes the following recommendations to:

- initiate and support social communication campaigns;
- develop integration between “*cure*” and “*care*” in compliance with the principles of the three Es, (Ethics, Evidence, Experience);
- establish a system for evaluating the quality of service provision;
- promote research, both on the pharmacological and psycho-social level;
- avoid inequalities between the various regions, ensuring that everyone living in our country has the same standards of mental healthcare;
- counteract the decline in the staffing of territorial services by increasing resources to reach the standards of spending of the most advanced European countries;
- support the families of people with mental illness, enhancing the support not only of psychiatric services, but of the entire network of health and social services on the territory;
- activate continuous training opportunities for operators;
- promote greater attention to mental health in childhood and adolescence;
- monitor the implementation of the new system of treatment after the closure of the OPGs;
- ensure the rights of people with mental illness, in accordance with the UN Convention on the Rights of Persons with Disabilities, with particular regard to freedom, equality before the law, social inclusion.

The draft opinion of the working group (proposed by Prof. Marianna Gensabella on 21 September 2015) was drafted by the coordinators, Prof. Carlo Caltagirone, Stefano Canestrari, Marianna Gensabella and Grazia Zuffa until

2016, the group was joined, starting from 2017, by Profs. Salvatore Amato and Monica Toraldo di Francia.

Integrations, contributions and suggestions useful for the drafting of the document were received from Profs.: Luisella Battaglia, Carlo Casonato, Francesco D'Agostino, Antonio Da Re, Lorenzo d'Avack, Silvio Garattini, Assunta Morresi, Andrea Nicolussi, Laura Palazzani and Carlo Petrini.

The final draft also took account of the numerous points made during the plenary discussions and during the hearings: with Prof. Alberto Siracusano, psychiatrist and director of the Department of Neurosciences at the Policlinico Tor Vergata (28 January 2016); Prof. Roberto Mezzina, Psychiatrist and Director of S.O. Department of Mental Health, Director of S.C. Center for Mental Health - Area 1 - Barcola and Altipiano, Head of the WHO Center for Research and Training / ASS. 1 Triestina (February 25, 2016); and Mrs. Gisella Trincas, President UNASAM (National Union of Mental Health Associations) in plenary session (27 May 2016); and with Prof. Giovanni de Girolamo, psychiatrist Scientific Director of the IRCCS San Giovanni di Dio Center, Fatebenefratelli, Brescia (June 22, 2017).

The opinion was approved unanimously by those present at the plenary session of September 21, 2017 by Profs: Salvatore Amato, Luisella Battaglia, Stefano Canestrari, Carlo Casonato, Francesco D'Agostino, Antonio Da Re, Lorenzo d'Avack, Mario de Curtis, Carlo Flamigni, Marianna Gensabella, Assunta Morresi, Rodolfo Proietti, Lucetta Scaraffia, Monica Toraldo di Francia, Grazia Zuffa.

The consultative members, Dr Maurizio Benato, Carla Bernasconi and Carlo Petrini also voted in favour.

Profs.: Carlo Caltagirone, Cinzia Caporale, Bruno Dallapiccola, Silvio Garattini, and Laura Palazzani absent from the plenary session subsequently adhered to the document.

Premise

The NBC accepts the definition of mental illnesses provided by the American Psychiatric Association, which identifies them as changes in thinking, emotion or behaviour (or a combination of these), involving distress and/or problems functioning in social, work or family activities.¹ Given the wide range of possible symptoms, when referring to mental illness, reference should always be made to a standardized classification system, that is to say, a list of disorders recognized to date, accompanied by their description and list of symptoms and other indispensable criteria for diagnosis. The most widespread in the world today is the DSM/Diagnostic and Statistical Manual of Mental Disorders (now published in the fifth edition), published by the American Psychiatric Association, whose structure follows a multi-axial system. The other international classification system is the *International Statistical Classification of Diseases and Related Health Problems Tenth revision.(ICD-10)*. The WHO makes reference to this in its latest mental health action plan, "mental disorders" is used to denote a range of disorders that fall into the ICD-10 classification.

Within the aforementioned classifications, we can find disorders of varying severity, with significant differences, both in the degree of suffering and effects on the person's social interaction skills. This opinion does not aim to analyze the clinical issues related to the range of mental illnesses, rather it aims to address the state of care of persons suffering from such diseases in our country. In particular, the opinion arises from the need to consider from the bioethical point of view the critical issues that emerge from the various research works carried out on the current state of psychiatric care within the territory. These critical issues burden the lives of those affected by mental illness and their family members, and are strongly denounced to Institutions by scientific societies, such as the Italian Society of Psychiatry, and by patient associations and patient family associations, such as UNASAM (National Association of Mental Health Associations).²

In addition, the NBC intends to discuss the prospects opened up by the legislative amendment (Law no. 81/2014) that has led to the closure of Judicial Psychiatric Hospitals (OPGs), as well as the implementation problems involved: this is the most important innovation in the field of mental health after the closure of mental asylums and the beginning of taking charge by the territorial care system.

¹ The original definition of the American Psychiatric Association (APA) can be consulted at <https://www.psychiatry.org/patients-families/what-is-mental-illness>, on the patient and family website: *Mental Illnesses are Health Conditions Involving Changes in Thinking, Emotion or Behavior (or a Combination of These). Mental Illnesses are Associated with Distress and/or Problems Functioning in Social, Work or Family Activities.*

² UNASAM is the largest national network of mental associations to which 70 organizations from all regions of Italy adhere (www.unasam.it).

1. Evolution in the concept of healthcare for persons with mental illness

The treatment of those affected by mental illness, as occurs in other contexts of healthcare, can be seen from two different perspectives which are distinct even as regard terminology, the perspective of "cure" which focuses on the neurobiological component behind the illness, and that of "care", which involves "caring for" the suffering individual, taking charge of subjectivity and the person's needs in the reality of personal life experience³. The two aspects intersect and integrate in a particular way in the healthcare for persons with mental illness, based on the recognition of the importance of effective treatment and the relational and socio-environmental components that affect the development of the disease and prospects of recovery.

At the bioethical level, both the principles of clinical bioethics and social responsibility towards the ongoing phenomena of stigma and discrimination, the lack of inclusion, and the incomplete recognition of fundamental human rights are called into question. Some major cultural changes that have crossed psychiatry need to be dealt with. Firstly, the transition from the "custodial paradigm" to the "therapeutic paradigm" through superseding the identification of the person as a "danger to himself and to others". The arriving at the therapeutic model in the field of mental health is deeply influenced by another paradigmatic revolution that has generally affected the field of medicine and care: superseding the so-called individual clinical approach (concentrated on the psychophysical deficit of the individual), prevalent until the sixties, in favour of the approach of the "the individual in context", which attempts to capture the interaction between individual characteristics and environmental components.⁴ In the specific field of mental health, this evolution has produced convergence on the "bio-psycho-social" model, which seeks to capture the interaction between individual biological and psychological components and the psychosocial and environmental factors that determine the development of the disease and affect its course.

³ The literature emphasizing the "therapeutic" importance of the conjunction of the two aspects is now very substantial and the same 2014 *Code of Medical Ethics* seems to recognize this requirement in Article 20. In this article it is stated that "the doctor in the relationship pursues the care covenant", founded not only on comprehensible and comprehensive information, "on mutual trust and mutual respect of values and rights", thus recognizing "the time of communication as a time of care".

⁴ For this paradigm shift see among others J. ORFORD, *Community Psychology*, Wiley, Chichester 1992; J. ORFORD, *Community Psychology: Challenges, Controversies and Emerging Consensus*, Wiley, Chichester 2008. The "individual in the context" approach is also recommended in international documents. See the *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health* (June 2017), where point 9 reads: the "limitations of focusing on individual pathology alone have been acknowledged, locating disability and well being in the broader terrain of personal, social, political and economic lives" (www.ohchr.org/EN/HRBodies/HRC/RegularSessions/.../A-HRC-26-31_en.doc).

Upon this new stimulus important surveys on the population have been conducted since the 1960s, which on the one hand reveal the role of negative circumstances (stressful events) on the most common disorders; and on the other show the importance of protective factors, in terms of relational and environmental resources, in overcoming the crisis. This second aspect allows a rebalancing in the traditional approach: rather than insisting on the "deficit" of the pathological aspects, one looks at the relational and social resources still available to the person, trying to support and increase them. It follows that there is a widening in the field of intervention in a preventive-proactive direction towards the promotion of individual and collective mental health, in addition to the treatment of the disease: seeking to follow the person in his or her life context, so as to strengthen the protection factors and be able to prevent crises as far as possible, and in the event of crises, to intervene in a timely manner to resolve them.

These steps are essential to understanding the mental healthcare model after the abolition of mental asylums a model centered on a widespread territorial network of mental health services, with a holistic approach to the person and with the goal of maintaining it in the person's living environment. To this end, interaction with the entire network of social services is crucial, in order to activate and strengthen the social and relational networks of the person. Mental health services must be able to perform early diagnosis and provide timely and continuous treatment to reduce chronic disorders, prevent crises as much as possible and, when these occur, resolve them as much as possible while keeping the person in his or her life context (limiting therefore admissions to hospital during the acute phase and especially CTOs)⁵.

The principle of respect for human rights provides an ethical guide to the operators and is at the same time a means of *empowerment* of the person towards the goal of *recovery* (the path towards the best possible state of health and towards better integration without discrimination)⁶. This objective is related to what is stated in the Preamble to the WHO Act (and reproduced in previous opinions by the NBC), according to which "possessing the best state of health that is capable of being achieved constitutes one of the fundamental rights of every being human. This is to affirm an ethical duty to ensure that each and every one can aspire to achieve this state, necessarily different from subject to

⁵ With regard to the model of promoting health and its theoretical assumptions, cf. B. DOHRENWEND, *Social Stress and Community Psychology*, "American Journal of Community Psychology", 1978, vol. 6, n. 1; M. E. SELIGMAN, T. A. STEEN, N. PARK, C. PETERSON, *Positive Psychology Progress: Empirical Validation of Interventions*, "American Psychologist", 2005, n. 60 (5); E. L. TEED & J. A. SCILEPPI, *The Community Mental Health System: A Navigational Guide for Providers*, Allyn & Bacon, Boston 2006.

⁶ For a closer look at the concept of *recovery*, cf. M. LEAMY, V. BIRD, C. LE BOUTILLIER, J. WILLIAMS, M. SLADE, *Conceptual Framework for Personal Recovery in Mental Health: Systematic Review and Narrative Synthesis*, "The British Journal of Psychiatry", Nov. 2011, 199 (6) 445-452. On the steps to be taken to ensure that everyone can strive to achieve the best possible health status "also in terms of increasing the operational capabilities of individuals", the NBC opinion *Bioethical guidelines for equal access to healthcare* 25 May 2001

subject, as part of a redefinition of the problem of health even "in terms of raising the operational capacity of individuals."⁷

This community care model, which finds a reference point in the so-called Basaglia law, still presents serious critical issues in its actual implementation, years after the transposition of this law within the wider legislation of the National Health Service. The difficulties still present with community-based care make it difficult to realize "healthcare" for people with mental illness that integrates as a fundamental part the respect for fundamental human rights, along with an adequate supply of social support. In most cases, social and relational support is confined to the work of families, where women, in particular, end up bearing often the entire burden of giving assistance.⁸

2. Care for people with mental disorders in previous NBC opinions

The National Committee for Bioethics has already devoted several opinions to the topic of mental health:

- On the ethicality of electroconvulsive therapy 1995, where electroconvulsive therapy is not totally condemned, although it is recommended that it should be used prudently;
- The treatment of psychiatric patients: bioethical problems 1999, which commented on the White Paper of the Council of Europe on the treatment of psychiatric patients, focusing in particular on the legality, motivation and methods of involuntary hospitalization and involuntary treatment, and ultimately highlighting "the need for a balance between the principle of beneficence and the principle of autonomy and the principle of autonomy in accordance with critical guarantism";
- Psychiatry and mental health: bioethical guidelines 2000, which, more than twenty years after the entry into force of Law no. 180 of 1978, the so-called Basaglia Law, raises a reflection on "ethical, professional and social aspects of mental health and psychiatric care", with a series of expert contributions preceded by a concise framework of recommendations;
- Medical restraints: bioethical problems 2015, which denounces the continued widespread practice of using medical restraints even in non-exceptional circumstances, in spite of the most current and accredited ethical and therapeutic guidelines.⁹

⁷ In the aforesaid preamble, the concept of possible health is also valued not only for the benefit of "connecting medical care with a non-reducing conception of health and prevention" but also "to introduce what is one of the major issues of health justice, that is, the impossibility of deciding on distribution issues by assigning the same share of resources to everyone. for the different natural and social distribution of diseases and psychophysical deficits, and therefore the different degrees of intervention needed to ensure the health possible" (see, in particular, the opinion of the CNB, *Bioethical guidelines for equal access to healthcare* 25 May 2001

⁸ See the results of research into the role of social support later.

