Pacini Editore & AU CNS

Position Paper

*Heroin Addict Relat Clin Probl 2013; 15(2): xx-xx*

HEROIN ADDICTION & RELATED CLINICAL PROBLEMS
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# The Italian Manifesto for the treatment of heroin addiction. The mixed care model

## A proposed layout for a new healthcare system for citizens with heroin addiction

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What is the point of writing a Manifesto about addictive diseases? The appearance and profiles of patients and their addictive diseases have inescapably gone through changes as the years have passed. Going back to the 1960s, sexual revolution was the ultimate frontier, whereas nowadays social media are the main challenge. What was once restricted or prohibited has become acceptable and available, to an extent which former promoters of change themselves consider excessive. Everything seems to have evolved and changed its array, everything but heroin addiction.

What has not changed, though, is the unrelenting stigma that afflicts men and women who fall ill of addiction, and extends out to their families and children, their environments and hopes.

"You are nothing but a junkie" – that is, more or less, what a lot of patients repeatedly get to hear as an immediate judgment given by their employers, friends and significant ones. This may be taken as a dramatic example of how this category of ill people is denied the right to be normal. On the other hand, it may also sound like a denial of the social duty to have these people cured, just like any other category of patients.

Although we are the ones who have been committed throughout our lives to explaining such medical platitudes, on a topic very similar to the normality of illness or the equal status of various diseases, we cannot disregard the persistence of a stigma as deep as this one.

This explains why a Manifesto about Addiction,

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written with the aim of improving society's ability to deal with addictive diseases, has been prepared as the most balanced way of portraying the thoughts we share as a group of scientists. This constructive document, which was originally proposed during the Addiction Medicine Expert Forum that was held in March 2013 in Pietrasanta, Lucca, Italy was thus intended as a structured, unified way of expressing, precisely and concurrently, a request for a change in the status quo of opiate addiction healthcare standards and trends.

As any Manifesto is supposed to do, this document aims to formulate and illustrate rules and principles put forward from the perspective of challenging the criticisms that have been made by experts, patients, their families and – why not? – those who are neither directly or indirectly involved in addiction-related issues.

None of us hope our children will have to live in world where ignorance and prejudice can easily prevail over skill and knowledge. Had we that in mind, we would probably have resigned from any commitment to the understanding and treatment of addiction, rather than dedicating most of our professional lives to it, and would have chosen any other field of interest and occupation.

In line with this feeling, our keenest wish is that this "Italian Manifesto for the Treatment of Addiction: a mixed model" may become a milestone upon which a new integrated model of intervention can be developed.

## 1. Addicted patients today: changes in drug use trends and drug-related environments in the last 30 years.

*By Isabella CECCHINI*

GfK-Eurisko is to date the most important Italian agency for market surveys, and it has the capacity to adequately cover the various aspects of social life and market dynamics as far as purposes, fields and sectors, methods and procedures are concerned, across a large number of nations worldwide. It has also developed sound expertise in the field of addiction research over the last decades. This research sector has included dozens of qualitative and quantitative investigations, and thousands of interviews held with both physicians and patients, so attaining the objective of a thorough analysis of the whole statistical universe of addiction-related topics. Out of this substantial body of data, one statistically significant finding has always emerged: the fact that the profiles of addicted patients and their drug-related lifestyle have gone through radical changes more than once over the years.

A recent study on a sample of 100 physicians working in addiction treatment units within Italy, and 378 addicted patients receiving agonist treatment in those same treatment units, sheds some light on the current approach to addiction and the role of available treatment in Italy.

It appears that the stereotypical addict no longer has to face a condition of isolation, social marginality or degradation of general living conditions. Patients with addiction can now count on agonist treatment, they often have a job, lead a normal social life and are able to maintain social ties. The Gfk-Eurisko survey described above, which was carried out during the Spring of 2011, portrays average addicted patients as work-competent, despite their history of drug addiction (around 50% of interviewed patients were currently employed), with at least a secondary level of school education (almost 50% had a high school diploma), and a stable social and family environment (one out of three was married or was living with their partner, one out of four had children, almost 80% were mainly living with relatives, a partner or friends). Younger patients are more frequently female than older ones (34% vs. 18%), had a higher educational level (54% had a high school diploma vs. 34% among older ones), but were less often employed.

Heroin consumption is typically the latest step in a substance use career that starts quite early: tobacco smoking and drinking during adolescence come first, running parallel to a variety of risk behaviours, to be followed by experimentation with amphetamines, LSD, ecstasy and cocaine (on average, before the age of 18). Younger patients have a more complex history, marked by a higher number of abused substances and heavier drinking. As a rule, patients are informed, motivated to enter treatment, show that they appreciate and feel grateful for what is offered by the healthcare system, and declare their full satisfaction with the treatment provided by addiction treatment units. They have usually have heard about different treatment options, and younger ones are more likely to have heard about newer medical drugs. Two patients out of three receive methadone, one out of four buprenorphine-naloxone, and 13% buprenorphine. Patients declare they are satisfied with their on-going treatment, and regard it as the way they have successfully used to break away from their previous drug-related lifestyle and environment, and so manage to get back to a normal lifestyle.

From this viewpoint, it is positively striking that as many as 71% are allowed take-home supplies (although each dosage is only enough to cover a few days, usually a week). In this way they reach a higher level of autonomy in the management of their therapeutic regimen, so that they are no longer obliged to attend treatment units on a daily basis to be able to receive supervised drug administration. On one hand, the chance of take-home supplies favours patients' social life and ability to do their job competently; on the other, it strengthens the therapeutic alliance with the physician, who shows he/she can rely on the patient to deliver the 'prize' of satisfactory compliance with treatment rules and objectively positive results, while entrusting the patient with the task of taking on increasing responsibility for their own treatment instrument.

