1st European Congress on Adherence to Therapy

Giovanni La Via
President of the Congress
Chair of the Committee on the Environment, Public Health and Food Safety - European Parliament

Gianni Pittella
Honorary President of the Congress
President of the Group of the Progressive Alliance of Socialists & Democrats in the European Parliament

Scientific Partners

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SEFAC - Social Engagement Framework for Addressing the Chronic-disease-challenge
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Giuseppe Pozzi
SIHA - Senior International Health Association

Alberico Catapano
European Atherosclerosis Society

Enrico Agabiti Rosei
European Society of Hypertension

Silvana Galderisi
European Psychiatric Association

Francesco Blasi
European Respiratory Society

Vincenzo Mirone
Italian Society of Urology
European Association of Urology
I feel honoured to be the President of the first European Congress organised by Senior International Health Association on the adherence to therapy.

From a European perspective, we have looked at the national health systems and at the deep demographic, economic, and social changes of our time, and have discovered a common finding: the increase in chronic diseases is a direct consequence of the progressively ageing population.

Adherence to therapy, in this context, is imperative for two main reasons. First, to improve the life of patients with chronic diseases, including people over 65 who are the main consumers of medicines and second, for assuring an efficient use of the resources in the medical field, further allowing potential financial savings.

As Chair of the Committee on Environment, Public Health and Food Safety (ENVI) of the European Parliament, I believe it is essential for the institutions to be in direct contact with the scientific communities and with the patients, which will both guarantee an essential contribution to the designation of strategies aimed at the enhancement of the health systems in Europe.

The European Congress for the adherence to therapy provides the opportunity to doctors, patients associations and representatives of national and European institutions, to work together to identify the main changes necessary for the improvement of the adherence to therapy. This can only be done by including all the relevant actors and by defining the core actions and priorities needed to reach the common goal.

Achieving these objectives will have two main positive impacts, which are improving the living standard of the European senior population, and reducing the waste of resources caused by the lack of adherence to therapy.

Finally, the European Charter for Adherence to Therapy, which will be drafted during the Congress and will contain the main strategies, can be considered a useful and valuable document to the European Parliament and other institutions, as it will also guide Member States towards the best direction to take on such fundamental topic, related to the health of the European population.

Giovanni La Via  
President of the Congress  
Chair ENVI, Committee on the Environment, Public Health and Food Safety - European Parliament
When I was invited, by Senior International Health Association’s, to take the honorary presidency of the European Congress on adherence to therapy I accepted with great interest and conviction. I did it to express my support to ageing policies and to gather inputs from patients and the medical and scientific world in relation to seniors’ health. Moreover I wished to express a commitment because, at European and national level, there is a clear need to develop interventions to increase adherence to medical treatments, to improve health outcomes and to lower costs for health care, involving all relevant actors and above all citizens/patients.

We know that a lack of adherence to medical prescriptions means worsening the health conditions of chronically ill patients and consequently leads to an increase in the costs that the health services have to support to deal with relapses and consequent hospitalizations of patients who do not follow care prescriptions adequately. We are speaking specifically about the elderly. We know that, in Europe, one out of two patients does not follow his treatment correctly and that the costs for governments, caused by poor adherence, are estimated at 125 billion and contribute to the premature death of about 200,000 people each year.

This is why the European Institutions should support an initiative, such as the European Congress for adherence to therapy, which sees patients assuming full awareness of the problem and recalling the European medical and scientific community and the institutions to stimulate a dialogue and a debate on this issue.

The goal of the congress, that I fully support, is to increase patients awareness and involve them, along with physicians, to outline strategies and proposals that can be useful to the same institutions that govern health in Europe.

In this sense we are ready to listen to the suggestions that will arise from the Congress and that will be included in a European Manifesto for adherence to therapy. This chart, that we will evaluate carefully, may involve all Member States in the framework of a common work shared by the scientific community, citizens and institutions.

Gianni Pittella
Honorary President of the Congress
President of the Group of the Progressive Alliance of Socialists & Democrats in the European Parliament

1st European Congress on Adherence to Therapy
According to Eurostat data, in early 2013 the population of the EU-28 was estimated at 505.7 million inhabitants, with a share of 18.2% represented by people aged over 65 years. Almost everywhere in the EU there has been an increase in the share of the older population, as a result of the increase in life expectancy, which in the last 50 years increased in the EU by an average of about 10 years, due to improved socio-economic and environmental conditions, health care and medical treatment. By 2025 over 20% of the Europeans will be 65 or older and the number of octogenarians will rapidly increase.

The increased life expectancy represents obviously a positive effect of the progress in prevention and care, but also implies a challenge for Health Services, due to the high level of complexity of the health needs of the elderly, making among others care and, in particular, the use of drugs a challenging task. We know by now that the fundamental conditions for active and healthy aging include not only prevention and adoption of healthy lifestyles, but also adherence to therapy. Typically, the elderly reveal the co-existence of more chronic diseases and clinical conditions that can’t be ascribed to a specific disease and frequently have multiple causes. Drug treatment of a complex patient is a challenging task for everyone involved in the care of the patient, considering that 50% of people over 65 years suffer from multimorbidity and that 40% of those over sixty-five consumes between 5 and 9 drugs.

It is estimated that each year the poor adherence to medical treatments in Europe causes about 200,000 deaths and burdens on health expenditure up to 80 billion euro a year (AIFA source).

Adherence to treatment by patients suffering of chronic pain reaches across Europe, with different values depending from the chronic diseases, approximately 50%. We know by now that the fundamental conditions for active and healthy aging include not only prevention and adoption of healthy lifestyles, but also adherence to therapy. We also know that non-adherence to treatment involves the risk of recurrence and adverse events, and that this, in addition to health risks, results in additional health care costs, which can be reduced. In the United States it was measured that non-adherence to treatment determines 100 billion euro of avoidable hospitalizations.