⁹ Related to specific diseases, but always in the context of mental health are the opinions: *Mental disability in developing age and autism* April 19, 2013; *Dementia and Alzheimer disease*:

Among the topics discussed in the previous opinions, is the importance of the centrality of the doctor/patient relationship, highlighted in the opinion of 2000, a relationship which today needs to be reviewed in the light of the model of an extended therapeutic alliance to be realized throughout the territory in community-based care. The need to overcome the "manicomial-custodial" model is fundamental: the care relationship, centered on respect for the dignity of the person with mental illness, is aimed at obtaining as far as possible the person's consent, seeing as the achievement of greater autonomy and best quality of life possible are the main objectives. The critical issues inherent in such a transition can not be silenced. In the case of people with mental illness, peer recognition and respect for and promotion of autonomy collide with the persistent conviction that such persons are, by way of their very illness, dangerous for themselves or for others, and such convictions justify involuntary hospitalization and involuntary treatment. In addition, doubts regarding mental capacity and competency undermine respect for autonomy at the time of consent/refusal of treatment.

Since the first opinion, on the ethicality of electroconvulsive therapy (1995), the NBC has expressed a clear bioethical orientation in favour of the promotion of autonomy, adopting a position, while recognizing the difficulties, regarding "the ethical indispensability of making every effort to acquire consent". The same perspective is present in the 1999 opinion, Treatment of psychiatric patients: bioethical problems. Here, commenting on the White Paper of the Council of Europe dedicated to the treatment of psychiatric patients, we discuss the legality of involuntary hospitalization and involuntary treatment, focusing on the concept of danger and its connection with social stigma, questioning whether danger is inherent in all categories of psychiatric nosography. In conclusion, the NBC highlights the need for a balance between the principle of beneficence and the principle of autonomy in accordance with critical guarantism: a balance that can be sought, for example, by providing alternatives to involuntary hospitalizations such as *day hospital* and *home care*. In the same document, the NBC adopts a position on the ethicality of particularly invasive therapeutic treatments and the integrity and dignity of the person, such as the psychiatric use of neurosurgery, and restrictive practices on freedom, such as the isolation and restraint. Regarding the first, it states that the risk-benefit parameter is such that its application is severely discouraged, while as regards the use of restraints and isolation it states that they must be drastically reduced and practiced only in exceptional cases. Concerning these two practices, the NBC already noted in this 1999 opinion that it would discuss in more depth in the subsequent opinion on containment, namely the convergence between the ethical standard of respect for personal dignity and the clinical-therapeutic criterion. The difficulties in balancing bioethical principles in healthcare for persons with mental illness are therefore not underestimated

but addressed in the perspective of respect and promotion of the greatest possible autonomy.

This is also the perspective adopted in the 2000 NBC Opinion, *Psychiatry and mental health: bioethical guidelines*. Care must be guided by a strong ethical tension: the affirmation of autonomy and promotion of the rights of patients, "even independently of their ability to exercise them."¹⁰ This tension does not translate into an unrealistic view of an alleged ability to be free, but as a help to "become as free as possible", in the belief that "recognition of prior rights constitutes for those who can not claim them for themselves, the only opportunity for a possible change."¹¹ In the opinion, the autonomy of the person is always pursued as an objective, as far as possible, even if it is seen as the implementation of the principle of autonomy in the practice of informed consent both in psychiatric patients, subject to particular difficulties, since it collides with the problem of ascertaining mental capacity and competency which in these patients often seems to oscillate, and is at times blurred, depending on the type and phases of the actual pathology.

The opinion calls attention to the definition of capacity, to clarify as far as possible the stage in which the person is. The thesis advanced is the need to steer clear from both a priori denial of capacity, almost a bias against the person with this kind of disorder, and simplistic optimism.¹² The perspective of respect for autonomy is also the perspective of promoting the rights of persons with mental illness. And the 2000 opinion focuses precisely on rights, distinguishing between the rights that fall within the relationships of care, rights that concern the respect of privacy, rights related to the relationship with society, and overcoming stigma and discrimination.

Years after the opinion *Bioethics and mental health*, which gives a broad and detailed look at the subject, the NBC intervenes on a particular issue, that of restraint, denouncing this ongoing widespread practice - which, moreover, does not concern only those affected by mental illnesses. In the 2015 opinion on *Medical restraints: bioethical problems*, the Committee denounces that the practice of restraining (pharmacologically and physically) male and female patients against their will is still being applied, even in non-exceptional circumstances, despite the fact that several international bodies and this same Committee, in previous opinions, have declared themselves against and advocate the need to make an increasingly reduced use of restraints, until this remainder from the asylum culture is ended. Taking a step forwards in relation to the 2000 opinion, the NBC argues that the principle of autonomy is not balanced here with the therapeutic principle, rather, it is a substantial part of it, becoming "the driving force of valid and effective therapeutic intervention".¹³

¹⁰ Cf. NBC, *Psychiatry and mental health: bioethical guidelines* 2000, 24 November 2000, Presentation p. 9.

¹¹ *Ivi. Summary and Recommendations*, p. 12.

¹² *Ibidem*.

¹³ NBC, *Medical restraints: bioethical problems*, 23 April 2015, p.7.

3. Care for people with mental illness today: bioethical perspectives

Today the NBC begins reflection on the care of persons with mental illness, moving in the same direction: guaranteeing and promoting the greatest possible autonomy, considering this promotion as an integral part of the same process of care. The principle of autonomy therefore has a strong emphasis on the bioethical horizon that serves as the theoretical background to the opinion, although it is neither the only one nor the first in hierarchical order. The balancing of the principle of autonomy and the principle of beneficence, the point of arrival of previous opinions, a balance which ultimately converges with their being integrated, seeing as achievement of greater autonomy is a fundamental part of the "good" of the patient, is, in this opinion, accompanied by the theoretical assumption of interaction between the four principles set out in the 1998 Barcelona Declaration¹⁴: namely, autonomy, dignity, integrity, vulnerability.

As stated in the Declaration, autonomy should not be interpreted solely in the sense of the ability to give informed consent to treatment, but more complexly, as a regulatory idea and at the same time as an ideal commensurate with human finitude, considering the biological and social, cultural and cognitive determinations and the limitations of capacities in individuals. The commitment is therefore to recognize, as democratic societies, the human person as a complex being, a living body located within a cultural context. The autonomy of minors and, in general, of "weak subjects" should therefore be defined and articulated in relation to the responsibility that their specific vulnerability imposes.

The second principle formulated by the Declaration is that of dignity, to be understood as "the property by virtue of which beings possess moral status". The third principle, integrity is "the condition of the expression of a worthy life, in its mental and physical dimension, not subject to external intervention". Integrity, therefore, constitutes respect for subjective rights and, in particular, concerns the "coherence of life" of beings who are recognized as possessing irreducible dignity and who can not be offended. When it comes to human beings, one must consider the whole of their remembered and narrated life. It is therefore their biography that must be referred to, that "fictional unity" which is the expression of every existence.

The fourth principle, vulnerability, refers to a situation of particular weakness and fragility, that of persons who by age, condition, etc. need special protection. In the general sense of the word, it concerns the very precarious

¹⁴ Signed by twenty-two European scholars from various disciplines and philosophical horizons, at the conclusion of a research project promoted by the European Commission, the *Declaration* sets four regulatory ideas - autonomy, integrity, dignity and vulnerability - useful to guide contemporary debate on biomedicine and biotechnology in a regulatory context, in the framework of an ethics of solidarity, responsibility and justice understood as equity (see JD RENDTORFF & P.KEMP, *Basic Ethical Principles in European Bioethics and Biolaw*, Copenhagen & Barcelona, 2000).

condition of all living entities, human and non-human, that are exposed, in the course of their existence, to the risk of being hurt and are therefore eminently "vulnerable". It is, in particular, this second meaning, with a strong ethical and anthropological value, which highlights important implications for the issue of care. The interaction between these four principles is the bioethical horizon for considerations on the current state of treatment of persons with mental illness and on the hypothesis to advance in order to address the critical issues that still exist.

To these principles we add the principle of justice, which focuses on the distribution of resources for mental health (always at risk, probably due to the particular vulnerability of the subjects involved, with greater restrictions than other areas of Healthcare)¹⁵; but also on the question of equality, equal access and social inclusion, fighting the stigma and discrimination still present against people with mental illness. The reiteration of these principles, often subject to "oversight"¹⁶ is the theoretical background that give rise to reflections on the discrepancies between the statements of principle on the rights of persons with these pathologies and the realization of these rights in community based care.

4. The rights of persons with mental illness: the Helsinki Declaration and the UN Convention on the Rights of Persons with Disabilities

The slow socio-cultural and legal process that has led to the affirmation of the rights of persons with mental illness needs to be re-read within the broader movement for the rights of people with disabilities, even in connection with other historical movements such as those of women and black people. In such a stream of demands the voices of people with mental illness arrive late. The reasons for this are due to a number of causes, which denounce all the particular vulnerability of these subjects: from institutionalization, to social perception, which marks them as being prone to violence, instability, and mental incompetency. Despite these adverse pressures, not completely overcome, it is possible to note significant progress, especially at a theoretical level, although there are some critical issues in the field of care. These steps forward have been recorded and, at the same time, encouraged by several international documents, subsequent to the NBC opinion in 2000, including two of particular relevance.

The first is the Declaration on Mental Health in Europe, signed in Helsinki in 2005.¹⁷ Here, in the part devoted to the aims, we take note of the evolution of many aspects of policies and services for Europe's mental health. This evolution is marked by the definition of the dual objective of social inclusion and equity

¹⁵ C. MUNIZZA, M. ZUCCOLIN, *Il ruolo etico dello psichiatra nell'era della razionalizzazione delle risorse*, in M. BASSI, S. DE RISIO, M. DI GIANNANTONIO, *La questione etica in psichiatria*, Il Pensiero Scientifico Editore, Roma 2000, p. 45.

¹⁶ C. DE BERTOLINI, M. RIGARELLI, *Questioni etiche nell'intervento dello psichiatra nell'ospedale generale*, *ivi*, pp. 55-56

¹⁷ World Health Organization, European Ministerial Conference on Mental Health, *Declaration on Mental Health for Europe*, Helsinki, Finland, January 12-15, 2005.

and also records a change in care "provided in a wide range of community services and not exclusively in large closed institutions". This new localization of care throughout the territory is recorded as a change that goes in the "right and necessary direction". In the various parts of the Declaration, the fundamental emphasis on mental health ("there is no health without mental health") is accompanied by the accentuation of the fight against stigma and discrimination in favour of the protection of human rights and dignity of persons with mental illness, as well as on their social inclusion.