Thanks to agonist treatment and psychological support, patients are able to attain a good level of mental and somatic health (61% subjectively evaluate their health status as good) and feel that their condition is stable (as many as 80%). In this context, local addiction treatment units play a crucial role: addiction physicians have a long-term career in the field of addiction (24 years, on average), are highly skilled in agonist treatment (with 19 years of experience, on average), are in charge of a high number of patients (each has 124 patients taking an agonist treatment, on average). Patients have a good opinion of the physicians who are in charge of their case and of the therapeutic efforts being made on their behalf by the staff: almost all patients report that they are definitely satisfied with their therapeutic experience.

Another outstanding datum is the demand by physicians for measures designed to promote and favour access to agonist treatment: the availability of safer drug formulations (a lower liability to abuse and to the risk of diversion would favour take-home practices), the implementation of dedicated facilities and resources, the development of an active network of addiction specialists, and, not least, the simplification of legal restrictions on treatment delivery.

## 2. The changing role of families in the treatment of heroin-addicted patients. The story of Elizabeth and Gail.

*By Elizabeth BURTON-PHILLIPS and Gail PITTS*

The family history of Elizabeth Burton-Phillips and Gail Pitts, founders of Drug-Fam exemplifies what cognitive changes took place in the families of drug addicts during the last 20 years. These two mothers each lost a child due to drug addiction. Elizabeth's son (Nicholas) committed suicide in 2004, and Gail's son died in his sleep after binging on abuse drugs, in 2007. Through their own painful experience, these two mothers learned that heroin and cocaine addiction is a chronic, complex and lethal disease. Elizabeth also concluded that patient recovery is only possible when medical intervention is performed by applying certain technical rules, and significant family members are involved in the therapeutic process. Since their sons' death, these two mothers have been travelling around the UK and other European countries to tell their stories, and highlight the importance that an active role played by families can have against addiction – a role born out of the victimization of families that is caused by addiction itself. As a general rule in the UK, but to a lesser extent in other countries too, the needs of families with drug-addicted members have been neglected or underrated. This customary neglect is in contrast with the potentially leading role of families in the management of addiction, namely as far as recovery is concerned. A UK-DPC (UK Drug Policy Commission) study indicated that some 1,500,000 people have either a son or daughter, or a significant other, suffering from drug abuse-related problems; other studies, though, estimate that number at a level as high as 8 million. It can, however, be stated that a great number of families is involved, daily, in taking care of drug-addicted relatives, and struggling to improve their quality of life. Evidence from research does clearly indicate that addiction treatment is more likely to be successful when parents, relatives and partners are engaged in the therapeutic and rehabilitative process together with therapists. The experience of Elizabeth, who lost one child but succeeded in saving the other, has helped us to understand that the support of families and friends is a crucial factor in winning the struggle against alcohol and drugs, and that a happy family life must be considered as one of the basic objectives of social life. Elizabeth and Gail learned that an addicted person must be determined, resilient and keep on struggling to reach one clear-cut goal: to break free of past addictive behaviours. Nevertheless, rehabilitation, to be understood in the broad sense of recovery, is a long path forward, on which patients proceed and have to face upcoming obstacles, may need to stop for a while, as well as go through slips and actual relapses. Although this process is part of one's personal history, the patient must be supported by, and form alliances with, other

social forces in order to stride forward and avoid surrendering. Families, friends, social operators, support groups and health professionals must make their contribution to improving treatment outcome. Elizabeth and Gail have learned that when parents support their children on their way towards change, treatment initiation is favoured, as well as the stability of their new lifestyle. Guidelines highlight that families and significant ones are a major resource to include within treatment programmes; of course, this can only be done while fully respecting the patient's wishes. In many a programme run by humanitarian organizations it has been noted that over half of all drug abusers indicate their mothers as the main source of help in achieving the move towards rehabilitation.

In the UK, an individual's social wealth is made up of the ensemble of resources one can count on through the management of one's social ties (for instance, families, partners, children, friends or peers). Moreover, families can rely on the main intrinsic resources for the recovery of patients: a home, money, values and ideals. The help produced by such resources is vital in ensuring a wider range of possible choices to be made for rehabilitation, to improve information about possible solutions and to provide oneself with independent resources in one's way out of drug-related impairment.

The attitude of families is going through changes, too. Satisfactory recovery depends on the network of support that patients can count on, and family members are usually the spinal column of this network, whereas social facilities and social operators play a central role in planning the steps towards recovery. However, the pathway to recovery is likely to be a long one for anyone who enters treatment; it is often hard to move forward, progress is made difficult by obstacles and challenges, and discomfort arises from the feeling that an addict will always bear the stigma of addiction in the views of others.

This is a heavy burden to share, and it poses a critical challenge for most families. Needless to say, we cannot expect that families will be likely to find their normality restored as soon as their addicted members ask for help. Elizabeth's and Gail's experiences warn us about the need to keep families informed, where "families" should be taken to include non-addicted members. Elizabeth, founder of DrugFam, a family-support organization, clearly stated that "Prevention in schools by spreading information about drugs is surely important, but the acknowledgement of families is the same as crucial. Parents must understand the powerfulness of this disease and what damage drugs of abuse can do". The time has come to take the issue of addiction even more seriously than we may have done so far, while accounting for the role of the family, independently of feelings of shame and while being careful to keep at a distance from any stigmatizing view [1].

## 3. Changes in the pharmacotherapy of heroin addiction. Buprenorphine and methadone: two different options for maintenance treatment of heroin addiction.

*By Gaetano DI CHIARA*

After nearly 50 years of experience, it has been soundly established that methadone maintenance treatment is effective in limiting the negative impact of heroin addiction by curtailing rates of mortality, drug consumption, criminal acts, and the spread and severity of blood-borne infectious diseases, along with the global improvement of somatic and mental health, and psychosocial adjustment.

In the last twenty years, though, buprenorphine treatment has been available too as an alternative to methadone treatment. Randomized controlled and observational studies have shown that, for those who are retained in treatment, buprenorphine is as effective as methadone in controlling heroin use. Nevertheless, buprenorphine treatment as an option is hampered by a higher rate of treatment dropout [21]. This dropout rate varies between single studies and according to the methodology used, but in observational studies it has been reported at as much as twice the value it has in methadone studies [29].