Europe and the Member States have a duty to attempt any possible solution to increase the level of adherence to treatment, in order to achieve important savings and improve the quality of life of citizens.
Scientific Conclusions

Dyslipidemia Area

Imperatives
- Lifestyle (physical activity, smoking etc)
- Diet
- Medications

*Increase in life expectancy over last 20 years has been 6 to 8 years of which 80% attributed to cardiovascular interventions*

Size of the problem (lifestyle and diet)
- Poor adherence to healthy lifestyles (political and health care system failures, environment and societal aspects)
- Availability of high quality food (political and health care system failures, environment and societal aspects)
  - education of person responsible for food preparation
  - educational gap which is cultural, starts in childhood
- Pill perceived as panacea

Size of the problem (medications)
- Even in people with CVD or diabetes adherence less than 50% at one year
- Well characterised issues such as
  - Side effects and perceived tolerability
  - Health professional and patient education
  - Inconsistent media messages
  - Need for lifelong therapy

Size of the problem
- Poorly characterised issues such as
  - Health beliefs
  - Peer pressure from social network
  - Influence of internet
  - Inappropriate prescribing
  - Feeling well but being «at risk»
  - Medicalisation of population

Issue particular to lipid field
- Use of lipid lowering goals
- Optimum timing of intervention
  - When to start and when to stop?
- Intensity of treatment according to risk
- Management of side effects
Scientific Conclusions

Dyslipidemia Area

Recommendations
- Multidisciplinary approaches - nurses and allied professionals (education, follow up)
- Communication skills - eg motivational interviewing to manage ambivalence
- Rewarding adherence (both health professionals and patients)
- Use of technology and social media
- Government engagement (schools, food industry, healthy cities, tax policies)
- Celebrity champions (eg Jamie Oliver)
- Improved understanding of cost and benefit drivers
- Improved patient understanding of risk and benefits
- Targeting primary prevention on basis of bio-markers and genetics and risk scoring
- Use of genetic information as an adherence tool
- Further research essential in order to generate evidence based interventions to improve adherence

Participants
Alberico Catapano
Chris Packard
Catriona Jennings
Giovanni Corrao
Lale Tokgozoglu
Luca Degli Esposti
Lampros Michalis
George Giannakoulas
Benedicte Heyndrickx
Alessandro Cavarape
Scientific Conclusions

Hypertension Area

Task Force
Enrico Agabiti Rosei (Italy) Chairman
Michel Burnier (Switzerland)
Renata Cifkova (Czech Republic)
Diederick E. Grobbee (The Netherlands)
Thomas Kahan (Sweden)
Bojan Jelakovic (Croatia)
Giuseppe Mancia (Italy)
Josep Redon (Spain)
Konstantinos Tsioufis (Greece)

Challenges in HTN management
- Lifetime burden of hypertension remains substantial
- Trend of decreasing BP values is lower in Europe than in other western countries
- Rate of BP control in the population remains low

Trends in SBP values (1975-2015)
Impact of different strategies to improve adherence and BP control

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Effect</th>
<th>OR</th>
<th>Change in BP (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP self measurement</td>
<td>no effect</td>
<td>+ 3%</td>
<td>0.97</td>
</tr>
<tr>
<td>Patient education</td>
<td>minor effect</td>
<td>+ 17%</td>
<td>0.83</td>
</tr>
<tr>
<td>Physician education</td>
<td>minor effect</td>
<td>+ 15%</td>
<td>0.85</td>
</tr>
<tr>
<td>Use of TTT protocol</td>
<td>Very positive</td>
<td>+ 55%</td>
<td>0.45</td>
</tr>
<tr>
<td>Recalls consultation</td>
<td>Very positive</td>
<td>+ 59%</td>
<td>0.41</td>
</tr>
<tr>
<td>Collaboration with Healthcare partners</td>
<td>Very positive</td>
<td>+ 70%</td>
<td>0.30</td>
</tr>
</tbody>
</table>

Cochrane meta-analysis 2010

General Overview

Improving adherence is aligned with the Healthy Ageing Program of EU
- Non-adherence is a common problem in all chronic diseases and conditions
- Multimorbidity in elderly populations is frequent and contribute to the low adherence
- To improve adherence, we need to:
  · Aware the importance across populations and stakeholders
  · Empower patients
  · Multidisciplinary approach (team support)
  · Earlier and better recognition

Improving adherence in Hypertension

The Patient Level
- Self-BP measurement
- Patient empowerment
- Use of Decision Support Systems
- Use technologies (reminders,...)
Scientific Conclusions

Hypertension Area

Eurohypertension-APP
ESH CARE

- Stores, shows in graphs and transmits BP values, body weight and height
- Provides educational material
- Connects patients with their physician
- Locates ESH Excellence Centres all over Europe

MY VALUES
Scientific Conclusions

Hypertension Area

Improving adherence in Hypertension

The Drug Treatment
- Symplification of drug treatments (*reduce number of pills with FDCs, polypill, pharma packaging,…*)
- Giving acces to those available treatments
- Regular follow-up of treatment objectives

Health Care System
- Recognize the saving in cost of improving adherence
- Facilitate the involvement of health care providers
- Encourage and facilitate introduction of use of technologies for disease management and improvement of adherence (ICTs, telemedicine, registries,…)
- Promoting awareness of the importance of adherence (tv, radio, press,…)
- Promote at EU-level transversal studies in adherence (relevance, cost-efficacy, methods to improve,…)

Awareness, treatment and control rates of HTN in Europe: Summary
- Hypertension is one of the most relevant challenges to health care in Europe
- More than 50% of treated and more than 60% in the overall population are still uncontrolled
- Control rates are heterogeneous among countries and regions
- Progressive but slow rates of improvement are observed
- A large room for improvement exists

The shared responsibility concept for improving BP control

<table>
<thead>
<tr>
<th>Track nonadherence</th>
<th>Fight against inertia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Promote adherence</td>
<td>More potent treatments</td>
</tr>
<tr>
<td>Preserve/organize access to care</td>
<td>Better evaluation of BP level</td>
</tr>
<tr>
<td>Primary prevention of HT</td>
<td>Simple and implementable recommendations</td>
</tr>
</tbody>
</table>