The need for respect for autonomy and dignity is specified in various commitments, including: "offering persons with mental health problems choice and involvement in their own care, paying attention to their needs and cultures"; to "review and, if necessary, introduce legislation to support equal opportunities or anti-discrimination"; and "apply measures that put an end to inhuman and degrading treatment". Once again what emerges is, the need for full involvement of persons with mental illness, their family members, the associations that represent them to plan and develop the services dedicated to them¹⁸. A key role is attributed to 'information', both to strengthen the capabilities of persons with mental illnesses, *carers* and non-governmental organizations, and to capture data that enable the monitoring of policies and activities that promote human rights and inclusion.

A greater emphasis, both for the commitments required from the signatory States, and for the theoretical framework and strong social impact, is given by the UN Convention on the Rights of Persons with Disabilities in 2006¹⁹. The purpose of the Convention is to "promote, protect and ensure the full and equal enjoyment of all human rights and fundamental freedoms by persons with disabilities, and promote respect for their inherent dignity."²⁰ Paragraph 2, specifying "who" falls within the definition of persons with disabilities, makes explicit reference to mental and intellectual disabilities, stressing that in all forms, disability is due to the interaction between the impairment and the barriers to full social participation based on equality.²¹ The Convention commits,

¹⁸ Helsinki Declaration, *Priority*, point V; *Responsibility*, item 11.

¹⁹ *UN Convention on the Rights of Persons with Disabilities*, 2007, <http://www.unric.org/documents-onu-in-italiano/51>. See the Motion of the CNB on the *Convention on the Rights of Persons with Disabilities*, of 27 June 2008, in which the Committee "is unanimous in urging the rapid adoption the Law on ratification and implementation of the *Convention*". The CNB also hopes that "after ratification, the Government will promptly and timely implement its commitment to promote, through revision of laws and active policies, the measures necessary to ensure that the rights and freedoms of the disabled are effectively and concretely recognized and protected".

²⁰ *UN Convention on the Rights of Persons with Disabilities*, *cit.*, Art.1, c.1.

²¹ The identification of people with mental illnesses as people with disabilities is justified in art. 1, c. 2 of the *UN Convention on the Rights of Persons with Disabilities*: "People with disabilities include those who have long-term physical, mental, intellectual, or sensory impairments that interact with various barriers may prevent their full and effective participation in society on a equality with others". *On this see* S. HOFFMAN, L. SRITHARAN and A. TEIPAR, *The United Nations Convention on the Rights of Persons with Disabilities Impacting Mental Health Laws and Policies in High-Income Countries*, Canada BCM International Health and Human Rights, 2016, 16, 28.

as is apparent from Art. 4, States Parties to "ensure and promote the full realization of all human rights and fundamental freedoms for all persons with disabilities without any discrimination based on disability".²² All rights therefore enshrined apply also to people who have problems affecting mental abilities.

The 2008 Implementation Manual for the United Nations Convention on the Rights of Persons with Disabilities, curated by the *World Network of Users and Survivors of Psychiatry* (WNUSP) clarifies the changes that an effective compliance with the Convention should bring to the lives of persons with mental disability or as it suggests they be defined, "people with psychosocial disabilities"²³. The focus is on compliance with Article 12, which concerns the legal capacity understood as "capacity to act", and the central role that this respect has for the recognition of other fundamental rights, such as the right to personal liberty, to not be subjected to coercive treatment, contrary to human dignity and the right to family and social life. The concept of legal capacity/incapacity has in fact been used to deny the status of person to people with mental disabilities and to prevent them from managing their lives. Article 12 of the Convention overturns this situation, affirming in paragraph 1 the right for people with disabilities to "be recognized everywhere as persons before the law". This means for States Parties the obligation to "recognize that people with disabilities enjoy legal capacity on an equal basis with others in all aspects of life" (2) and at the same time the obligation to ensure support for people with disabilities to apply in the exercise of their legal capacity (3) and to "ensure that all measures regarding the exercise of legal capacity provide adequate and effective safeguards to prevent abuse".

What does all this mean for people defined here with psychosocial disabilities? According to WNUSP, in compliance with the articles of the Convention, they will no longer be treated as "non-people", that must be acted upon by others, rather, they must be given the necessary assistance in times of crisis, confusion or anguish: assistance which they have the right to accept or refuse. This also means abolishing the existing laws on protection and incapacity that go in different directions and to provide for mechanisms of support in the decision-making process, which do not go against their judgment and will; unlike what may occur with protection and substitute decision making. Also noteworthy are the effects on the lives of such persons in article 14 of the Convention, which enshrines the right to liberty and security. The space

²² *UN Convention on the Rights of Persons with Disabilities*, cit., Art. 4.

²³ The word psychosocial refers to the interaction between psychological and social/cultural components of our disability. The psychological component refers to ways of thinking and processing our experiences and our perception of the world around us. The social/cultural component refers to societal and cultural limits for behaviour that interact with those psychological differences/madness as well as the stigma that the society attaches to labelling us disabled. However, in using the term psychosocial, we have no intention of associating ourselves with the psychosocial rehabilitation movement" (*World Network of Users and Survivors of Psychiatry, Implementation Manual for the United Nations Convention on the Rights of Persons with Disabilities, February 2008*, http://www.wnusp.net/documents/WNUSP_CRPD_Manual.pdf).

reserved in this article in paragraph b) deprivation in compliance with the law excludes justified deprivation on the basis of disability and requires that persons with disabilities should not be deprived of their liberty unlawfully or arbitrarily. This means, according to the commentary of the *Implementation Manual*, that in order to implement the Convention, it is necessary to: abolish all laws that justify the deprivation of liberty by reason of disability (e.g. mental health laws which include restrictions on freedom); to free all those who are deprived of liberty in institutions or on the basis of their psychosocial disability; ensure fair access to legal proceedings to determine criminal liability; to provide *reasonable accommodation*²⁴ for criminal liability.

The implications of Article 15, which prohibits torture and cruel and inhuman treatment, involve the condemnation of invasive methods such as electroshock - considered as a form of torture or cruel, inhuman and degrading treatment, even if implemented with the consent of the person –and lead to immediate arrest, as well as criminal sanctions for those carrying out forced, coercive and deceptive psychiatric treatments²⁵. Electroshock is also condemned, along with psychotherapy and neuroleptic drugs, for their harm to health, autonomy and creativity, based on respect of art. 17 of the Convention which sanctions the right to respect for mental and physical integrity.

The *Implementation Manual* also focuses on the implications of Article 19 of the Convention, which guarantees the right to life in their community, and which implies for persons with mental illness the right not to be locked up against their will in institutions and to be able to enjoy homes and services within the community, respecting individual autonomy. Also believed to have an important impact is article 25, which guarantees equality for access to care, including the request for free and informed consent. In the psychiatric field, this means: ensuring that the right of the mentally ill person to give consent is legally recognized and that this right must be respected without discrimination; promoting alternatives to the psychiatric medical model; informing about the use of psychiatric drugs, electroshock and psychosurgery; making sure that physical health problems are not mistakenly identified as psychosocial discomfort problems; and putting an end to discriminatory practices in health and life insurance.

From these considerations, the *World Network of Users and Survivors of Psychiatry* sees the UN Convention on the Rights of Persons with Disabilities as the beginning of a revolution and, in particular, the application of Article 12, in the context of care for persons with mental illness, as a great victory.

²⁴ With regard to Article 5 of the Convention, which ensures equal protection by the law for the disabled it indicates as its objective the identification of reasonable solutions/adjustments (*reasonable accommodation*) for persons with disabilities. It specifies that: "Situations where *reasonable accommodation* may be needed include interactions with government agencies (including police and penal law systems), education, work, and exercise of legal capacity (supported decision-making)" (*Implementation Manual*, p.13).

²⁵ As can be seen from electroshock, the *Implementation Manual of the UN Convention on the Rights of Persons with Disabilities* clearly condemns it, when both the 1995 NBC opinion, and the Constitutional Court ruling 282/2002 continued to allow it, albeit with reservations.

It remains questionable if and how all the rights established in the Convention can be realized in the lives of persons with mental illness, and in particular if they are so, in whole or in part, in our country, which is among the states that have signed the Convention.

The Committee on the Rights of Persons with Disabilities, with the task of monitoring compliance with the Convention, issued guidelines in art.14²⁶ in September 2015, starting from the interpretations of that article by some States, interpretations which allow involuntary hospitalization and forced treatment. Against such interpretations, the Committee clearly reaffirms that the freedom and security of the person is one of the most precious rights and that all persons with disabilities "and especially persons with intellectual disabilities and psychosocial disabilities must be entitled to freedom, in accordance with 'Article 14 of the Convention'. The latter is seen as directly linked to the main purpose of the Convention, namely to ensure, against all discrimination, the full and equal enjoyment of human rights and fundamental freedoms for all persons with disabilities. The fact that in some States - but as we will see, not in Italy - persons can be deprived of their freedom on the basis of their actual or perceived impairment, pursuing other reasons, including the fear that they may be dangerous for themselves and for others, is considered a "discriminatory" practice incompatible with art. 14, and "corresponds to an arbitrary deprivation of liberty".

The concerns and recommendations expressed by the Committee on the Rights of Persons with Disabilities in the Guidelines come back to some points in the Concluding remarks of Italy's first report of 2016²⁷ Here, in particular, the recommendation is for "reforming regulations and prohibiting detention policies, including forced hospitalization and/or compulsory treatment orders based on disability as described above, thus harmonizing laws and policies with the statement of the Committee on Art. 14".

In this regard, it can be noted that Italian legislation on CTOs does not establish compulsory hospitalization "on the basis of disability", but provides for it as an exceptional institution as it is subject to a series of guarantees (by mayor's order, the transmission of the order to the tutelary judge within 48 hours, possibility of recourse of the person or members of the family against the measure, further requirements for extension of compulsory treatment beyond the seventh day). It may be noted, however, that in the application of the law, the guarantee mechanism has in many cases turned into a simple bureaucratic routine. Moreover, the strong differences in CTO numbers initiated at regional level suggest that there is a very irregular interpretation of the conditions for CTOs across the territory.

²⁶ Committee on the Rights of Persons with Disabilities (CRPD), *Guidelines on Article 14 of the Convention on the Rights of Persons with Disabilities*, www.ohchr.org/Documents/HRBodies/CRPD/GC/GuidelinesArticle14.doc.

²⁷ CRPD, *Concluding observations on the initial report of Italy*, 6 October 2016, http://tbinternet.ohchr.org/_layouts/treatybodyexternal/Download.aspx?symbolno=CRPD/C/ITA/CO/1&Lang=EN.

The Committee's invitation should therefore be welcomed as a request for policy control and the implementation of standards. Finally, it should be noted that the recent law establishing the National Guarantor of persons detained or deprived of their liberty (law no. 10 of February 21, 2014) appropriately provides that even persons subject to CTO are to be monitored by the Guarantor, in order to guarantee protection of their rights .

Referring to art. 19, The Committee is said to be "seriously worried about the tendency to re-institutionalize people with disabilities and the lack of reallocation of economic resources from residential institutions to the promotion and guarantee of access to independent living in their community" (par 47). Lastly, the Committee itself requests the repealing of norms providing for substitute decisions by legal guardians and also administrators, while advocating forms of support for decision-making by persons with disabilities (paragraph 28).By contrast, it should be noted that, as will be explained later, the support administrator was introduced to protect as far as possible the legal capacity of persons in critical conditions related to illness and to minimize the use of interdiction and incapacitation.

The 2006 UN Convention is therefore an important reference point, as it frames "care" for persons with mental illness, in the double-sense indicated in the premise, on the basis of rights. However, its application today still seems problematic, to say the least, even in our country, despite the progress made in the past. Notes on the difficulties still-present and how to overcome them are outlined in recent UN documents.