The higher frequency of dropout among buprenorphine starters is not caused by lower dosages, since it is constant above 8 mg, nor is it due to slower induction procedures, since it occurs in a later phase in the course of treatment [29]; it is, rather, related to buprenorphine's mechanism of action and the way it interacts differently with patients' baseline features. Buprenorphine is a high affinity (<1nmol) partial agonist of opiate receptors, so that it occupies most brain opiate receptors (80-92%) even at an oral dose as low as 16 mg [9]. Its profile differs sharply from that of methadone, which only occupies 22-35% of available receptors at an equipotent dosage (30-90 mg) [13].

At dosages that are equally effective in preventing heroin use, a key difference is that methadone acts only as an agonist, whereas buprenorphine also acts as an antagonist (and to a greater degree, on phar-

macological grounds). This difference between the two is consistent with their different retention rates during the maintenance phase of the two respective treatments. In this connection, retention in buprenorphine treatment programmes also depends on the impact of treatment on the special features of each case. Indeed, there cannot be said to be a standard predictable retention rate, given the high level of variability between studies, just as there are no well-defined discriminant criteria for patient-treatment matching between methadone and buprenorphine. As a result, the most pragmatic approach is to replace buprenorphine with methadone when it fails to buffer withdrawal from heroin adequately [12].

Despite its shortcomings, buprenorphine displays some practical advantages due to its partly agonist profile, which implies the self-limiting potency of its depressant effects and a consequently lower risk of death from breath failure in case of overdose, a milder impact on cognitive, sensorial and motor functions, and a beneficially higher level of manageability than methadone. For these reasons and also due to the lower degree of physical dependence induced by buprenorphine, patients and non-patients have both tended, from the earliest stages of its introduction, to identify it as a medicine rather than as a substitute for heroin, as happens, by contrast, for methadone.

The sum of these features qualifies buprenorphine as a feasible option for the general practitioner, when it is combined with naloxone, so as to reduce its misuse [5, 14, 32]. It should, of course, be prescribed under the supervision of specialized centres and compatibly with the therapeutic programme they may design.

## 4. Harm reduction within an integrated treatment perspective

*By Gilberto GERRA*

Harm reduction interventions should not, on ideological grounds, be considered as opposed to the perspective of addiction treatment and recovery. Harm reduction and treatment can be complementary rather than conflicting strategies.

Harm reduction is a mode of intervention that works at a low-threshold level, which is therapeutic in itself [26]. This kind of intervention aims to reach out to all addicts, especially the most impaired ones and those with the lowest level of motivation, in order to give them a chance to improve their health status and lower their addiction-related risks (infections, overdose, social adjustment, involvement with organized crime). In other words, harm reduction is focused on the health, social and individual needs of the addicted person, rather than on instruments that aim to interrupt limit addictive behaviours.

This mode of intervention, which often appeals to those who have never been in touch with the healthcare or social care system, or those who are going through relapses after spending some time in treatment, and can be assessed as severely ill, does attempt to communicate with patients before they are in a position to ask for support independently, whether on the street, at home, in jail, or in meeting places.

The objective is to preserve people's health and protect their social status without imposing any conditions on them, that is, not in exchange for attending a structured programme. Harm reduction provides patients with facilities that are likely to increase their chances of survival and preserve their dignity at any stage of the disease, regardless of their level of motivation to detoxify.

Taking care of people with a severe degree of impairment allows basic forms of alliance to be set up between operators and patients, which then favour the discovery of new reasons for motivation and access to treatment facilities.

Along with basic healthcare measures featured by harm reduction, integrated treatments are focused on the crucial aspects of the disease, and aim at detoxification, by overpowering the compulsive circuit induced by the use of psychotropic substances, so reducing the intensity of craving and preventing relapses [6, 25, 28]. For responders to treatment, the interruption of maladaptive behaviours and the reinstatement of social adjustment are achieved by the stable control of craving and drug-seeking behaviours. On this view, it is reasonable to expect a positive impact of integrated treatment on patients' physical and mental health status too, together with the reduction of infective and overdose risks, which means achieving further elements of harm reduction.

Harm reduction methods do not aim simply to bring substance-use related symptoms under control, nor do they have the purpose of influencing the positive reinforcements of abuse drugs; as a result they have no direct impact on the natural course of addiction [19, 34].

In other words, harm reduction appears to be a patient-centred method, whereas integrated treatment functions as a disease-centred one that allows the two practical dimensions to become intermingled in a complementary way. The outreach effort associated with harm reduction practice often paves the

way for patients to apply for detoxification; treatment programmes, in their turn, make patients more aware and more concerned about their own health.

Rehabilitation is surely a necessary component of the effective treatment of heroin addiction, but the general principle is to resort to one of various strategies, to be selected according to the current stage of the disease. One consequence is that a variety of different pharmacological interventions may be required for the same patient during induction, stabilization-maintenance, and/or withdrawal from treatment at the end of the therapeutic programme. Certainly, many patients should be contacted on the streets or at their homes, where counselling and harm reduction are at their most effective. All kinds of intervention, though necessarily differentiated from one another, should share a common objective: the protection of patients as individuals, starting with their dignity and quality of life, and the potential of their social ties.

It is true that interventions are indispensable in winning control over drug-seeking and drug-using behaviours, with the aim of extinguishing whatever conditioning has been brought on by drug use, but health-preserving measures are still important, since they favour a normal life expectancy, nutritional support, hygienic standards, shelter, and opportunities for social integration.

In this way, therapeutic actions appear to comprise a pyramid of interventions, whether integrated or sequential, which in any case are topped by quality of life and the stable extinction of addiction behaviour [15].

Harm reduction and integrated treatment have, regrettably, been considered as two distinct modes of intervention, on the cultural and political levels. In many countries they have been forced to compete against each other for funding and, as a result, have been treated as mutually exclusive.