1st European Congress on Adherence to Therapy
Scientific Conclusions

Psychiatric Area

Task Force
Silvana Galderisi, University of Campania “Luigi Vanvitelli” (formerly SUN), Italy
Istvan Bitter, Summelweis University of Budapest, Hungary
Andreas Erfurth, Medical University of Wien, Austria
Palmiero Monteleone, University of Salerno, Italy
Stefano Pallanti, University of Florence, Italy
Marie Tournier, University of Bordeaux, France

Introduction
In the 1st European Congress on Adherence to Therapy the Psychiatric Area included 6 experts: Istvan Bitter, Professor of Psychiatry at the Summelweis University of Budapest, Hungary, expert of schizophrenia; Andreas Erfurth, Guest Professor, Medical University of Vienna, expert of Bipolar Disorders; Palmiero Monteleone, Professor of Psychiatry at the University of Salerno, Italy, expert of Eating disorders; Stefano Pallanti, Professor of Psychiatry at the University of Florence, Italy, expert of Anxiety Disorders and Marie Tournier, Professor of Psychiatry at the University of Bordeaux, France. The Chairperson of the group was Silvana Galderisi, Professor of Psychiatry at the University of Campania “Luigi Vanvitelli” (formerly SUN), Italy, and President of the European Psychiatric Association.

The group shared the opinion that treatment adherence is a key issue in mental health care terms. In fact, poor adherence (discontinuation or different degrees of partial adherence) is very common and, as observed in chronic patients treated by other medical specialties, involves up to 70% of users. The lack of adherence worsens the brain morphological and functional changes associated with psychiatric disorders, leads to increased disability, to higher somatic morbidity as well as higher mortality rates and suicide. Especially for senior people, often suffering from multiple diseases (including somatic and psychiatric diagnoses) and requiring many concurrent treatments, shared knowledge and cooperation among different medical specialists is needed to address the adherence problem.

In spite of the largely recognized importance, the topic is not covered adequately in psychiatric training and textbooks. In addition, most of the literature has focused on psychotic disorders, neglecting other important areas.

Since in different diagnostic categories poor adherence might have different features and require different approaches to its assessment and treatment, the experts were invited to discuss the topic for more common mental disorders.

General issue included the used terminology, the definition of adherence to treatment provided by the World Health Organization, and the importance of the doctor-patient relationship in programs targeting adherence.

**Terminology**

Adherence and compliance are often used interchangeably; however, adherence presumes patient’s agreement with the recommendations, whereas compliance implies patient’s passivity. The term concordance has also been suggested to emphasize the role of the patient as decision-maker in the process and to denote patients-prescribers agreement and harmony. In this paper the term adherence was kept, as it is the most largely used, proposed as theme of the Congress and preferable for communication purposes.

**Definition**

According to the World Health Organization, adherence to treatment refers to the extent to which a person’s behavior—taking medication, following a diet, and/or executing lifestyle changes—corresponds with agreed recommendations from a health care provider. To improve the current definition adherence should be regarded as a dynamic process leading to a collaborative relationship between the patient and the therapist, and add “attending psychosocial treatment programs” to the list of person’s actions that should correspond with agreed recommendations from a health care provider.

**The importance of the therapeutic relationship**

A good communication between patient and doctor is increasingly recognized as a key factor for adherence. A full involvement of the patient in therapeutic decisions is regarded as essential. In some instances, also due to patient’s poor insight, it might be difficult to achieve and certainly requires skilled doctors and full awareness of the impact of adherence on patients’ functional outcome.

**Adherence to treatment in people with schizophrenia**

About 80% or more of those having an episode of schizophrenia do have repeated episodes and/or continuing course of schizophrenia with fluctuations between severe and moderate disability. Complex treatment including antipsychotic pharmacotherapy, psychotherapy, social support, lifestyle changes management (such as diet and exercise) and vocational rehabilitation improved the course and outcome of schizophrenia. Recent data strongly support the beneficial effects of continuous treatment already after the first episode of/hospitalization for schizophrenia.

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However adherence to treatment in usual care settings is generally low, e.g. no greater than 50%\(^7\)\(^8\). The early identification, prevention and the efficacious treatment of non-adherence can be improved with consideration of the most frequent risk factors\(^9\): 1. Risk factors related to schizophrenia (e.g. cognitive deficit); 2. Alcohol and drug abuse; 3. Risk factors related to patient characteristics (e.g. young male); 4. Risk factors related to health care (e.g. access); 5. Risk factors related to antipsychotic medication (e.g. inefficacy). Medication taking is associated with stigma. The main consequences of treatment discontinuation include increased number and severity of symptoms, increased number and duration of relapses, increased rates of hospitalization, increased suicidality and mortality, decreasing social functions, progressive brain tissue loss and increasing cost for the society and caregivers\(^9\)\(^10\). Furthermore, treatment discontinuation (even supervised discontinuation with planned reintroduction of antipsychotic treatment after the recurrence/deterioration of psychotic symptoms) leads in about 1 out of 6 patients to treatment resistance\(^11\). A complex treatment model with well planned and integrated acute treatment, relapse prevention, and rehabilitation, would improve treatment efficacy and adherence to treatment. Pharmacotherapy without psychotherapy, social interventions and lifestyle management cannot be as successful as the combined effect of complex interventions. However without adequately dosed and long term pharmacotherapy the vast majority of patients will suffer from progression of schizophrenia.

Considering the data about the side effects of high dose treatment clinicians should strive to use the lowest effective dosage of antipsychotics both for the control of symptoms and relapse prevention. Available data suggest the importance of doing as much as possible to ensure treatment adherence as a way of preventing relapse since the time of illness onset\(^10\).