In the UN Resolution of 29 June 2016, *Mental health and human rights*, there is concern that persons with mental health or psychosocial disabilities, particularly those who use mental health services, may be subject to "discrimination, stigma, prejudice, violence, social exclusion and segregation, illegitimate and arbitrary institutionalization, hyper-medicalism and treatments that do not respect their autonomy, their will and their preferences."²⁸ Recalling the World Health Organization's work on integrating the protection of human rights in mental health care and calling on States to bring this integration into effect by implementing the UN Convention on the Rights of Persons with Disabilities, the Resolution called for the High United Nations Commissioner for Human Rights to prepare a report on this implementation, to highlight current challenges, good practices, and identify ways and means for enhancing assistance.

This report came out in March 2017 *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*²⁹, as a result of a wide-ranging consultation with the

²⁸ UN, General Assembly, Human Rights Council, *Mental Health and Human Rights*, 29 June 2016, A/HRC/32/L.26, http://ap.ohchr.org/documents/dpage_e.aspx?si=A/HRC/32/L.26.

²⁹ UN, General Assembly, Human Rights Council, *Report of the Special Rapporteur on the Right of everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, 28 March 2017, A/HRC/35/21, <https://documents-dds-ny.un.org/doc/UNDOC/GEN/G17/076/04/PDF/G1707604.pdf?OpenElement>.

various *stakeholders*, including representatives of the disabled community, mental health service users, civil society representatives, and mental health professionals.

The starting point is the persistence of strong critical issues in the relationship between physical health and mental health, in fact nowhere in the world is there an equal distribution of resources between the two aspects of health. Globally it is estimated that less than 7% of health resources are allocated to mental healthcare: "Forgotten issues generate forgotten people". It can be said that mental health is remembered in words and forgotten, or little remembered, in facts.

If the insertion of mental illness within the context of disability has allowed to broaden the gaze from the pathology of the individual to its connections with the social, political and economic context in the wake of the biopsychosocial interpretation model, it is also true that, a decade away from the UN Convention on the Rights of Persons with Disabilities, progress is still slow. Public policies continue to forget that the preconditions for mental health are social, economic and political, and that forgetting this impacts negatively not only on the care of people with mental illness, but also in terms of prevention.

The Report identifies the current moment, marked by Agenda 2030 *For Sustainable Development* and the initiatives of the WHO and *Movement for Global Mental Health*, a precious opportunity for international synergy to improve the status quo on mental health.

At the same time, however, they identify the three major obstacles to this improvement, reinforcing each other. The first is the dominance, which still exists, the biomedical model, focused on biological factors alone, at the expense of several other aspects of mental health care, and its reflection on clinical practice, research, medical education and economic investments. The Report, on the other hand, proposes an "appropriate balance" between the biomedical model and the psycho-social model, which has emerged, highlighting, based on evidence, the influence of psychological and social experiences on mental health.

The second major obstacle is the imbalance of power: the power of decision-making is concentrated in the hands of those who manage the biomedical model and this can not but cause harm to the modern principles of holistic care and can only reinforce paternalism. We see that there is still a strong belief that people with psychosocial disabilities are dangerous, "despite the clear evidence that they are commonly victims rather than perpetrators" and that they are incapable of making decisions for themselves, although they show that they can live independently if they have legal protection and support.

The third obstacle is the bias surrounding scientific evidence. The field of mental health research suffers from a lack of differentiation of funds and remains focused on the neurobiological model. For decades, there has been some evidence, based on scientific research and experience in support of psychosocial services aimed at recovery and at alternatives to compulsory

treatment. However, without promoting these services and investment in their support, they will remain peripheral and will not result in the promised changes.

Focusing on the evolution of the regulatory framework in the field of mental health, the Report sees the difficulties of the present moment, defined as "a moment of impasse" on the interpretation to be given of the application of the UN Convention on the Rights of Persons with Disabilities especially as regards non-consensual treatments. In this problematic framework, the various points are highlighted in order to guarantee the right to the best mental health possible: international cooperation; effective participation of all in decision-making; fighting discrimination; the need for monitoring of all mental health services by independent authorities; providing services that are available, consistent with the principles of medical ethics and respect for human rights, and of good quality; measures to reduce coercive medical practices in view of their elimination; the need for states to act on the social determinants of mental health.

5. Legal Measures for the Protection of Persons with Mental Illness

As has been seen, a crucial point in the integration of the treatment of people with mental illness within the perspective of human rights, is the concept of "capacity" and its correlation with the principle of autonomy, with the applications to self-determination, for all that pertains to life choices and consent to healthcare treatment. Is it possible and how can autonomy be protected at best even when the disease undermines the individual's capacity rendering it dubious or oscillating?

We recall that one of the recommendations of the Opinion on *Psychiatry and Mental Health: bioethics guidelines*, 2000, was devoted to re-examining the concept of "incapacity", placing it in the "continuum between the extremes of normality and the total loss of any cognitive ability." Noting that in most psychiatric disorders there is a reduction, but not an abolition of capacity, the NBC recommended revision of the regulations regarding interdiction and incapacitation in order to achieve "more flexible forms of protection", highlighting the 'opportunity to introduce even within our legal system, the figure of support administrator³⁰, which already exists in other European countries.

Years later, regarding the legal instruments currently available to our country for the protection of the person with mental illness, the National Committee for Bioethics first refers to what has already been written in the opinion on *Dementia and Alzheimer's Disease: ethical issues* (2014).

Even when seeking to protect persons affected by mental illness, rendered mentally incompetent to a greater or lesser extent, in order to guarantee not only their patrimonial but also their existential rights and interests, legal instruments are given by the support administration (art. 404 ss. c.c.) from "Interdiction" and "Incapacitation" (art. 414 ss. c.c.).

³⁰ NBC, *Psychiatry and Mental Health*, cit., Summary and Recommendations.

The decision on which instrument to apply in consideration of the severity of the state of infirmity or rather physical or mental disability, including partial or temporary disability, is the responsibility of the Judge; who will have to ensure, to the incapacitated person, the most appropriate protection for the case; limiting as little as possible his/her decision-making and allowing for the range of powers of those representing the individual to be proportionate to the characteristics of the specific case.

Of the legal protection measures for persons completely or partially lacking in autonomy, the support administrator is certainly the most recent measure (Law No. 6/2004) as well as being the one most used in court. It aims to overcome the strict norms of the legislator's rules for the protection of psychic sufferers, it is in line with the Council of Europe Recommendation of 23 February 1999 and the subsequent international declarations and conventions that invite states to conform their internal discipline on the legal safeguarding of the incapacitated, principles that are less restrictive and less exclusionary for the individual. Our same doctrine has called for a modification of the entire system of incapacity: a real overturning in the safeguarding of the person, in relation to interdiction and incapacitation which determine the status of being incapable, referring to strict and not easily adaptable norms to individual and often different circumstances.

The primary purpose of the support administration is, therefore, to protect, with as little restriction as possible, the ability to act of persons, either totally or partially lacking in autonomy, to perform the functions of everyday life by means of temporary or permanent support interventions. The norm makes use of the principle of "gradualism" and "flexibility" in the measures of support. And by virtue of these principles, the judge must choose from among the instruments of protection provided by the legal system the one making the least possible restriction on the capacity of the person concerned, taking into account the function of protection. The support administration is also likely to be adapted to the needs of the concrete case, since, unlike the other cases (interdiction and incapacitation), attributes to the judge the function of determining the content of the measure, revoking it, decreasing and increasing its intensity during its time in force.

From the general lines of the arrangement it is evident that the preeminent interest is the protection of the person, as a subject of rights. The appointment of the support administrator does not confer on the beneficiary the subjective quality of being 'incapacitated', rather, the subject must consider himself/herself as being "capable", and incapable solely of those acts forming part of the object of the administration. By virtue of art. 409 c.c. the beneficiary continues to retain the ability to act for all acts that do not require exclusive representation (substitute administration) or assistance (assistance administration) by the support administrator. Furthermore, it is always the duty of the administrator to inform the beneficiary regarding the steps to be taken (Article 410, paragraph 2, c). And the information requirement is not resolved in the present case in a

mere communication of choices, but in the necessary information to discuss, as far as possible, with the beneficiary of the choices to be made, so that they correspond as much as possible to the subject's needs and interests. The family, in all the legal actions described, is not excluded from the decisions of the judge.

And in the scope of the residual capacity of the beneficiary, however, the problem of so-called. very personal acts, identified by doctrine in different events (recognition of the child, will, marriage, donation). Consider that for this category of acts, even if a limitation of capacity is expressly provided for in the court's decree, no substitution of the beneficiary is permitted. Jurisprudence is then divided on the possibility that the support administrator may substitute the beneficiary in expressing consent to healthcare treatment. Given the speed of the procedure and the minor implications with respect to interdiction and incapacitation, the support administration could have a greater use for matters of consent or refusal regarding medical care. Indeed, the figure of the supportive administrator may be particularly useful in the context of the therapeutic alliance, with the obvious objective that there is always a person able to interact with the doctor, in order to avoid that the patient, not fully capable of self-determination, is left without a voice.

However, despite the potential of this arrangement and the perceived need (especially considering the steady rise of elderly people who are not self-sufficient), a study on the spread of the support administration published in 2013 by the Associazione Amministrazione di Sostegno Onlus and Fondazione Emanuela Zancan reports that the distribution of this institution in Italy is below expectations.³¹

The legal arrangement of the support administration in the case of particularly serious illnesses, does not exclude recourse to Interdiction and Incapacitation. In Jurisprudence however, interdiction has a residual nature, meaning it is reserved according to legislature, given the severity of the effects deriving therefrom, in those cases in which no protective effect would result from a different measure.³²

Of particular importance in these situations of mental illness is the possibility that clinical research may move forward for the benefit of the health conditions of the patient and the affected population. Of course, as in all cases of particularly vulnerable subjects, who do not have the capacity to give consent, subjected to experimentation, the International Charters generally recommend that special protection, be guaranteed, based on ethical and legal standards that States must adopt.

On these issues the debate is always ongoing and normative regulation of the principle of consent encounters different solution. The position of Italy, also

³¹ Cf. Associazione Amministratore di Sostegno Onlus, Fondazione Emanuela Zancan Onlus (edited by) *L'amministrazione di sostegno in Italia dopo la legge n. 6/2004*, Padova, Fondazione Emanuela Zancan Onlus, 2013.

³² Const. Court no. 440/2005 and among many Cass. civ. n. 9628/2009.

given by D.I. 2011/2003, which implements Directive 2001/20/EC, also confirmed by the latest European Regulation 536/2014, is to allow experimentation on mental patients, presenting "at least partially therapeutic" aspects, with the consent of the legal representative, also considering the general social benefit and in particular the population represented by the incapable persons concerned.

However, strict conditions must always be met and among these: that research can not be conducted on a healthy person; that it presents at least some indirect benefit to the patient or at least the group of patients with the same pathology; that risk and discomfort are minimal; that no incentives or financial inducements are given except allowances; that the consent of the legal representative may be withdrawn at any time, without prejudice to the incapable person; that the mental patient has received from experienced personnel information commensurate with the patient's capacity of understanding regarding the trial, risks and benefits and is able to express, according to the subject's discernment, informed consent; that in the case of reacquisition of his/her decision-making ability, the subject is required to give informed consent to the continuation of the trial; that the protocol has been approved by an ethics committee with expertise in this area and that it has availed itself of psychiatric counselling.

The informed consent of the legal representative, as in general in the field of healthcare, should therefore involve the patient proportionally to his/her age, maturity and actual awareness of the situation in question.

It should also be noted that the legislation introduced by D.I. 2011/2003, in the case of experiments on incapable persons, does not provide any exception to the need for informed consent of the legal representative, although there are cases of need and urgency and the effectiveness and safety of the therapeutic intervention are strongly conditioned by the speed of the intervention itself³³. It follows that the informed consent of the legal representative may be excluded only in the case of a "state of necessity" according to the general exemption contained in art. 54 of the Penal Code.