In countries which chose a complementary strategy, rather than a strategy of competition, a consolidated and extremely effective clinical practice has been established:

For those patients who are most severely ill, for whom individual and social risks are the only achievable goals, harm reduction is resorted to, even if this means using pharmacological solutions; in this case methadone dosages are kept low enough to avoid blocking the perception of heroin-mediated reinforcement, and can be negotiated by the patient

For those who respond to high-threshold interventions, and achieve a stable remission of their disease, displaying a profile of lower illness severity, a sequence of treatment interventions is employed; these aim to achieve a drug-free condition, and rely on high-dose methadone or high-dose buprenorphine combined with naltrexone. It may therefore be stated that harm reduction and substitution therapies are founded on resources and methodologies that are different in nature but should be integrated, with each treatment taking account of the characteristics of the individual patient and of the phase reached in the course of the addictive disorder.

It should be remembered that a patient in treatment, even when not responding to the treatment itself, and continuing to use drugs is still protected from HIV infection to a greater extent than an untreated addict, who is not in touch with healthcare or social services.

Moreover, one should not forget that anti-retroviral treatment, crucial as it is in acting against HIV epidemics, is most effective on patients who are undergoing treatment and have been stabilized.

Certainly, harm reduction procedures are useful; in fact, when high-threshold services are the only ones available, more severely ill patients are destined not to heal, and they get left behind, without having the chance to survive or even have their sufferings soothed, which does not meet general medical standards or allow for basic human rights. On the other hand, when harm reduction methods are predominant or are used in isolation, there is no opportunity to treat heroin addiction. The conclusion is that heroin addicts may be protected against most of the social and health consequences of their disease by successful harm reduction practices, but they will still remain affected by a behavioural disorder that is so severe that it is bound to produce major damage in individual, relational and professional well-being.

It is therefore reasonable to conceive of harm reduction as one level of therapeutic strategy, instead of something isolated, standing in opposition to treatment. In the documents of the International Narcotic Control Board (INCB), the organization that is responsible for supervising drug control measures, harm reduction is clearly approved of, as long as it is not practised as an isolated method, or as standing in opposition to demand-reduction interventions, but is fully integrated with therapeutic, rehabilitative and reintegration objectives.

## 5. Change or evolution? Are drug addicts really different from mentally ill patients, and is it possible to conceive of

**the treatment of addicts within mental health departments?**

*By Icro MAREMMANI and Fabrizio STARACE*

Until now, non-scientific approaches to the problem of addiction have been prevalent, influencing both clinical judgments and treatment solutions. Gradually through the years, addiction has been recognized simply as a chronic relapsing brain disease, and its treatment has become handled more and more according to common medical principles.

The guidelines developed by the European Opiate Addiction Treatment Association clarify that [8]:

- Opiate addiction must be regarded as a disease with a chronic, relapsing course;
- Detoxification from opiates is neither the essential nor the primary mode of treatment, since it exposes the patient to a heightened risk of overdose, besides failing to provide the patient with any form of relapse prevention;
- There is no scientific evidence to indicate that addiction treatment needs exceptional medical principles or non-medical ones;
- Addicted patients should be treated as normal patients, in order to avoid useless and counterproductive stigmatization;
- Long-term treatment should be started immediately after the patient has asked to enter treatment, and should be based on methadone, buprenorphine, or a buprenorphine-naloxone regimen at adequate drug dosages;
- Drug dosages should be tailored to each patient's case, and dose-splitting may sometimes be required in order to achieve a better response and stabilization;
- For patients who cannot tolerate traditional treatments, other opiate agonists may be employed;
- Treatment programmes must meet the patient's needs, whether medical or non-medical, and the place of treatment should be close to the patient's life environment;
- Polydrug use is not an exclusion criterion for enrolment into agonist treatment programmes.

The separation of addiction treatment centres from the rest of healthcare structures is no longer acceptable, as long as integration with other medical facilities looms as an impending need. The attitude of neglect shown by general psychiatrists towards commitment to addiction treatment and research is no longer endurable. There are sound, simple reasons for regarding the science of addictive diseases as a branch of neuropsychiatry. Moreover, apart from the involvement of psychiatrists in traditional roles (case management, pharmacological treatment, psychosocial interventions, psychotherapies and residential treatment), a priority of increasing urgency is the need to handle cases of dual diagnosis (including interactions between the drugs used to treat the two diseases). Lastly, research data seem to indicate the existence of a psychopathological syndrome running parallel to the presence, staging and current severity of core addictive symptoms [16, 17, 20].

Psychiatrists are certainly used to acting as good case managers: besides treating patients, they also take care of them, listen to them and give hints in the form of counselling or psychoeducational sessions, since the patient's cognitive array is not functional to treatment. Psychiatrists also plan rehabilitative interventions, considering that psychiatry was itself born with rehabilitative aims, in the pre-pharmacological era. In any case, psychiatrists end up being called upon to participate in the management of addiction, because of the high prevalence of dual diagnosis. No one but a psychiatrist is competent to deal with mood disorders, anxiety disorders, psychoses, personality disorders, and aggressive or suicidal behaviours that may become manifest during the course of addiction in over half of these cases.

If research should confirm the existence of a specific psychopathological syndrome running parallel to addiction, that newly acquired knowledge would necessarily become part of the skill of anyone who managed cases of addiction as a psychiatrist. These being the premises, what differences are left to be accounted for between the technical skills of an addictionologist and those of a psychiatrist? Addiction medicine could simply be regarded as a branch of psychiatry, similar to adolescent psychiatry, geriatric psychiatry, psychiatry of affective disorders, psychiatry of chronic psychoses, or whatever.

In a future perspective, addiction science should intermingle with general psychiatry not only as far as university studies are concerned, but for everyone who is active in the field of addictive diseases, at any level. Patients should then find their ideal place of treatment there, once integration between mental health structures and neuroscience departments comes to incorporate addiction-related services.