Providing patients and relatives with more and adequately tailored information about the clinical presentation, course of and treatment options in schizophrenia may also improve adherence. To this aim, as highlighted by the Section of Psychopharmacology of the European Psychiatric Association, education and training in psychiatric pharmacotherapy needs improvement in Europe. Gaps have been detected in teaching medical students, in residency training programs and in continuing medical education of psychiatrists. Patients and their relatives may trust well trained and informed doctors and other health care workers more than those whose knowledge is not up to date. Last but not least: the adherence of health care workers to various guidelines is generally low. Good graduate and postgraduate education and improved quality control in psychiatry could help.

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Adherence to treatment in people with bipolar disorders

Disorders of the bipolar spectrum\(^{13}\) are frequent, about 5 percent of people are estimated to meet broader diagnostic criteria for bipolar disorder at some point in their life. Diagnostic conversion from depression to bipolar disorder is high (60% over 50 years). Diagnosis of bipolar disorder (as compared to unipolar depression) is particularly difficult: patients might ask for help when suffering from depression and anergia, but less when experiencing hypomania and increased energy. Identification of the underlying bipolarity is often delayed up to 10 years after the first manifestation of symptoms. Comorbidities with other psychiatric and medical conditions are frequent. Creating adherence is difficult when the diagnostic process is so particularly complex.

Most bipolar patients have complex medication regimens when released from hospital. Polypharmacy (that often lacks a scientific background) undoubtedly reduces adherence rates. In the relapse prevention of severe mania treating patients with long acting injections of antimanic substances might be a possible strategy to increase adherence\(^ {14}\). In addition, therapeutic monitoring is of particular importance in the treatment of affective disorders.

Particular lack of adherence has been demonstrated in adolescents with bipolar disorder, in late-life bipolar disorder, in patients with depressive residual symptoms and in bipolar patients with cyclothymic temperament. Bipolar patients exhibit characteristic cognitive deficits that distinctly influence their capacity to adherence.

While it has been shown that medication non-adherence is a significant problem in bipolar disorder and that even brief interventions of e.g. psychoeducation\(^ {15}\) can improve medication adherence, the availability of such interventions is still limited (e.g. to special Bipolar Disorder Programmes established in larger cities with University Hospitals).

In summary, a holistic approach to adherence in bipolar disorder should be implemented: cognitive remediation, psychoeducation, social interventions and recognition of psychiatric and medical comorbidities are required to increase adherence to treatment and to medication in particular. Local consensus initiatives\(^ {16}\) to increase adherence are as necessary as global projects.

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Scientific Conclusions

Psychiatric Area

Adherence to treatment in people with eating disorders

Eating disorders (EDs) represent a group of serious and complex mental disorders, which includes anorexia nervosa (AN), bulimia nervosa (BN) and binge-eating disorder (BED), besides other forms of sub-threshold and unspecified/specific eating disordered behaviors. Along the past decades, their constant increase in prevalence and the gradual precession of their age at onset have led the World Health Organization to include EDs among the priority mental illnesses for children and adolescents\(^\text{17}\). Although in recent years many treatment models integrating pharmacological, psychological and nutritional approaches have been put forward and received empirical support (particularly, those based on cognitive-behavioral and family-based therapies), the long-term prognosis of EDs still remains poor, with a high degree of morbidity, comorbidity and mortality especially for severe and enduring AN\(^\text{17}\).

One of the most compelling issues that negatively affects the treatment and outcome of EDs is represented by the high treatment dropout rate estimated as up to 66% for medications and up to 38% for psychotherapy, although significant differences are present among studies\(^\text{18}\). Dropout rates are usually reported to be lower in BN (5-40%, with a median value of 20%)\(^\text{19}\) and BED (slightly above 20%) than in AN\(^\text{20}\) in outpatient settings. Overall dropout rates ranging from 20% to 51% for inpatients and from 29% to 73% for outpatients have been observed.

Factors linked to a higher risk of treatment dropout in EDs include greater clinical severity, longer duration of illness, greater general psychiatric difficulties, higher psychiatric comorbidity rates (especially with depression and some personality disorders), the presence of specific psychological traits (e.g., impulsivity or maturity fear), low family members involvement (in particular, for adolescents with AN), poor service/care organization and coordination. Moreover, clinical subtypes of EDs (e.g., AN of the binge-purging subtype), treatment setting (e.g., group vs. individual setting; outpatient vs. inpatient settings) and type of treatment (e.g., psychotherapy vs. pharmacotherapy vs. nutritional counseling vs. their combinations) seem to exert a significant influence over treatment adherence in ED patients. Finally, therapeutic adherence represents a crucial and specific problem in the management of ED patients due to the ambivalence that these subjects hold towards their symptoms. Indeed, besides the “burden” perception of their illness, many ED patients are agreeable about at least some aspects of their clinical symptoms, and this often underlies a lack of motivation to change or a blunted attitude towards therapeutic engagement.

The high dropout rate of ED patients may have many negative clinical consequences such as poorer prognosis, delay in referral to specialized centers, greater risk of hospitalization, lower therapist motivation and greater economic costs.


Scientific Conclusions

Psychiatric Area

Because of these fatal negative consequences, future clinical management strategies for EDs should aim to improve the adherence to treatments of ED patients. To achieve this objective, researchers should focus on a shared and agreed definition of dropout in EDs, promote research to identify reliable predictors of dropout and develop specific interventions to improve therapeutic adherence for EDs by integrating specific motivational enhancement strategies.

Adherence to treatment in Anxiety Disorders

The most frequent mental disorders in terms of the estimated number of persons are anxiety disorders, with a yearly prevalence of 14% (61.5 million persons) in Europe. Anxiety disorders also display remarkably high costs (about 1076 euros per subject and 65995 millions of euros as total costs), of which more than 60% are direct healthcare costs. These have been shown to be drastically reduced by the implementation of appropriate treatments: in example, treatment with SSRI reduce both the mean number of ER and laboratory visits per individual and the mean cost of these visits per individuals. Anxiety disorders are also correlated with other diseases, particularly inflammatory ones. For instance, variations in pro-inflammatory interleukins have been shown in patients with GAD and an increased vulnerability to viral diseases has been reported. Anxiety affects the whole body, exerting its effects over multiple districts, such as the cardiovascular, endocrine, respiratory, gastrointestinal and reproductive system, as well as over the nervous system.