6. From the enshrinement of Principles to treatment plans: Mental Health Plans

The theoretical framework of "care" for persons with mental illness integrated from the perspective of respect for human rights is confirmed by the international mental health plans launched by the World Health Organization (WHO), both world-wide and at European level, and by the national plan.

³³ Cf. The critical position of the National Bioethics Committee in the opinion: *Clinical trials in adult or minor patients who are unable to give informed consent in emergency situations* 28 September 2012.

The WHO 2013-2020 Mental Health Action Plan³⁴, details the persistence of violations of human rights against people with mental illness which gives rise to "the need to provide services, policies, legislation, measures, strategies and programs to protect, promote and enforce the rights of people with mental disorder." Strong focus is given to the *empowerment* of people with mental disorders and psychosocial disabilities, and their involvement, that of their family members and reference associations in the design and planning of both services and initiatives taken at political, social and legislative level on the protection of mental health. As far as Mental Health services are concerned, there is a clear recommendation to systematically move the place of treatment from long-term psychiatric hospitals to the community services network.

A *recovery*-based approach is also recommended that, as illustrated, does not indicate clinical healing, rather the individual path that the person with mental disorder pursues to achieve the best possible quality of life interacting socially and without stigmatization/discrimination. This is the WHO definition and the cornerstone of the Global Action Plan, which is divided into six principles: universal coverage, human rights, evidence-based practices, lifecycle approaches, multi-sectoral approaches in relation to the various social sectors, educational, labour and judicial, in order to meet all the needs of persons with mental illness.

Other important goals set out in the document are:

a) strengthening the governance of mental health through the updating of legislation, taking into account the Convention on the Rights of Persons with Disabilities, considered the basic document;

b) offering a range of integrated global services capable of responding to social and health needs within community settings and throughout the territory (the WHO states that this target should increase by 20 percent by 2020 the coverage of treatment for people with severe mental disorders);

c) promotion and prevention in mental health to lower the suicide rate by 10 percent by 2020, a crucial point because the economic crisis of these years is operating in the opposite direction in the world;

d) increasing research and data collection for mental health, which is by no means self-evident, because in Italy, at the time of the drafting of the WHO plan, there was no comprehensive national data collection neither for expenditure nor for the clinical and health outcomes of mental health; it lacked a systematic view, also because of the regional system that fractures data collection and does not render the systems homogeneous: a lack now only partly remedied, as will be seen later.

Lastly, the importance of the human rights approach is highlighted, and in particular the need for strategies, actions for the treatment, prevention and promotion to be in line with the UN Convention on the Rights of Persons with

³⁴ World Health Organization, *Mental Health Action Plan 2013-2020*, tr. it. by the Department of Mental Health, A.A.S. n. 1 Triestina, 2013, http://www.salute.gov.it/imgs/C_17_pubblicazioni_2448_allegato.pdf.

Disabilities. The emphasis is on the fact that services must be offered within the framework of respect for rights, reporting violations.

The same horizon of values is also present in the European Mental Health Action Plan launched by the WHO in 2013³⁵, which includes many of the issues covered in the aforementioned Plan. Three reference values are expressed as complementary to each other: equity, which includes in itself the struggle against discrimination, prejudices and negligence; *empowerment*, based on the right to be as autonomous as possible, to take responsibility and to intervene in decisions that affect their lives, health and well-being; safety and efficacy of therapeutic interventions. Central is the reference to people with mental illness problems as "citizens" whose rights must be respected and promoted.

Recurring, as a goal to reach across Europe, the change of direction from the large hospital to services within the territory. There is a tendency to close "large hospitals associated with abandonment and ill-treatment", favouring the implementation of "mental health services organized to promote (normal) life within society", and integrating mental health services with general services, provided in decent facilities and made accessible to all. There is a clear recommendation to "make every effort to encourage hospitalization and voluntary treatment in order to avoid any form of coercion". In the case of compulsory hospitalization and compulsory treatment, it is recommended that "strict forms of protection, such as independent consultation, control of detention conditions and access to opposition proceedings, independent legal assistance and other forms of assistance" should be guaranteed. The role of information also seems important, both to support the choices of the different parties involved, and to assess and monitor the services provided.

The National Action Plan for Mental Health launched in Italy in 2013³⁶, moving in the same direction and in the light of the same principles, focuses on the changes registered in the care of persons with mental illnesses in recent years in our country, the growing importance of residential psychiatric treatment and day-care, but also on the critical issues still discernible, albeit unevenly, among the different regions. There are two guiding principles: prioritizing the methodology that "starts from the bottom" from existing good practices; taking as a framework of reference "community psychiatry and childhood neuropsychiatry". The clinical path of taking charge of the adult is seen in the perspective of a relationship of care that is a mark of alliance and trust, and aimed at achieving patient autonomy. It is recommended that the Regions not only ensure the Essential Levels of Assistance (LEA), guaranteeing the appropriateness and continuity of care, but also monitoring and verifying the

³⁵ World Health Organization, European Mental Health Action Plan, 2013, tr.it. by the Department of Mental Health, A.A.S. n. 1 Triestina, 2015, http://www.salute.gov.it/imgs/C_17_pubblicazioni_2447_allegato.pdf

³⁶ Ministero della Salute in collaborazione con il Gruppo Tecnico Interregionale Salute Mentale (GISM) della Conferenza Regioni, *Piano di Azione Nazionale per la Salute Mentale*, 2013, http://www.salute.gov.it/imgs/C_17_pubblicazioni_1905_allegato.pdf..

results obtained "in the logic of providing information which allows a comprehensive national view.

The vision that emerges from the different action plans is inspired by the respect of the so-called 3 "E"s, "Ethics", "Evidence" and "Experience"³⁷: scientific evidence is not enough, but it needs to be rooted in an ethically founded vision that takes into account real-world experiences in the field, which also includes the way in which care is provided and where services are organized. The latter must be inspired by principles of participation, effectiveness, non-discrimination, globality, fairness, transparency, and the ability to offer coordinated action. There emerges a paradigm of care centered on the person, as a whole and in his/her context of life, opposed to a reductionist view of illness and psychiatry. The fundamental paradigm shift is the overcoming of psychiatric treatment in closed structures, extracted from the relational and social context of people: in favour of an organization of services in response to people's needs, with resource-based and relational programs.

The theoretical framework of reference of international documents, as well as that of the Mental Health Action Plans, is therefore the same as that of previous NBC opinions, and gives rise to this opinion: the promotion of autonomy and inclusion, defence of the dignity of persons with mental illness, with the consequent fight against stigma and discrimination, and the translation of this into recurring recommendations on "care" that goes beyond institutionalization and custody, implemented within the territory, integrating medical and psycho-social aspects.

7. Analysis of the mental health services system

But if this is the clear theoretical framework of reference, what is the reality of mental health services in Italy? The question is whether and how the rights of people with mental illnesses are being implemented in our country if and how the goals set out in the international and national mental health plans have been achieved. In order to evaluate the system of psychiatric services in Italy, at the start of the millennium the largest study ever designed at international level was conducted.

The study analyzed residential care (PROGRES-residential project) and hospitalization of acute patients (PROGRES Acuti)³⁸. It is an important project,

³⁷ For an in-depth study of the principle of the three "E"s in the field of mental health, see: University of Gothenburg, 14th International Conference on Philosophy and Psychiatry (2-4 September 2011), *Ethics, Experience, Evidence. Integration of Perspectives in Psychiatry* http://flov.gu.se/digitalAssets/1507/1507531_eee_abstracts2_v2.pdf; Graham Thornicroft, Michele Tansella, *Better mental health care*, Cambridge University Press, Cambridge 2009 http://www.langtoninfo.co.uk/web_content/9780521689465_frontmatter.pdf.

³⁸ The PRO-GRES project (PROGetto RESIDENZA) was promoted by the Higher Institute of Health in 2000, with the aim of studying all the psychiatric residential facilities present on the national territory. The PROGES-Acuti research was conducted from 2002 to 2003 on 262 Psychiatric Services for Diagnosis and Care and on 16 Mental Health Centers, able to accommodate acute patients.

both in general to respond to the need to assess the application of the psychiatric reform as well as for the picture it provides of care, especially in relation to some important issues: the relationship between care in the community/in residential structures (*outpatient/inpatient care*); between care in periods of acute need/long-term care, between public/private facilities; the evaluation of the quality of provided services. The importance of studying the residential structures stems from two factors: the prevalence of private residential facilities after the psychiatric reform, so as to outweigh the public ones in terms of the number of beds; the need to ensure that new residential structures do not reproduce the effects of institutionalization of its abolished mental hospitals.

Using the broad base of the PROGRES research data, specific studies have also been carried out, they are particularly valuable since they shed light on qualifying aspects of the functioning of the services and their degree of innovation. Research has been carried out on: the quality of life of patients in residential structures, the prospects of discharge, the probability of returning to the territory; the CTO rate and the reasons for its variations; the characteristics of the most frequently hospitalized patients for acute crises; the analysis of the time between the appearance of the first symptoms and the services taking charge. The analysis of the system of services we are going to illustrate is based on the two large-scale, progressive national PROGRES studies already mentioned, and on two subsequent reviews on it in scientific literature in 2007 and 2014³⁹.

7.1 Residential facilities: functioning and prospects for the reintegration of patients into the territorial community

Types of residential facilities (SR) are very varied, ranging from similar facilities to nursing homes, family homes, assisted residences and apartments. The average number of beds is 12.5 beds per facility, with intensive care: almost three-quarters (73%) have a 24-hour staff. Most of the facilities (84%) only accommodate long-term patients. In addition, three quarters of the structures did not set any limits on the length of hospitalization. Discharge rates are low and turnover is limited, blocking new admissions (24% did not admit any new patients during the year and 26.3% only one or two). 35% of patients are hosted by a SR for 3 years or more. This suggests that SRs often represent "homes for life" rather than stages of a route to rehabilitation, as already indicated in the Mental Health Project 1998-2000.

Socialization activities are generally planned, though not specific, and targeted social training programs are rare. In particular, there is a scarcity of

³⁹ G.DE GIROLAMO, M. BASSI, G. NERI, N. RUGGERI, G. SANTONI, A. PICARDI, *The Current State of Mental Health Care in Italy. Problems, Perspectives and Lessons to Learn*, "Eur Arch Psychiatry Clin Neurosci", 2007b, 257, 83-91; M. PICARDI, I. LEGA, V. CANDINI, J. DAGANI, L. IOZZINO, and G. DE GIROLAMO, *Monitoring and Evaluating the Italian mental health system*, "The Journal of Nervous and Mental Disease", 2014, 202), pp. 451-459.

individualized rehabilitation plans, based on careful assessment of disabilities, resources, and people's needs: a disadvantage for younger patients who would have real opportunities to acquire skills to live in the community. Drugs are widely administered (to 96% of patients) and on average every patient takes 2.7 psychotropic drugs. Conventional antipsychotics and the second generation of antipsychotics are prescribed to 65% and 43% of the sample, respectively. There is a need to check on the appropriateness of treatments, as many prescriptions are poorly related to specific diagnoses. As for patients, many of them show a marked degree of disability and have no short-term discharge prospects.

Of particular note is the study published in 2006 about the quality of life of patients.⁴⁰ Recently, *Quality of Life* (QOL), which measures the patient's perception of his/her well-being, has become a key index in medicine and psychiatry to evaluate de-institutionalization policies⁴¹. While on the one hand psychiatric hospitals have been closed, however, as seen, there is a high number of long-term patients in residential facilities (SR) with very different characteristics and levels of assistance, and for many the option of being discharged is limited.⁴² Among the most important findings of the above-mentioned study: Inpatients have scores similar to patients living in the territorial community, in care services. This seems to testify that many residences are able to recreate similar home-like environments, without rigid rules and with guaranteed spaces for privacy. The comparison with the control group (people without psychiatric disorders) shows lower scores in the sample of patients in the physical and the psychological sector, as was to be expected.