## 6. Change or evolution? The point of view of a physician working in local Addiction Treatment units

*By Lorenzo SOMAINI*

In the latest years we have witnessed a continuous evolution of addictive phenomena. Healthcare institutions have been asking themselves about the best strategies to: facilitate access to treatment for new patients, who are becoming younger and younger; to improve conditions and perspectives for those who are already in treatment; and to refer patients who have been abstinent and stable for a long time to general practitioners. Nowadays, the objectives of heroin addiction treatment are not merely to be understood as the reduction and extinction of substance use and the prevention of drug-related mortality, but primarily as the achievement of optimal adjustment, in terms of both somatic and psychic health. Obviously, objectives should be tailored according to the distinctive characteristics of each patient and planned according to the current grade of disease severity. As a result, the therapeutic programme should be designed to achieve the best results attainable on the basis of each patient's features and needs. In this connection, we shall account for some variables which are expected to influence both the prognosis of addiction and the outcome of treatments. The best known are:

- years of active addiction;
- concurrent psychiatric disorders;
- polydrug use.

As far as the duration of addiction is concerned, neurobiological evidence indicates that the changes induced by heroin in intracellular transduction systems become more and more stable through relapsing and ongoing substance use. As a result, patients who start treatment as early as possible after the development of addiction have the best prognosis. Criteria for enrolment into methadone and buprenorphine programmes have changed over the years in response to that knowledge: very restrictive criteria dating back to the 1960s have gradually been modified until now the only safety criterion left is that of avoiding iatrogenic addiction. Patient profiles have also changed, from the stereotype of selective heroin injectors, who were started on a single-drug treatment regimen, to a the current prevalent profile of polydrug users, who are under multidrug treatment regimens, possibly due to concurrent psychiatric disorders and/or infective diseases. This evolution has brought an increasing need for different specialists to collaborate, but also for general practitioners to be in charge of the surveillance of the patient's global health status.

On the basis of all these considerations, we should reasonably revise the concept of therapeutic objectives, so as to fill the gap between the objective outcome results we expect from agonist treatments (extinction of drug use, extinction of craving, mortality reduction, and so on) and the subjective rating of the patient (which should account for improvement in life quality, coping with treatment-related stigmas, opportunity to lead a normal life, and so forth). This gap corresponds to the room for personalized objectives, to be achieved according to the patient's individual features, and as a function of the level of treatment implementation. A two-phase intervention system may be hypothesized, to be enacted in a way similar to what is available for other illnesses: the first phase corresponds to the level of specialized addiction treatment units (which is exactly what an Italian Ser.T is) mainly engaged in the achievement of symptomatic disease control and monitoring, together with behavioural stabilisation; and a second level, corresponding to general practice, to which patients may be referred in a second phase, once stabilization has been attained, in order to simplify the management of stable, long-term treatment prescription and delivery. Obviously, synergy between the two levels is needed, as well as a dedicated study pathway to develop and update addiction treatment skills at both levels.

An integrated model, which has been called "Shared Care Model" or "Hub-Spike Model" in some countries, could ensure benefits both to the patient and to the healthcare system it is developed within. Supposedly it is likely to favour treatment access for new patients and avoid the stigmatization of the treatment process in all its elements, by creating a web of intermingled facilities at the heart of the healthcare system. It might also promote the return of stabilized patients to the levels of basic care, so increasing available resources for patients who need intensive care and/or specialized skills, or display more complex clinical pictures.

## 7. Change or evolution? The point of view of General Practice

*By Alessandro ROSSI*

As long as General Practitioners have to hold their practice according to the blinkered prerogatives indicated by the Healthcare System (Ministry, Regional Authorities, Local Healthcare Units), GPs are simply excluded from playing any role in the management of addicted patients. In fact, the priorities of

the healthcare system are basically:

- Chronicity (Chronic Care Model)
- Continuity of care (H24, AFT, UCCP, etc.)
- Limitation of costs

On the other hand, addiction scenarios involve new types of drug users that reflect new patterns of consumption. The epidemiological standards of addiction are those that have been subject to the greatest changes, both in terms of the social features of patients (comprising a phenomenon of social levelling) and the type of addiction (e.g. polydrug use, gambling). New drug users are more and more often employed and socially integrated, and may not tolerate wearing the badge of addiction that arises from attending specialized centres. Moreover, addicts who do not inject (such as smokers and inhalers) and those who suffer from non-chemical addictions would hardly regard themselves as addicts, sometimes not even as patients.

From this standpoint, the challenge to be faced by General Practitioners is that of winning a role in intercepting those patients as a category of subjects affected by a chronic disease (consistently with the prerogatives of chronicity indicated by the healthcare system) which definitely represent a major public health issue.

The Italian Association of General Practitioners (SIMG), based on its experience lasting two decades in the field of formation, publishing and carrying out research on the issue, has put forward some proposals. The first is to build up a nationwide network of GPs, on a voluntary basis, which would have the advantage of building bridges between single participants, and providing them with professional and logistic support, so allowing them to share the management of selected cases with specialized centres. Patients who have already been stabilized, and show a clear motivation to recover, may be then be assigned to a new professional figure, the "GP with a special interest in the field of addictive diseases", following the British model (GPwSI), or following the Italian model that is already operative for the management of chronic pain, as indicated in "Law 38". Such GPs would:

- Limit the costs of and curtail the need for specialist consultations, by allowing GPs to become consultants within their own general practice, and, whenever possible, extending their knowledge to their collaborators.
- Organize workshops to acknowledge and train colleagues in order to spread the skills of addiction treatment among GPs, by integrating the views held at the level of general practice with addiction medicine as a specialty.
- Optimizes the provision of treatment, by favouring access to health facilities, reducing delays and allowing treatment administration at home.
- Improve the standards of patient care by integrating the addiction-focused care provided by specialists within a holistic approach, the patient being considered as a whole, while utilizing the typical know-how of General Practice.