Nevertheless, a high prevalence of non-adherence to pharmacological and psychotherapeutic treatment has been shown in Anxiety Disorders: 57% of subjects appear to be non-adherent to antidepressant therapy at 6 months, whereas 36.8% of the patients do not complete the psychotherapeutic treatment considering rejections and drop outs. The major reasons for drop out seem to be the lack of a secure base, fear and catastrophizing thinking, biased decision and the inability to wait for results. Therefore, an efficacious communication is essential in order to allow clinicians to activate and engage patients in self-management through collaborative goal-setting and action planning and to foster shared decision-making about medications.

In brief, anxiety and anxiety disorders represent a relevant cause of interference in the medical and psychological setting (about 50% of ER accesses are associated or due to anxiety symptoms), and are still underrated by general physicians, whereas the first and most important step is to recognize that Anxiety is a disease itself, with high prevalence, costs and related consequences on life expectancy.

Scientific Conclusions

Psychiatric Area

Adherence to treatment in people with depression

Antidepressants play an important role in depression treatment. They are recommended in moderate to severe depression in all guidelines. Non-adherence to antidepressant is estimated around 40-60% of patients. Early discontinuation occurs within 1 month in 25-42% of patients, within 3 months in up to 72% and within 6 months in up to 82%. The consequences of non-adherence include relapse and recurrence, chronification, poor psychosocial outcomes and increased suicide rates.

Adherence to antidepressant may be assessed by using medication event monitoring system (MEMS), clinician rating scale, pill count and self-report (e.g. Medication Adherence Questionnaire). The MEMS is a medication bottle cap with a microprocessor that records the occurrence and time of each opening of the bottle; it is known to be the gold standard.

Non-adherence to antidepressant is a multifactorial phenomenon. Considering the treatment itself, upward dose titration was associated with adherence and persistence. As antidepressants have similar efficacy, other factors affect choice such as patient comfort, prior treatments, cost to patient, comorbidities, drug-drug interactions. Tricyclics and side effects (only at severe levels) were associated with early discontinuation.

Antidepressant non-adherence demonstrated also strong associations with patients’ perceptions of their relationships with providers, including lack of shared decision-making or trust. Four components appear important to any doctor-patient relationship: education of patient and relevant family members, communication, collaboration, respect of the patient’s personal models. Frequent follow-up improves adherence as well as discussions about expected duration of treatment and adverse events. Some factors of adherence are related to health system: good cooperation between primary care and psychiatrists, reduced out-pocket money. Some factors are linked to the patient and his/her disease. Adherence is better in patients with high education, good social adjustment, previous antidepressant use, comorbidity with anxiety disorders, co-prescription, and in females. It is worse in case of narcissistic or histrionic personality or substance use disorders. Patients with more severe depression tend to have greater insight. However, the increased insight of depressive patients was not associated with treatment adherence. The most established factors are the attitudes and beliefs of patients and their family about health, depression and antidepressant. Beliefs about medication in general are most relevant for adherence at the start of treatment. In the acute phases, changes in beliefs about antidepressants occur: perceptions become more pro-adherence with treatment experience.

In the maintenance phase, the different degrees of adherence are explained by the balance between the perceptions of need and potential harm\textsuperscript{28,30}. Perceived necessity was associated with older age, severe symptoms, long anticipated duration of symptoms, and attribution of symptoms to chemical imbalance. Perceived harmfulness was highest among patients who had not taken antidepressants before, and had an unclear understanding of depression. Patients filter the actual costs and benefits of treatment through their individual attitudes and knowledge\textsuperscript{31}. Some interventions were conducted in order to improve adherence to antidepressant: shared decision making, educational interventions, behavioural interventions, cognitive and behavioural therapy. The most effective were multifaceted interventions that used all these strategies and increased the intensity and the frequency of visits.

Conclusions
The following general conclusions were agreed upon by the working group:

a) the pharmacological treatment should be kept as simple as possible;
b) the use of long-acting medications where and when available and indicated should be considered and proposed to the patient;
c) programs should be implemented to increase patient’s motivation and social functioning and provide education about her/his disorder and relevant treatments;
d) efforts to improve communication with patients and relatives, increase consultation time and use shared decision-making method should be in place, as they are cost-effective;
e) policies are needed to promote the collaboration of psychiatrists with pharmacists, general practitioners and specialists in other disciplines;
f) initiatives aimed to improve the knowledge about psychiatric disorders and available treatments in the general population, among physicians and other health care providers should be promoted;
g) new technologies (e.g. text messages, apps) aimed at improving adherence should be applied where and when appropriate.

Scientific Conclusions

Psychiatric Area

References

Scientific Conclusions

Psychiatric Area

Scientific Conclusions

Respiratory Area

Introduction
According to the European Respiratory Society (ERS) Lung White book, respiratory diseases are among the leading causes of death worldwide. In the EU, every year as much as 600,000 people die for respiratory diseases. In Italy, respiratory diseases are the third cause of death (second if lung cancer is included).

According to the World Health Organization (WHO), Chronic Obstructive Lung Disease (COPD) is the fourth cause of death in the European region and the fifth among the causes for Disability Adjusted Life Years (DALY).

In the EU, approximately one third of the population will develop asthma at some time between age 5 and 80. Both COPD and Asthma are increasing in prevalence and burden. This trend could be reversed by an effective primary prevention, through actions for smoking prevention/cessation and for decreasing environmental pollution. Smoking is the major risk factor for chronic respiratory diseases and its elimination should be the first preventive target. Avoidance of environmental risk factors would prevent 30-45% of these diseases.

For people already suffering from respiratory obstructive diseases (asthma and COPD), we have effective and safe treatments. Unfortunately, like for any other chronic disease, adherence in these diseases is at its best about 50% across most Countries, even lower within certain patient groups such as adolescents and those with low socioeconomic status (Tottenborg 2016).