What is worrying is the major difference in the social relations sector: the lack of social relationships, both inside and outside the SR, is a considerable limit for patients, since a satisfactory relational fabric is an important prerequisite for possible discharge and the transition to an independent life. The indication is to intensify rehabilitation activities on the basis of evidence available to offer residents opportunities for social exchanges outside the SR, in particular the possibility of safe work and social integration.

These indications appear to be confirmed by a recent study published in 2014, conducted in 23 medium to long-term residences, with the aim of verifying the possibility of dismissal of inpatients and the factors that predict it.⁴³ Patients

⁴⁰ A. PICARDI, P. RUCCI, G. DE GIROLAMO, G. SANTONE, G. BORSETTI, P. MOROSINI, *The Quality of Life of the Mentally Ill living in Residential Facilities. Findings from a National Survey in Italy*, "Eur Arch Psychiatry Clin Neurosci", 2006, 256, pp. 372-381

⁴¹ J. ENDICOTT, J. NEE, W. HARRISON, & R. BLUMENTHAL, *Quality of Life Enjoyment and Satisfaction Questionnaire: A new Measure*, "Psychopharmacology Bulletin", 1993, 29(2), pp. 321-326.

⁴² Two thirds of sample patients had a diagnosis of schizophrenia or other psychotic disorders, with a long duration of illness (averaging 24 years). The majority are men (60%) in old age, the vast majority unmarried (79%).

⁴³ G. DE GIROLAMO, V. CANDINI, C. BUIZZA, C. FERRARI, M. E. BOERO, G. M. GIOBBIO, N. GOLDSCHMIDT, S. GREPPO, L. IOZZINO, P. MAGGI, A. MELEGARI, P. PASQUALETTI, G. ROSSI, *Is Psychiatric Residential Facility Discharge Possible and Predictable? A Multivariate*

were tested to check psychopathology, cognitive functioning, and social interaction skills⁴⁴. After a year, the living conditions and the clinical condition of patients were tested again in order to identify the factors associated with discharge (of the 403 patients, during the year 104 were discharged, equal to 25, 8%, about half of whom had gone home). The *follow up* also allowed for checking the predictions made by doctors a year earlier regarding patients with greater/lesser possibility of being discharged in their judgment.

Unlike the healthcare staff who focused on the severity of psychiatric symptoms as the most responsible factor for failure to be discharged, research has identified as a strong predictor the impairment of psychosocial functioning. The main obstacle to dismissal appears to be the lack of a social support system. In most cases the main social support comes from the family. Analyzing the profile of patients that were discharged and reintegrated into the home environment, the improvement of psychopathology and the presence of work skills emerge as being major predictors. The conclusion of this research is that doctors should use more of the evidence in planning treatment, while the SR should on the one hand adapt to ensure patients the best quality of life (with structures that do not exceed 12-15 patients, single rooms with bathroom and rules for respect of personal privacy); on the other hand differentiating typologies in order to respond to the different needs of patients, building on the evaluation of services research.

In conclusion, it highlights the need to differentiate the types of SR according to precise criteria, anticipating: 1) residences with intensive rehabilitation programs; 2) long-term residences for patients who are unable to return to the community due to the severity of the disease and/or lack of family and social support; 3) residences for people with severe disabilities. Although the research supports the differentiation of rehabilitation paths and type of residences, decades later the problem still exists. On the one hand the importance of increasing research needs to be reiterated; and on the other the need to monitor the development of services on the basis of available evidence, in order to avoid the SR reproducing the same mechanisms of asylum institutionalization.

Of note, finally, a recent study of patients being treated at residential facilities, with a history of violence prior to admission. In comparison with patients who had never had violent behaviour in the past, the former did not show more violent behaviour than others during their stay in SR. It therefore seems that the intensive treatment works in the prevention of recurrence of

Analytical Approach Applied to a Prospective Study in Italy, "Soc Psychiatry Psychiatr Epidemiol", 2014, 49, pp. 157-167.

⁴⁴ Regarding the profile of the patients: they were predominantly middle-aged men, unmarried, suffering from schizophrenic symptoms manifested in youth; with a moderate degree of severity of disease symptoms and cognitive deficits, but high levels of disability in psychosocial functioning.

violent behaviour⁴⁵. This study is of particular importance because the association between mental illness and violence is a fundamental part of stigma and constitutes an obstacle to full social integration.

7.2 Caring for acute care patients

The system consists of Psychiatric Diagnosis and Treatment Services (SPDCs) in general hospitals and university clinics and a small number of spatial services open 24 hours a day with beds available for acute care patients. There are also beds in private facilities⁴⁶. The relationship between public and private structures appears anomalous compared to other medical and surgical facilities, as in the psychiatric sector the number of private beds exceeds that of the public sector.⁴⁷ In addition, the average length of stay is higher in private clinics (39 days) than in university hospitals (18 days) and SPDC (12 days). The number of beds varies considerably from region to region (the number of beds is eight times greater in the best-equipped region compared to the least equipped).

In Italy, the proportion of compulsory treatment orders in relation to the total number of admissions to Psychiatric Services for Public Disease and Care in 2001 was 12.9% at a rate of 2.5 per 10,000 inhabitants, with large variations from region to region. Even with the use of restraint, the differences between services are remarkable, with some reporting a couple of cases a year and others several episodes each week.⁴⁸ It should also be noted that no-restraint services do exist, they have chosen not to make use of restraints.⁴⁹ Comparing subjects with multiple hospitalizations to other patients, the first are younger, more often unmarried and unemployed. Even the category of homeless and SR residents is more represented. Analyzing the group of people in hospital for the first time, it emerges that 46% did not receive any previous treatment: an

⁴⁵ G. DE GIROLAMO, C. BUIZZA, D. SISTI, C. FERRARI, V. BULGARI, L. IOZZINO, M. M. BOERO, G. CRISTIANO, A. DE FRANCESCO, G. M. GIOBBIO, P. MAGGI, G. ROSSI, B. SEGALINI, V. CANDINI, for the VIORMED-1 Group, *Monitoring and Predicting the Risk of Violence in Residential Facilities. No Difference between Patients with History or with No History of Violence*, "Journal of Psychiatric Research", 80, 2016, pp. 5-13. The prospective study was carried out on a sample of 139 inmates, of which 82 with a past of violent behavior and 57 as a control group. The comparison between the two groups did not show statistically significant differences

⁴⁶ According to the data collected in the Progres Acuti project, there were a total of 4113 public beds, available in 266 Psychiatric Services for Diagnosis and Treatment in General Hospitals, for a total of 3498 beds; in addition to 399 beds in 23 university clinics and 98 beds in 16 spatial services. There were also 4862 beds in 54 private establishments.

⁴⁷ Compared to an average 83.1% in the public sector versus 16.9% in the private sector, while in psychiatric facilities, the percentage is 45.8% in the public sector and 54.2% in the private sector.

⁴⁸ Patients are distributed similarly as regards sex, the average age is 42 years. About half have never been married, and one third lives with the family of origin. The prevalent disorders consist of non-affective psychoses (schizophrenia) for 36%, followed by depression (21%), bipolar disorder (18%). About 40% of patients had had 3 or more admissions over the past 12 months.

⁴⁹ Cf. NBC, Restraint: bioethical problems cited. p.8.

indication of the difficulty of psychiatric services within the territory to promptly intercept those in need.

There is also a problem with being discharged as in many cases this is planned without the involvement of families. Not even community services are regularly involved: in Psychiatric Diagnosis and Care Services, involvement occurs in 64% of cases, but drops to 47% in private structures and 29% in university clinics. One of the major concerns regards the large differences between regions in the number of beds, especially public beds, which is not justified by clinical reasons, since the prevalence of severe pathologies requiring acute care interventions is mostly the same throughout the country. It therefore seems that differences are to be attributed to health policy choices. The other critical issue is the severe logistical and architectural constraints observed in public facilities, such as limitations that have a negative impact on patients and on staff, but also on strengthening the stigma associated with mental illness.

There is also a significant difference in the presence of very different styles of care among services, which can be summed up in the "open doors" option, that is, without compelling and intrusive rules affecting the privacy of patients, following the example of other hospital departments; differently from the "closed doors" option, with severe limitations, to a greater or lesser extent, imposed on patients. As far as treatment is concerned, pharmacotherapy is used everywhere, with supportive psychotherapy interventions in 70% of facilities. Rehabilitation interventions are only in half of these. This is reflected in the type of staff, few other professional figures are present, apart from doctors (psychologists, rehabilitation technicians, etc.). It is therefore necessary to create more multidisciplinary teams.

7.3 Community mental health services (CSM)

In accordance with the reform, community services play a central role in prevention and care. In 2005, the PROG CSM project (Project Mental Health Centres) was launched with the aim of verifying the functioning of local services and defining quality standards (relating to coordination with the general socio-economic system, continuity of care, etc.)⁵⁰. Interesting information comes from data collected from 2009 to 2010 through an information system based on a national sample of 22 CSMs. The SEME (Epidemiological Surveillance in Mental Health) system aimed at identifying the clinical features of users at first contact in order to detect those who were in the diagnostic categories for the most serious disorders. The psychotic disorders detected amounted to 42% of cases, bipolar disorder I at 30%, depression increased to 19%.

⁵⁰ A total of 636 centers (out of 707 operating in 2001) were surveyed, covering 195 mental health departments (out of 211). 57% of patients were women, 42% below 44 years of age. Psychotic disorders accounted for more than a third of the diagnosis for users, and about a sixth for users at first contact.

The most common service delivery channel is the general practitioner, but many are also sent by hospitals, including emergency departments. A critical issue is the ability of the services to intercept the most serious cases at an early stage: the average interval between the first symptoms and the taking charge by services is five years for patients with psychotic disorders and bipolar disorder I, and two years for people with major depression. Even in the case of CSM, there are differences in operating models. It would therefore be important to build quality service indices to identify good practices.

Along these lines, some quality indicators can be outlined: 1) absence or minimization of restraint; 2) a low number of admissions to hospital for acute care (as a result of the effort to offer continuous care); 3) a low number of CTOs (as a result of the ability to keep users in care and to build a valid therapeutic relationship); 4) the ability to intercept the most serious cases at the earliest symptoms of the disorder; 5) coordination with other social services in the territory; 6) the comprehensive socio-rehabilitative offer, following the directions of the research; 7) ability to identify the different needs of patients, to differentiate rehabilitation programs and types of residential facilities.

7.4 Mental Health Services Survey 2015

We recently have an overall mapping, implemented under the auspices of the Ministry of Health by the Information System for Mental Health (SISM), which provides key data on users, tasks and staff of the Mental Health Services in Italy, with reference to year 2015⁵¹. It is the first time that such information is so extensive, there is no doubt that it can be useful to monitor and evaluate the situation of assisting people with mental illness in our country. Fully comprehensive coverage has not yet been achieved, as some Regions have not sent data for all ASLs. Furthermore, the analysis presents the intrinsic limits of the information system: it contains, in fact, data on diagnosis and performance, but no data on incidence, prevalence, access to services, outcomes.

However, some observations can be made from the reading of the data on the type of assistance provided and on its therapeutic efficacy. The observed network of services consists of mental health centres, day centres and residential and semi-residential facilities. The data related to staff are significant because they reveal the percentages among the various professional figures involved, there being a clear prevalence of nurses (45.8%), followed by doctors (16.9%) care assistants – known as OTA/OSS, (10, 6%), other figures (8%), psychologists (7, 6%), social workers (4, 4%). Therefore, the prevalence today of a medical approach to mental disorder can be deduced. A hypothesis confirmed by another piece of data related to the service provision figure: 75% is provided by the Department of Mental Health, and its practitioners are

⁵¹ *Rapporto salute mentale: analisi dei dati del Sistema informativo per la salute mentale (SISM) anno 2015*, www.governo.salute.it.

predominantly doctors (30, 9%) and nurses (41.3%). Another point for observation regards the distribution of interventions by type of care, it shows how 31.9% of nursing activities are at home and in the community, 28.2% are psychiatric activities and only 12.3% concern rehabilitation and re-socialization.