We should then develop the figure of the GP who has a particular interest in addictive disease (GPwSI) within the Italian health system, by adapting the corresponding British model. Such a figure would be a GP who has gained specialized knowledge and skills about the prevention, diagnosis and treatment of addictive diseases, and may become a referee among his/her peers for field formation, peer-to-peer consulting, and referring patients to dedicated health facilities.

Those participating in the GP network would then have the following prerogatives:

- Prevention and early diagnosis
- Treatment
- Relationships with families

As far as early diagnosis is concerned, we need to refer to a shared basis of knowledge about the patterns of risk factors, in order to be able to identify vulnerable groups, families and single subjects in need of preventive interventions.

Treatment would certainly be limited to a subgroup of addicted patients, namely those who have already been stabilized both on clinical and psychosocial grounds. At this stage, some of the available medical treatments may be handed over to GPs, depending on the laws that regulate prescriptions, and pharmacological features and risks. That is to say. buprenorphine-naloxone treatment has been shown to be feasible in a general practice setting, due to its low abuse liability and the simplicity of its administration; as such it looms as the optimal therapeutic instrument around which to favour the development of a hybrid network between GPs and addiction specialists.

## 7. Change or evolution? The point of view of humanitarian institutions and organizations

*By Massimo BARRA*

The objective of treating drug addicts – all drug addicts – is a core health concern for the government of any country. If it is true that a drug addict, apart from being an ill person, may also be dangerous to

others, untreated drug addicts, those not yet reached by the healthcare system and left to their natural destiny, are far more likely to be dangerous to society, and – to a greater extent and in many different ways – be responsible for drug-related crime and a source of infectious diseases. A government that takes decisions in the interest of its community should therefore develop a public healthcare system that is capable of contacting and reaching out to the highest possible number of addicts. To do so, therapeutic interventions should be multidisciplinary and integrated, and enhance the work of whoever, within a private or public context, works systematically to produce beneficial effects against addiction at any level, from the encouragement of initial contacts with health and social operators to the actual therapeutic overpowering of the core addictive mechanism. Instead of engaging in 'holy wars' between methods that claim to be able to heal drug addicts in a thorough and definitive way, we had better regard all the efforts made towards the therapeutic engagement of addicts with equal respect, and be able to provide each intervention with adequate funding.

To illustrate, we may distinguish between interventions that are "high-threshold", "intermediate-threshold", "low-threshold" and "very-low-threshold", the first three corresponding to different levels of active compliance by the patient with the treatment, running in parallel to a proportional underlying motivation. A request for help, especially when the aim is the avoidance of withdrawal, to be followed by detachment from the object of craving, is, as a rule, accompanied by an ambivalent, dilatory and hesitant attitude. For many addicts in this predicament, the prospect of living without their drug of abuse is feared as viewed suspiciously as an intolerable frustration.

A typical static addiction treatment centre is open for patients to come and ask for help, but it automatically selects those whose illness is mild enough to leave room for the addict's capability to take action and apply for treatment. Although the request for treatment may be deceitful, and have the underlying aim of obtaining other advantages, or simply be feeble and unstable, it is up to therapists to turn an ambivalent, weak motivation into to a structured and constructive motivation to be admitted to long-term treatment. It is, in any case, unacceptable that healthcare policies should ever leave behind or exclude those who feel it awkward to even begin asking for help, because of the high level of their disease severity.

If those applying for treatment must be approached as ill individuals, those who cannot even imagine any alternative to continuing to live an addict's life, even if they feel it is contrary to their ideal plans, must be twice as seriously ill. Those patients are the ones to whom we should dedicate the greatest attention, instead of regarding them with scorn and avoiding them, as do those doctors who go no farther than looking out for 'ready-made' treatment responders as their reward.

Hence we decided to try to build up a network in the urban area of Roma, back in the 1970s. It was called the Metropolitan Integrated Anti-drug Web, and served as a beacon for all those who wished to mediate between patients, wherever they had met them – possibly even in the streets – and treatment centres to refer them to. According to each patient's presumed level of motivation, and the resources and skills of the referee, the patient was referred to a range of facilities, going from high to very low threshold ones.

From this perspective, no contradiction should arise between agonist and non-agonist treatment regimens and residential treatment of any kind, or between general practitioners and addiction specialists, since each of these may act in synergy to get the patient moving forward on the long-lasting path to recovery. Indeed, the longer the patient has been working with health operators, the better the results. A patient may choose a physician to be his/her case-manager, – a choice that should not be limited by territorial rules, which Olivenstein indicated as the "new feudalism of mental health". A figure like this must be able to formulate a diagnosis and plan a therapeutic programme, with a second-choice or second-line option to resort to in cases where the previous strategy fails or is no longer feasible, so as to prevent the patient from the harmful consequences of dropping out and relapsing. As long as treatment is a long path, it is crucial to always have a rescue plan, without which the risk of treatment failure is an impending threat, with the possible consequences of causing individual and social damage.

## 8. Economic viability of Care Models for heroin addiction

*By Lorenzo MANTOVANI*

In Italy, the costs of drug use are estimated to be as high as 2% of the National Annual Income, which was 31 billion euros in 2011. Related health costs have been estimated to be slightly over 5% of total State expenditure. In Italy there are 1,630 dedicated treatment units, 563 corresponding to territorial

addiction treatment centres, and 1,067 therapeutic communities of different kinds. Addicted patients in need of treatment are estimated to be just over half a million; if this figure is correct, the 170,000 treated subjects cover only about one third of the total number of addicts. An investment of as little as 1 Euro in the treatment of addiction generates a benefit of as much as 6 Euros [30]. As far as heroin addiction is concerned, appropriate treatments have reliably proved to be cost-effective as a means of patient management, even in the Italian context. They are currently recommended by several agencies of Technology Assessment in Scotland, Wales, the UK, Canada and Australia [4, 10, 24, 33]. Shared or Mixed Care Models may help to fill the gap between the estimated total population of addicted subjects and those currently on treatment, in a highly cost-effective way, to the point of actually reducing the comprehensive cost of heroin addiction [23]

## 9. Addiction and the network of territorial facilities

*By Pier Paolo PANI*

Addiction is one of the diseases that have the strongest social impact. Dole and Nyswander, in the first article ever published on the effectiveness of methadone treatment stated: "By this medical drug, and by a global (holistic) rehabilitation program, patients have displayed they improve markedly; they started to attend school again, have found new jobs, have rebuilt their familiar relationships…. This kind of treatment requires close medical supervision and several social facilities. In our opinion, the drug and the support facilities are both essential" [7]. Many years later, the work of Thomas McLellan proved the effectiveness of psychosocial intervention within methadone maintenance programmes [22].