Non-adherence is associated with excess exacerbations (i.e. worsening of symptoms), healthcare utilization (both accident and emergency visits as well as hospitalisations), mortality, indirect costs and lost work productivity (Van Boven Respir Med 2014, Vestbo Thorax 2009, Williams JACI 2011). Optimal adherence to treatment could reduce some costs of health care (GP consultations, A&E visits, Hospitalisations) while increasing others (GP consultations, drugs, laboratory exams). Even if the problem of adherence to treatment is widespread and well known in every disease, the problem can be even worse in respiratory medicine, if one considers that the treatment of bronchial obstruction consists of inhalation therapy.

Inhalation Therapy
A treatment via inhalation is very effective and has many advantages: a smaller dose is delivered than via systemic administration, the drug is quickly delivered to the target organ, the drug action starts very rapidly with fewer and less severe systemic side effects.

However, this kind of treatment has also some drawbacks: the proper use of inhalers is necessary for effective treatment and must be learnt. There are differences among different inhalers which are larger than differences among tablets. There can be wide variability in delivered drug doses.

Last but not least, any inhalation therapy is not perceived by patients as effective and necessary treatment when compared to pills or injection.

As a result, the adherence to treatment in obstructive lung diseases can be even lowest than in other chronic diseases, and it has been demonstrated that patient’s adherence is lower in real life than in RCTs respiratory studies.
Different behavioural types of non-adherence

Generally speaking, there can be different types of non-adherence. An erratic non-adherence is observed when the patient forgets to take the drug. This non-adherence can be reduced by using reminders, by linking the administration to daily habit, by using social help from family members or caregivers, by making e-regimens easier.

There can be an intentional (or “intelligent”) non-adherence, due to a conscious decision. It can be due to fears of side effects or interactions with other drugs which the patient is already treated with or to a perceived negative balance between the benefits and the risks of the treatment. This non-adherence can be reduced by shared decision making and motivational interviewing and is obviously easier to overcome if the patient is educated to his/her disease.

Patient education is also central in the so-called unwitting non-adherence, i.e the non-intentional one. It is usually due to lack of knowledge. This type of non-adherence is central in respiratory medicine since it includes the inhaler technique. Beside education, it can be reduced by carefully matching patient and inhaler and by producing a self management plan.

Below, there is a summary of different types of non-adherence, their interactions and possible solutions.

Multiple Causes of Non-Adherence: our targets

Adapted from Bourbeau. Thorax 2008
Inhalers and inhaler technique

Inhalers and inhaler technique are central in promoting adherence to respiratory disease treatment.

Over the past 40 years, inhalers have changed and improved very much and through this evolution they have become easier to use and more user friendly. However, patients’ inhaler technique has not improved in parallel. An “ideal” or “perfect” inhaler probably does not exist, but there surely is the “perfect” inhaler for that particular patient.

Indeed, there are many unsolved questions on inhalers. They are listed below.
- Matching patient and device
- Identifying “serious” errors in inhaler usage
- Better disease outcomes by easier to use devices
- Safety and effectiveness of switching inhalers
- Effectiveness of technical or m- and e-health tools in monitoring and educating patients
- Better real life adherence results, better clinical decision making and outcomes
- Taking into account patient preferences and satisfaction

Some of them are very critical in the respiratory patient management. Anyway, all require the full collaboration by patients and caregivers and should be studied in real life settings.

How to improve Inhaler technique

Currently there are many proposals to improve inhaler technique. First of all, the choice of the most appropriate device for each patient. For instance, an aged patient not fully assisted by caregivers will be helped by the prescription of a simplified regimen, not including in the same prescription different inhaler device types. A patient who is familiar with one inhaler should not be prescribed another device unless education is provided.

All these actions are time consuming and this must be taken into account when deciding the reimbursements. Time is necessary to train each patient in proper inhaler technique by observing his/her technique and letting patient observe him/herself. Obviously, placebo containing devices are very useful in this kind of patient’s education. Time is also required to recheck inhaler technique on each control. Video assisted demonstration available on-site or on the web can be very useful, as well.

To get these results, many requirements are to be fulfilled. The first one is a multidisciplinary approach leading patients to full adherence. Doctors, pharmacists & nurses with good inter-communication and task assignment should be trained and ready to deliver uniform information and education. An international promotion of uniform inhaler instructions based on validated checklists will be helpful for all involved health professionals. Pharma industry can implement innovative inhaler technologies.
Scientific Conclusions

Respiratory Area

Monitoring and improving adherence: what is going on in Italy

Senior Italia, an Italian association which includes over 3 million members, is trying to use e-health and m-health to assist aged people and to measure and foster adherence. The first initiative has started in November 2016 and consists of a network (named „Pronto Senior“-„Hallo Senior“) to assist aged people and caregivers in solving problems in everyday life (i.e. bureaucracy (fiscal and general assistance) or social (loneliness, abuses, need for assistance)). This network is also aimed at giving medical information and advice about health problems frequently encountered in aged population, like Osteoporosis, Atrial fibrillation, Diabetes, Cancers, Reumathoid Arthritis, Psoriasis, Hearing loss and COPD. Pronto Senior also include a telephone-administered interview through a standardised questionnaire which aims at investigating adherence to treatment.

The second action by Senior Italia is due to start in the first half of 2017. The idea is to measure the cost savings made possible by the use of Information and Communication Technology (ICT) in managing health issues in aged people by promoting prevention, diagnosis, treatment and monitoring of diseases and by educating to healthy lifestyles through ICT. Part of this project is to create an app able to collect data and deliver information and education through mobile technology. The final aim is to demonstrate how and how much the costs of health care can be reduced by increasing adherence through patients’ education and empowerment.

The aim is not only to Increase adherence but also to decrease defensive medicine and to shift assistance network; providing care in primary rather than secondary level, whenever possible. Eventually, there should be significant cost savings obtained with less hospitalisation (-5%) and less rehabilitation stay (-10%).