Another interesting point is the CTO hospitalization rate, which can represent, along with the data on repeated hospitalizations in psychiatric wards of public hospital facilities, an indirect measure of the actual therapeutic effectiveness of rehabilitation programs. Some interesting observations could, perhaps, be made from measuring the costs incurred for drugs.

8. Priorities for a more effective healthcare system which respects the rights of persons with mental illness.

From the body of research described, indications emerge to overcome the most critical issues and improve the quality of care and the functioning of the mental health services system. These indications, which are also supported by the National Union of Associations of family members and patients (UNASAM)⁵², may be summarized as follows.

1. Overcome the existing variability in the approach of services (in particular regarding the number of beds in residential facilities and those for acute care patients) not justified by clinical reasons. The question of variability implies that people with the same clinical features can not benefit from homogeneous services in the various regions of a country. This calls into question the lack of respect of the ethical principle of justice.

2. Increase the capacity of residential facilities to discharge patients and bring them home, differentiating residences with intensive rehabilitation programs from those for long-term patients (see section 7. a).

3. Identify quality indices of services for the evaluation of provided services (see paragraph 7.c). The lack of these indices, while accentuating the variability, prevents overcoming the most serious problems, reported in detail by UNASAM: the inadequate number of opening hours in many centres, with the result that emergencies are not followed by community services; absence in the majority of services of home-care interventions, resulting in services failing to intervene in times of need; persistence of Psychiatric Diagnosis and Treatment Services (SPDC) with a "closed-door" treatment style (unlike other hospital departments), still using restraint, not only in exceptional circumstances, and having a high number of compulsory treatment orders. Included among the quality indices, is enhancing the capability for reception of the service (very poor throughout the national territory, according to the associations of family members and patients) and the ability of physicians to establish a good therapeutic relationship with patients, urging active participation as much as

⁵² UNASAM President, Gisella Trincas, spoke as an authority on issue to the Committee. UNASAM's positions refer to this hearing.

possible in their own process of care, so that they can express themselves even as regards pharmacological treatment.

4. Rectifying the shortcomings of interventions at the social level, which constitute one of the most important obstacles to reintegration (see paragraph 7.a). This point is particularly advocated by associations, which see the first right of citizenship as restoring the ability of patients to relate to the world again, without families solely bearing the burden of assistance and social support. On this line, they demand a rebalancing of the professional figures in services, providing them with professionals for recovery and rehabilitation; reinforcing networking with other services in the territory and with general practitioners in order to adequately support the family in its care work.

5. Increase research. There are many areas where research is scarce: from epidemiological data to drug use; the effectiveness of psychotherapies, the molecular basis of mental disorders; from the location of the sick within the territory, to the services to relieve the burden of the disease on families. Pharmaceutical industries have abandoned research and development in the field of psycho-pharmaceuticals. As regards funding, there is a huge disproportion between the severity of the disease and the funds dedicated to carrying out research. Mental illnesses are certainly causing serious suffering, not only for those affected by them but also for their family members, yet the research quotas for these diseases are inferior to those for less serious illnesses. This is true not only for public funding but also for private funding⁵³. In particular, the research on psychotropic drugs (see also section 7.a) and the long-term effects and risks of the use/abuse of various psychoactive substances by teenagers (tobacco, alcohol, drugs) are highlighted as a priority.

6. Make use of research results in the planning and implementation of interventions and care systems.

7. Check the appropriateness of pharmacological intervention. To this end, it is advisable to set up research groups assessing the use of psychotropic drugs as well as their appropriateness with regard to the illness for which they are intended for, through an analysis of the risk-benefit ratio. The use of psycho-pharmaceuticals is widespread, with them often being used for pathologies different from those indicated by the regulatory authorities. Typical examples are the *off-label* use of psycho-pharmaceuticals in children and adolescents as well as the increase in mortality due to the use of antipsychotics in the elderly. This is due to the asymmetry of information. Doctors are only provided with the propaganda from the pharmaceutical industry, while independent information that should be provided by AIFA, the Regions and the Ministry of Health, is completely missing.

8. To make effective the right of the sick to timely diagnosis and increase the taking charge of children and adolescents. We have seen the limited ability of services to intercept the most serious cases at early stages of the disease.

⁵³ In fact, unlike the fundraising carried out by AIRC for tumors and Telethon for rare diseases, there is only one national funded organization dedicated to fundraising for psychiatric disorders.

Specific attention should be paid to this point due to its particular importance and delicate nature. Early diagnosis is as important to the possibilities of prevention and care, as it is difficult to obtain, or even to look for, due to the widespread fear of those directly concerned and their family members, regarding the stigma of "mental illness": These fears need to be overcome by promoting proper information. It is the task of the health care providers to give a proper framework to diagnosis: this should not be understood as a permanent classification of "different" subjects under stable conditions of incapacity, resulting in being labelled as "unhelpable"⁵⁴. Recent international research evidence indicates that early diagnosis and continuity of drug treatment are the two most important aspects in reducing chronicity of psychiatric disorders and limiting collateral risks such as suicide and substance abuse such as alcohol and drugs. Lack of one or both of these factors can have important repercussions on the course of the disorder and response to therapies for patients. Regarding developmental mental health problems, epidemiological research has shown an increase in the prevalence rates of psychological disorders in growing children⁵⁵. In particular, approximately 10% of boys in the pre-adolescent and adolescent age range (14/18 years) suffer from a form of psychological disorder. It is therefore obvious that it is necessary to detect these disorders early in order to receive early treatment. Early intervention would increase patient recovery and would allow a lower risk of exacerbation and chronicization of the disorder, less disability and impairment of overall functioning, both in social and working life, and less hospitalization. The lack of intervention, in the case of serious psychopathological disorders, leads to a progressive loss of cognitive abilities and promotes social retreatment of the subject, which inevitably leads to further symptomatic and behavioural worsening.⁵⁶ The Mental Health Action Plan of 2013, already mentioned, has supported the need to initiate clinical experiences dedicated to the onset of serious mental illness and the need for integration with adult mental health services. The treatment of psychological disorders in the adolescent age range, in fact, presents several critical issues. First of all, the poor referral of teenagers and pre-adolescents to operative territorial units (neuropsychiatry of infancy and adolescence), which remains within 4% despite the estimation of

⁵⁴ On the contrary, as already recalled in the NBC opinion in 2000, "one must take into account the progressive and variable nature, even within the same individual, of the evolving phases of the disease (...)and it is often difficult to establish a clear boundary between normality and mental illness, which are unstable and changeable conditions" (*Psychiatry and mental health: bioethical guidelines*, p. 8). And again, on the same page: "A clear understanding of mental illness is also an essential tool to counteract prejudice and the resultant discrimination of patients, which are based on the idea that mental illness is a state rather than a process, and on the legitimacy of a classification system under which some individuals are declared unhelpable." See also: P. W. CORRIGAN, *How Clinical Diagnosis Might Exacerbate the Stigma of Mental Illness*, "Social Work", 2007, Vol.52, Issue 1, pp.31-39.

⁵⁵ K. R. MERIKANGAS, E. F. NAKAMURA, R. C. KESSLER, *Epidemiology of Mental Disorders in Children and Adolescents*, "Dialogues Clin Neurosci", 2009, 11(1): 7-20.

⁵⁶ A. COCCHI, A. MENEGHELLI, *Rischio ed esordio psicotico. Manuale d'intervento precoce*, Edi-Ermes, Milano 2013.

psychopathology being around 10%; the poor link between school and mental health services for interventions, for adolescents, regarding primary prevention and early taking into charge. There are also difficulties in managing psychiatric acuity in adolescence due to the shortage of beds and infant neuropsychiatry departments able to receive emergencies. Finally, the passage from infant neuropsychiatry taking into charge to actual psychiatry, at the age of 18, is often difficult due to the lack of integration of services. Lack of timely specialist intervention, and especially inappropriate management of therapies, apart from acute care conditions, can expose the patient to new relapses having important consequences even in terms of social costs thus affecting not only the patient but, in the final analysis, the same community. To speak about early diagnosis is especially important when dealing with the topic of psychosis. Research, in recent years, has supported the possibility of early detection of risk of psychotic onset, Ultra High Risk or Mental States at Risk, which identify subjects considered at risk of developing a serious disorder, based on the presence of prodromal signs and symptoms to developing psychotic disorders⁵⁷. The time, on average, between the occurrence of the first signs of illness and acute psychotic onset is about 5 years⁵⁸, which could be exploited to enable interventions to prevent the onset of the explicit disorder or reduce its consequences: early intervention in fact, produces favourable effects in the long-term on the course of negative, depressive and cognitive symptoms, as well as on the social functioning of patients. Intervention in order to reduce the duration of the untreated disease therefore means improving the outcome and recovery of these subjects. It would be opportune to form teams of trained specialists on the topic of onset, and have them work in the key areas of life for youths: schools, places of social gathering, to raise awareness of the disease and report cases at risk, so as to initiate patient therapy as soon as possible.

9. Closure of Judicial Psychiatric Hospitals (OPG) problems and future prospects

In 2014, the provisions of Law no. 81 provided for the closure of Judicial Psychiatric Hospitals (OPG) and outlined a system of treatment for offenders considered to be of `unsound mind` at the time of committing crime (total loss of judgment) and therefore acquitted to be started on special treatment (security measures). The Judicial Psychiatric Hospital has survived for many decades the abolition of asylums established by Law no. 180. The closure of these institutions is therefore a major stage in the process of de-institutionalization of

⁵⁷ P. FUSAR-POLI, F. SCHULTZE-LUTTER, *Predicting the Onset of Psychosis in Patient Satclinical High Risk: Practical Guide to Probabilistic Prognostic Reasoning*, "Evid Based MentHealth", 2016 Feb;19(1):10-5; L. R. VALMAGGIA, M. BYRNE, F. DAY, M. R. BROOME, L. JOHNS, O. HOWES, P. POWER, S. BADGER, P. FUSAR-POLI, P. K. Mcguire, *Duration of Untreated Psychosis and Need for Admission in Patients who Engage with Mental Health Services in the Prodromal Phase*, "Br J Psychiatry", 2015 Aug; 207(2):130-4.

⁵⁸ J. EDWARDS, P. D. Mc Gorry, *Implementing Early Intervention in Psychosis. A Guide to Establishing Early Psychosis Services*, Taylor & Francis Book Ltd, London 2002.

persons with mental illness, it is the result of a large movement that involved practitioners, patient and family associations, and civil society sectors.

Despite law no. 81 does not touch the institution of acquittal for total or partial "mental disorder", (art. 88 Criminal Code), it is, however, an important anchor in the representation of persons with mental illness, sanctioning the evolution from being perceived as a socially dangerous subject (to be interned in a criminal asylum) to a patient in need of care (through the new system that Law No. 81 establishes). Since this evolution is crucial, it is appropriate to go into further detail. The long experience of Judicial Psychiatric Hospitals (OPG) has revealed how the conflictual relationship between clinical, social and criminal treatment of persons with mental illness can be central. For a long time, these structures became veritable places of exclusion and marginalization in which the repressive element was the overriding concern over any therapeutic and care perspective.

If the Penal Code focused on the concept of social dangerousness which made the dividing line between the sentence and the security measure very unstable, even the mentality with which judicial psychiatric facilities were conceived and managed was that of the guarantee of social control with minimal attention to the protection profiles of the right to health. In short we had, and we continued to have, even after the Basaglia Law (which also has fully transcended the concept of the psychiatric patient being, as such, a danger to himself and others), prisons-asylums forming the other side of the coin of asylum -prisons.