In some contexts an integrated approach is more feasible, due to the complex interactions between health and social factors, whereas single interventions, when they are kept separate, may be a failure or even cause damage, as long as specialists work on single aspects rather than exchanging information about their experiences [27]. Some Cochrane reviews by the drug-and-alcohol study group evaluated the effectiveness of psychosocial interventions combined with agonist treatment for opioid addiction [2, 3] or case-management for the coordination and continuity of care [11]. Despite this, the advantages and costs of integration practices need further clarification.

In the public Health System, the gold standard of integration should be backed up by a clear-cut matrix system, where each treatment unit is at the same time part of a District (which is responsible for the necessary integration between services and institutions) and a Department (which looks after the scientific quality and adequacy of interventions). If such a model can be properly implemented, Addiction Treatment Services will follow a hub-and-spoke mode of functioning, which consists in deriving all general functions (operative planning, coordination, clinical activities) from a common pole (the "hub"). Other nodes and spots within the network (the array of "spokes"), spread out over the territory, would then serve as peripheral centres and receive treatment requests (from territorial treatment units; substance-specific treatment units for alcoholism, tobacco dependence, and so on; but also from general practices, mental health centres; family support centres, social services, and so forth). A system constructed on this model can be expected to guarantee the uniformity of treatment practices and give patients access to dedicated skills at any level and at any point of the network, thus avoiding any need for them to be transferred from one treatment centre to another just to perform ordinary treatment programmes. Transfers could then be correctly limited to special cases or to the transition between different phases of treatment.

The arrangement of any such network may start with the implementation of spontaneous pilot projects, as has happened in other countries [31], with the involvement of institutional healthcare structures and other related services.

Further interventions may be addressed to encouraging virtuous trends in terms of the promotion of integrated treatment. Currently, our public health refunding mechanism does not account for the economic value of integration and coordination, and fails to offer any incentives to promote collaboration between different levels of intervention. We may also look forward to the inclusion of continuity of care among the essential care levels, with a corresponding economic evaluation.

The organization of a care model of this kind, able to provide continuity and integration of treatment, implies the drawing up of regulations that will help to dismantle barriers, whether to horizontal integration (between institutions, services and operators playing medical and social roles) or to vertical integration (between institutions, services and operators at a basic [GP], specialist, and inpatient level), in terms of prerogatives, logistics, treatment administration practices and refunding.

## 10. A glance at the near future: the Mixed Care Model

*By Icro MAREMMANI*

In the near future, healthcare measures for heroin addiction may, reasonably, be updated to suit current clinical pictures and therapeutic options. As in other medical areas, healthcare measures should be arranged at different levels, in accordance with guidelines elaborated by Europad and WFTOD (World Federation for the Treatment of Opioid Dependence, NGO with Special Consultative Status within the Economic and Social Council (ECOSOC))[8]. There is no scientific evidence to support the omission of general medical principles from the treatment of addictive diseases (criterion J), so that addicted patients should be treated as normally as possible, with the aim of avoiding the need for shunning any stigmatizing special regulations (criterion K). Level 1 (the first level of intervention) is represented by GPs; level 2 (second level of intervention) corresponds to local addiction treatment units; lastly, university centres correspond to level 3 (third level of intervention). GPs may provide an active link between the general population and specialized centres; these latter may function as an outpatient practice and arrange for inpatient treatment to take place in therapeutic communities or clinics (first level of inpatient treatment), or directly in hospitals, within which addiction centres should be physically located (second level of inpatient treatment). University centres can provide third-level facilities, both in the form of out- and in-patient treatment, and make available training and skill-developing activities, including dedicated teaching within degree courses in medicine, nursing, psychology and sociology; the teaching of these subjects should also be included in postgraduate specialization and updating courses (figure 1).

Actually, it is just a matter of reproducing, in the Italian setting, a model that already exists in other parts of the world; it is usually called the "Shared Care [or Hub-Spoke] Model", or else the "Mixed Care Model".

By now it is clear that this is the only feasible way to enhance the treatment of addictive diseases, while minimizing stigma-related obstacles.

When a group of physicians decided to found the "Progetto Comunità Aperta" ('Open Community Project') in Pietrasanta, back in the 1980s, they put