As regards respiratory medicine, six diseases will be monitored: Rhinitis and Rhino-Sinusitis, COPD, Asthma, Interstitial Lung Diseases, Bronchiectasis and Cystic Fibrosis, OSAS.
La definizione di incontinenza ha subito profonde modifiche nel corso degli anni. In questa sede si è scelto di adottare la definizione proposta dall’International Continence Society (ICS). In particolare, nel 2005 la definizione è stata fornita con riferimento ad una generale perdita involontaria di urina. Successivamente, nel 2014, è stata definita più specificamente come segue: «The complaint of involuntary loss of urine, with three primary subtypes of UI identified: urgency UI (UUI), stress UI (SUI), and mixed UI (MUI; both UUI and SUI)». In passato la definizione comprendeva anche il concetto di «problema igienico o sociale». Tale concetto è stato superato al fine di uniformare le diverse realtà sociali (non tutte le situazioni sono equiparabili per disagio igienico e sociale). Questa nuova definizione ha consentito anche di stimare, più precisamente rispetto al passato, la prevalenza e l’incidenza di tutte le tipologie di incontinenza. Tuttavia il 57,2% di chi soffre di incontinenza urinaria non ha mai parlato del problema con familiari e conoscenti; da qui una ulteriore difficoltà a fornire stimpi precise.

La perdita di urina sia nella donna sia nell’uomo può essere classificata a seconda della sintomatologia della perdita, in:

1. Incontinenza da urgenza: spesso associata all’impellente sensazione di dovere urinare, è generalmente provocata da contrazioni irrefrenabili ed incontrollabili della vescica.
2. Incontinenza da sforzo (stress): si manifesta quando aumenta la pressione dell’addome sulla vescica in occasione di uno sforzo fisico, ma anche quando semplicemente si ride, si tossisce o si starnutisce.
3. Incontinenza mista: quando sono presenti i sintomi caratteristici di entrambi i tipi.

L’entità dell’incontinenza è variabile ed è correlata sia alla frequenza sia all’entità delle singole perdite. Si identificano attualmente 4 livelli di incontinenza, sulla base della gravità del livello di perdite della persona:

1. **Lieve**: fino a 200 ml
2. **Medio**: da 200 ml a 350 ml
3. **Grave**: da 350 ml a 500 ml
4. **Gravissimo**: oltre 500 ml

Tali valori sono intesi come la quantità di perdite tra un cambio e l’altro, dunque applicabili ai pazienti che utilizzano gli ausili assorbenti.
Stima Epidemiologica
La stima epidemiologica del fenomeno è necessaria al fine di individuare correttamente il potenziale bacino di utenti che esprimono un bisogno legato all’incontinenza, per poi effettuare una valutazione sui tassi di copertura e sull’efficacia dei servizi in essere. Individuare stime complete e aggiornate sul tema incontinenza non è tuttavia impresa semplice dal momento che la maggior parte degli studi e delle pubblicazioni scientifiche fanno riferimento a dati consolidati, ma ormai risalenti a diverse decine di anni fa. Coerentemente con gli obiettivi del presente studio, si è cercato di contextualizzare al territorio italiano le stime esistenti in letteratura, aggiornando, laddove possibile, le proiezioni sulla popolazione e sulle sue stratificazioni possibili. La scarsa attitudine a parlare della patologia da parte delle persone che ne sono affette, rende ancora più difficile effettuare le stime in oggetto.
Le donne rappresentano la popolazione maggiormente afflitta dall’incontinenza urinaria: circa una donna su tre soffre di questa patologia in quanto l’anatomia degli organi pelvici femminili predispone a problemi dei meccanismi di tenuta. Le principali cause di incontinenza nella donna sono il parto naturale e l’invecchiamento.
Nell’uomo, invece, il problema è meno frequente, ma si calcola che una percentuale variabile dal 2 al 10% della popolazione maschile sia affetta da qualche forma di incontinenza. Le principali cause di incontinenza nell’uomo sono infiammazione, asportazione della prostata e invecchiamento.
Per la stima del numero complessivo e per fascia di età degli incontinenti (comprendendo sia uomini sia donne) si fa riferimento ai tassi di prevalenza frutto dell’indagine dell’istituto di ricerca SWG e Finco del 2005, utilizzando i dati della popolazione residente in Italia al 1 Gennaio 2016 per definire una stima complessiva del fenomeno. I risultati sono sintetizzati nella tabella seguente.

**TABella 1. Tasso di prevalenza e stima epidemiologica per fasce d’età (dati 2016)**

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<th>Età</th>
<th>Numero</th>
<th>Prevalenza</th>
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<tr>
<td>18-34</td>
<td>461.584</td>
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<td>1.446.929</td>
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<td>55-70</td>
<td>1.175.657</td>
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<td>70+</td>
<td>1.395.444</td>
<td>15,3%</td>
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<tr>
<td>Totale</td>
<td>4.479.614</td>
<td>7,8%</td>
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</table>

Il numero complessivo di persone maggiorenni affette da incontinenza in Italia si stima sia di 4.479.614. Nella fascia di età compresa tra 18 e 70 anni vi è una netta prevalenza delle donne (12,3%) rispetto agli uomini (1,8%).
L’insorgenza dell'incontinenza urinaria cresce all'aumentare dell’età: per i soggetti non ospedalizzati di età superiore ai sessant'anni, infatti, la prevalenza dell’incontinenza urinaria varia dal 15% al 35%. Nelle case di riposo, nelle residenze assistite e nelle corsie geriatriche fino al 70% dei degenzi risulta incontinenti, senza contare le persone anziane che vivono al proprio domicilio e ne sono frequentemente colpite. Da questo punto di vista, considerando il progressivo invecchiamento della popolazione, si sottolinea come il problema legato all’incontinenza urinaria sia inevitabilmente destinato ad accrescere le proprie dimensioni: infatti, dalle più recenti proiezioni ISTAT (2016 - Figura 1) emerge come, a fronte di una popolazione complessiva in lieve crescita (+3,1% al 2050), la fascia di popolazione over 65, che ad oggi rappresenta poco più del 20% della numerosità totale, possa superare la soglia del 30% entro il 2040 e spingersi intorno al 33% nel 2050.