This situation of decline and neglect, in itself hardly acceptable, was aggravated by a widespread judicial practice, used in order to cover the lack of adequate social or family care services, that of resorting to the so-called category of "latent social dangerousness". This meant that the subject remained interned not for their crimes or their pathological conditions, but the unavailability of adequate means of support outside the OPG: a sort of "mental hospital prison sentence". In our country it seemed impossible to remedy this absurd condition of never released but 'releasable' detainees; people who, for some time, should have been released or subjected to non-custodial measures and who, instead, remained indefinitely in prison, a veritable so-called "white life sentence," due to the lack of adequate forms of hospitalization and rehabilitation outside the prison circuit.

It is true that the entry into force of the Constitution had resulted in a clear theoretical overturn, with the affirmation of the principle, repeatedly emphasized by the Constitutional Court, according to which "the requirements of community protection can never justify such measures as to cause harm, rather than benefit, to the patient's health." In this perspective, individual custodial security measures should have been applied, through a balanced reconciliation between the containment of social dangerousness and care and protection of the incapacitated person, because such measures have a constitutional justification only if they 'respond simultaneously' to both of these connected and non-

detachable purposes». Nevertheless, the repressive mentality of Judicial Psychiatric Hospital persisted throughout the last century.

An complete re-examination of our system came to fruition in particular with the laws n. 9 of 2012 and with the mentioned law no. 81 of 2014 which, in addition to providing for the permanent closure of the OPG, have established a system of treatment and rehabilitation of territorial rule, and in extreme cases in a residential system at REMS (Residences for Security Measures) This is with the clear intent of overturning definitively the manicomial logic and ensuring an effective system of protection of the right to health of the individual. The marginalization and the alienation of "where do we put them?" (so no one sees them and hears them) has been replaced by the social commitment of "how do we socially recover them?" (To return to them and to the society they live in, the sense of dignity of existence)⁵⁹.

This reform can not obviously remain isolated, but involves a wider revision of the sanction system. With the bill passed by the government recently approved by the Parliament on "Amendments to the Penal Code, the Code of Criminal Procedure and Penitentiary systems" (Law No. 103, June 23, 2017) that foresees, inter alia, a positive rethinking of the definitive model of mental infirmity, more adherent to the variety of personality disorders, in line with the currently established scientific positions, to which a different conception of security measures, more adherent to constitutional principles, with periodic assessment of persistence of dangerousness and adopted therapeutic measures, until the withdrawal of these measures when no longer necessary.

However, as has been stated by several parties, proposed, in the same approved text of the law, is the access to REMS not only for those who have been diagnosed with mental illness at the time of the offense but also to all those to whom the onset of mental illness has occurred during execution of the sentence, including detainees for whom psychological conditions need to be established, in cases of inadequacy of the special sections of prisons to guarantee therapeutic and rehabilitative treatment. This would lead to an inevitable return to the outdated logic of undifferentiated and therefore depersonalized treatments in structures that would soon become overcrowded and therefore unmanageable (although the limited number rule should ensure against this risk). Moreover, there would mean a partial return to the idea of the psychiatric or supposedly mentally ill person, whose disturbance would, in itself, represent a cause of social danger: this would be the rationale behind the referral of prisoners with psychiatric problems to the arranged care system for the acquitted, or for those deemed unsound of mind, at the time of committing a criminal act.

It therefore raises the issue of paying special attention to mental health in prisons, by not preparing new mental hospitals, but acting on the actual taking

⁵⁹ A. PUGIOTTO, *Dalla chiusura degli Ospedali psichiatrici giudiziari alla (possibile) eclissi della pena manicomiale*, in *Costituzionalismo.it*, 2-2015 http://www.costituzionalismo.it/download/Costituzionalismo_201502_515.pdf.

charge by the departments of mental health through the services provided in prisons and the possibility of accessing suspension of punishment for health reasons and alternative detention measures. It is also promising that the Chamber of Deputies by dismissing the measure, has approved eight orders of the day calling on the Government to restrict to the utmost as exceptional the expectation of hosting at REMS subjects other than the acquitted or the exercise of delegated powers.

The NBC can not and does not wish to go into an in-depth analysis of the individual aspects of a reform that is still being implemented and which is encountering significant organizational and even interpretative difficulties.⁶⁰ The Constitutional Court has had to intervene (Judgment of 23 July 2015, No. 186) to reiterate the legitimacy of this law, as there are no justifications for "unnecessarily inhumane detention measures for the sick and those with a mental infirmity". Such measures can therefore only be taken in cases where the person's mental conditions make them necessary and they should not be an instrument to compensate for the inadequacy of social structures. In short, the Court reiterated that persons with mental illness should be judged for the actions they have committed and for the condition they are in: they can not continue to pay for what society is unable to prepare and achieve with them.

However, the NBC intends to express its appreciation for the principles underlying the new territorial treatment system and the establishment of REMS (for those who need intensive residential treatment). First of all, it is extremely positive that the simplest path of "medicalization" of OPGs has been abandoned in order to fully accept the different logic of small structures that operate, through individual rehabilitation projects, in the territory so as not to interrupt "normally" the affective and social ties of those admitted. The REMS security measure in any case is considered the exception that can only be used when there are no valid alternatives that provide adequate therapeutic perspectives.

This principle of residuality is closely linked to a clear stance which radically eliminates all the misunderstandings of the past, whereby "the lack of individual therapeutic programs is not an element capable of supporting the judgment of social dangerousness", along with economic conditions or family members. The reshaping of the diagnosis of social dangerousness operates, therefore, at the time of entry, limiting the use of REMS to the most serious situations, as well as at the time of exiting, favouring the revocation of custodial security measures through targeted paths and periodic assessments. In short, danger must not be seen with the eyes of the prejudices of a society that does not want uncomfortable subjects to disturb its tranquillity, but it must be commensurate with the actual pathological conditions of the persons judged with mental illness. In this respect,⁶¹ the introduction of the principle of maximum duration of

⁶⁰ The difficulties can be summed up in the phrase "there is topos but not yet logos", as Prof. De Girolamo pointed out at the NBC hearing on 22 June 2017.

⁶¹ D. BERTACCINI, *Cosa resta del reo-folle? Gli esiti provvisori e le questioni irrisolte nel processo di superamento degli ospedali psichiatrici giudiziari*, in "Raccolta di scritti in onore di

custodial measures, whether provisional or definitive⁶², should be considered with interest, but also with attention.

With respect to this provision, it should be noted that there have been well-founded reservations regarding the exception established for crimes punished with life imprisonment, which may revive forms of "hidden life sentences", not dissimilar from the so-called "white life sentences" for which it was intended to be a remedy. On the other hand, it is necessary to further investigate which remedies should be refined for the situation of the mentally ill perpetrators of violent crime whose therapeutic rehabilitation path started or continued in the course of the execution of a security measure, for the former commission of a presumed crime the non-achievement of any reliable progress or stabilization for the voluntary continuation of the individual program, which according to the best acquisitions of forensic psychiatry is, for example, the case for patients with persistent chronic psychoses or with irreversible cognitive impairments, with viable therapies of little or no effect, these subjects being rather or solely in need of socio-sanitary assistance for maintenance and control.⁶³

Therefore, the reform moves around a series of principles that could play a major role in the general rethinking of the relationship between the penal system and the psychiatric system⁶⁴: the principle of residuality of the security measure, the principle of territoriality in its execution and respecting the capacity provided for in REMS; the principle of individuality of the therapeutic project, the principle of the primacy of patient welfare over the requirements of social control and the justification of the measures taken. There still remain, however, several problems to be solved. As can be seen from the extensive discussion contained in the resolution of the Superior Council of Magistracy of 12 April 2017, "Urgent provisions on replacing Judicial Psychiatric Hospitals (OPG) and institution of residences for the implementation of Residences for Security Measures (REMS)", pursuant to law n. 81 of 2014. Interpretative issues and application problems, "the law has so far had a patchy implementation with important structures of excellence and serious critical situations".

It should also be noted that, in relation to the question of the total capacity of REMS, which can not be extended without running the risk of undermining the logic of residuality, exceptionality and transience of the time in custody, the significant lack of homogeneity and the complexity of the pathological picture of admitted patients would call for not only a greater diversification of residential structures - which could not be achieved in the first period of implementation of the law, but should be considered as a model to be achieved within a

Luigi Stortoni", a cura di M. CAIANIELLO, F. CURI, M. O. MANTOVANI, S. TORDINI CAGLI e V. TORRE, Bup, Bologna 2016.

⁶² On this, the Constitutional Court expressed its decision, rejecting the question of legitimacy raised by the Tribunale di Napoli (Judgment of 23 July 2015, No.186).

⁶³ U. FORNARI, *Trattato di psichiatria forense*, V ed., Utet, Torino 2013; R. CATANESI, F. CARABELLESE, A. VALERIO, C. CANDELLI, *Malattia mentale e comportamento violento: la percezione degli psichiatri italiani*, "Quaderni Italiani di Psichiatria", 2004-4.

⁶⁴ M. PELISSERO, *Ospedali psichiatrici giudiziari in proroga e prove maldestre di riforma della disciplina delle misure di sicurezza*, in "Diritto penale e processo", 2014-8.

reasonable period of time - but also greater support for the functionality of other health care facilities within the territory, in particular community Psychiatric Diagnosis and Treatment Service, (SPDC), which should be monitored accurately and consistently in the commitment to taking charge of patients from REMS for the necessary therapeutic and rehabilitative synergies.

Recommendations

The analyses on the current state of care for persons with mental illness show the importance of an integrated approach centered on the person and his/her inclusion within the community at large: an approach centered on the realization of fundamental human rights, yet still confronted with the persistence of stigma and discrimination. People who live in a state of mental suffering are still today identified with the disorders they suffer from, hereby erasing their identity, according to the usual process of stigmatization. The fight against prejudices that define our perception of mental illness as a status from which there is no way out, as a condition that excludes from the context of social interaction, creating discrimination, has not yet been won and strong resistance still persists.

To counteract discrimination and improve the living conditions of persons with mental illness, we propose the following recommendations:

- Initiate and support social communication campaigns - promoted in synergy between institutions such as the Ministry of Health and Education, Research and University, Scientific Societies and Associations of Persons with Mental Illness and their Families – aimed at young people, in order to promote information on mental illness, prevention, and the fight against stigma and discrimination;
- Develop integration between “cure” and “care” in compliance with the principles of the three Es, (Ethics, Evidence, Experience), activating practices respectful of human rights that make use of available scientific evidence and experience in the field, in order to promote the autonomy of persons with mental illness and their social inclusion;
- Establish a quality performance assessment system that rewards services that adhere to the principles outlined above;
- Monitor the concrete implementation of the care model throughout the territory, denouncing the survival of practices that resemble the manicomial/custodial model;
- Promote research, both pharmacological (in particular on the use of psycho-pharmaceuticals) and psycho-social research, and ensure that the information deriving from research has the best impact on service practices;
- Ensure that everyone living in our country has the same standards of mental health care, avoiding inequalities across the different regions;
- Carefully monitor the distribution of mental health resources in order to: avoid disproportionate distribution compared to other areas of health; reach the

higher standards of spending of other European countries; counteract the current reduction in the staffing of territorial services;

- Ensure the realization of the rights of persons with mental illness, in compliance with the UN Convention on the Rights of Persons with Disabilities, with particular regard to freedom, equality before the law, social inclusion;

- Support the families of persons with mental illness, enhancing care and social support to the sick through the entire health and social services network within the territory;

- Activate continuous training paths for social-health workers working in the field of mental health;

- Promote, through appropriate training of school staff, greater attention to mental health in childhood and adolescence, monitoring the higher risk factors while at the same time avoiding labelling, pathologization and stigma;

- Monitor the passing from Judicial Psychiatric Hospitals to the new treatment system provided by law no. 81/2014, to prevent recurrence of the manicomial logic. In particular, the following must be guaranteed: the principle of the primacy of patient welfare; the principle of residuality of the safety measure; the principle of territoriality of its execution; the principle of individuality of the therapeutic project.