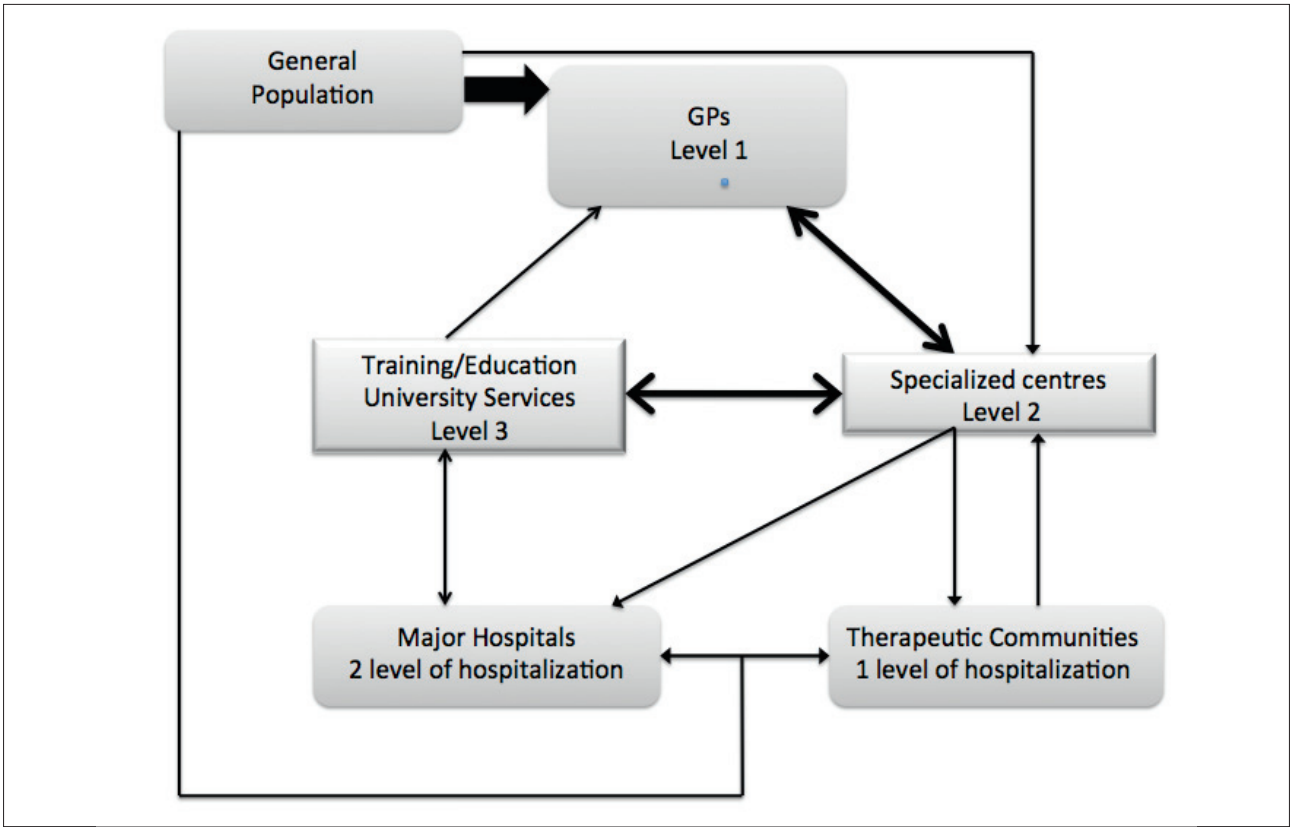


**Figure 1.** Future perspectives in the care of heroin addicted patients in Italy.

into practice the idea of handling heroin addiction directly within the heart of the town community of Pietrasanta, placing the centres in one of the main shopping areas, with the most crowded streets, where patients would be able to mix with tourists and common citizens [18]. This initiative – a tough one – as it may appear visionary rather than far-sighted, aimed to abolish the barrier that was keeping addiction treatment communities out of urban health centres.

Pietrasanta's daily Centre was based on the on-site integration between psychosocial and pharmacological interventions, and was intended to prevent and reject the stigma that afflicts addicted patients who take the steps needed to get their condition treated. Integration was, indeed, the concept that inspired the project, which still stands as an example for setting up a model of integration between different therapeutic approaches within the natural environment in which addiction first occurs and to which patients should be readapted, in order to be regarded as 'healed' and as having truly recovered. Keeping the patient apart from his/her natural context may be wrong-headed as a method, since it is likely to make re-adaptation traumatic or unpredictable, and be followed by fatal relapses, during the spontaneous chronic course of addiction itself.

Pharmacological interventions alone cannot be the fulcrum of any new philosophy for the treatment of addictive diseases: when pharmacotherapy for depression was introduced, for instance, it seemed obvious that such an approach would favour the recovery of the patient's working ability, soften the impact of depressive symptoms on relationships, and allow patients to remain within their social context while under treatment. This line of reasoning was not proposed again either in psychiatry or in the field of addiction treatment.

Given the advances made recently in neuroscientific knowledge, can we now move forward on the way to integrating pharmacological and psychosocial treatments, so as to avoid the segregation of therapeutic programmes for heroin addicts and combat cultural stigma?

For the time being, we should ask ourselves whether isolation from the company of addicts – at least of addicts who have been stabilized – has any social, let alone therapeutic, meaning. Is such isolation expected to bring any advantage to society or to patients themselves? The news is that "Martians walk among us", since the latest generation of addicts consists of fathers, employed people, and children belonging to socially integrated families.

It would be a therapeutic milestone to be able to treat addicts while they are living in their homes, or keeping or finding their jobs. From this perspective, we look forward to being able to count on an integrated network of various healthcare and social resources, coordinated by two key figures: the physician specialized in addiction medicine, and the general practitioner.

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All authors critically reviewed the manuscript and had full editorial control, taking final responsibility for the decision to submit the paper for publication. The views of the authors do not necessarily reflect those of the institutions they belong to.

*Role of the funding source*

This document, the result of AMEF2013, was funded by an institutional Grant of the AU-CNS (Association for the Application of Neuroscientific Knowledge to Social Aims), Pietrasanta (Lucca), Italy.

*Conflict of interest*

IM was a member of the Scientific Board supported financially by Reckitt Benkiser, D&A Pharma, Lundbeck.

*Acknowledgments*

The authors of the Manifesto wish to thank all those who participated in the Addiction Medicine Expert Forum, which was held in Pietrasanta, Lucca, March 8, 2013 under the auspices of the World Federation for the Treatment of Opioid Dependence (WFTOD, New York, NY, USA), the European Opioid Addiction Treatment Association (EUROPAD, Brussels, Belgium – Pisa, Italy) and the Association for the Application of Neuroscientific Knowledge to Social Aims (AU-CNS, Pietrasanta, Lucca). The AMEF2013 group discussed the speeches during the conference, proposed amendments to the final document and signed it. The AMEF2013group includes is composed of:

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