**FIGURA 1.**
Andamento della popolazione in termini assoluti e distribuzione percentuale per fasce d’età (2011-2050)
La Qualità della vita

I fattori contestuali, ambientali ed individuali hanno un notevole impatto sulla persona, in particolare quando l’incontinenza urinaria interessa soggetti che richiedono un alto grado di protezione socio-sanitaria, quali pazienti con disabilità neurologiche o soggetti anziani fragili. L’incontinenza urinaria è una condizione altamente invalidante, che induce notevole ansia e frustrazione nel paziente e che, oltre a comportare un cospicuo onere assistenziale per le famiglie e per il personale di assistenza nelle strutture di ricovero, implica un costo economico per la collettività. Questa patologia, inoltre, ha un impatto molto negativo sulla vita quotidiana della persona che ne è affetta: la paura di bagnarsi, il disagio legato all’odore e alla sensazione di scarsa igiene provocano ripercussioni negative sullo stato di salute complessivo, nelle relazioni sociali e nella qualità della vita. È stato dimostrato, infatti, che i pazienti incontinenti sono più depressi, soffrono d’ansia e sono più insoddisfatti dei soggetti non colpiti da questa condizione. Per questo motivo, poter usufruire di ausili per l’incontinenza di qualità che allevino le difficoltà ed i disagi connessi a tale condizione, deve essere un obiettivo di primaria importanza per coloro che devono tutelare la salute dei cittadini.

L’incontinenza rappresenta infatti un problema socio-sanitario rilevante per il quale è importante trovare risposte soddisfacenti sia in termini di efficacia, sia di rapporto costo/beneficio, soprattutto in relazione all’invecchiamento della popolazione.

In relazione alle evidenze fin qui esposte è importante distinguere le persone affette da incontinenza non solo sulla base dell’età e del sesso, ma anche della condizione motoria e del livello di incontinenza, poiché a ciascuna di queste situazioni corrispondono esigenze e tipologie di risposte che possono variare notevolmente. Ben il 70% dei pazienti incontinenti ha bisogno di assistenza (allettati e deambulanti con fatica) ed il 37% è affetto da un’incontinenza di livello lieve verso un 59% che presenta un livello medio, grave o gravissimo. L’incontinenza urinaria ha un impatto negativo significativo su molteplici aspetti della vita di chi ne è afflitto.

La presa in carico del Paziente ed i Trattamenti disponibili

Nonostante siano disponibili linee guida internazionali per la diagnosi e cura dell’incontinenza, attualmente il problema risulta scarsamente affrontato e trattato. Infatti, a causa (i) della mancata definizione di percorsi diagnostico-terapeutici assistenziali (PDTA) dedicati all’incontinenza, (ii) della diffusa asimmetria informativa e (iii) della condizione di fragilità, fisica e psicologica, in cui versa la popolazione di riferimento, si registra una risposta poco efficace tramite il sistema sanitario ai bisogni espressi dai pazienti incontinenti.

La Figura 3 delinea, in modalità semplificata, il PDTA secondo quanto si evince dalle Linee Guida Internazionali e dagli estratti di articoli scientifici italiani.
Ciascuna tipologia di incontinenza è trattabile con una o più modalità specifiche. In casi selezionati sono possibili trattamenti multidisciplinari.

Tra i principali trattamenti si annoverano:

- **Terapia ambulatoriale**: consiste in iniezioni parauretrali, che utilizzano un agente volumizzante. In regime ambulatoriale e attraverso l'uso di speciali siringhe, in anestesia locale, si applica, un gel nei tessuti adiacenti all'uretra in modo da assicurare un sufficiente supporto, al fine di ristabilire il meccanismo di chiusura dell’uretra stessa.

- **Terapia farmacologica**: somministrazione di ormoni, antispasmodici e parasimpaticolitici. Tratta efficacemente l'incontinenza nei casi in cui l'indebolimento del tono sfintereo sia dovuto principalmente alla carenza ormonale causata dalla menopausa.

- **Rieducazione pelvica**: esecuzione di esercizi fisici specifici o con l'utilizzo di apparecchiature elettriche per la stimolazione passiva, al fine di rinforzare la muscolatura pelvica.

- **Terapia chirurgica**: la chirurgia tradizionale tratta il problema per via addominale, ricostruendo le strutture di sostegno della vescica. Altre tecniche mini-invasive limitano l’apporto traumatico dell’intervento agendo con l’ausilio di strumenti tecnologicamente avanzati come le sonde ed introducendo materiali di sostegno biocompatibili (es. bande o reti di sostegno), con un più rapido recupero completo post-intervento. La tecnica TVT (Tension-free Vaginal Tape Procedure), in tutte le sue varianti, consiste nel posizionamento di una “bendarella” di un materiale sintetico che faccia da sostegno all’uretra.
Scientific Conclusions

Urologic Area

- **Ausili per cura e protezione della persona**: consistono in cateteri e prodotti assorbenti, con funzione di raccolta dell’urina. Vi si ricorre quando l’incontinenza non è trattabile, quindi nella maggior parte dei casi. In virtù di tale loro rilevanza, il presente documento si occupa di approfondire la tematica della presa in carico degli assistiti tramite questa modalità di risposta ai bisogni.
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## Members of the Technical Commissions

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Via Flaminia, 1068 - 00189 Roma
Tel. +39 0633053.1 - Fax +39 0633053249
siha2016@aimgroup.eu
www.aimgroupinternational.com

Senior International Health Association

Avenue de Tervuren 67 - 1040 Bruxelles
Tel. +32 27437010 / +39 0412794810 - Fax +32 27437019
info@sihassociation.org
www.seniorinternationalhealthassociation.org