EUROPAD 

EUROPEAN OPIATE ADDICTION TREATMENT ASSOCIATION

EUROPAD formerly EUMA was founded in Geneva (Switzerland) on September 26, 1994. It shall remain independent of political parties and of any government.

The vision
EUROPAD exists to improve the lives of opiate misusers and their families and to reduce the impact of illicit drug use on society as a whole. The Association works to develop opiate addiction treatment in Europe but also aims to make a major contribution to the knowledge of, and attitudes to, addiction treatment worldwide.

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When the news of the death of Vincent P. Dole reached me this morning, I felt as if I had been stabbed.

We are now all of us feeling a bit more lonely.

I would ask all those who, without preconceptions, dream of a better world for our heroin-addicted patients to remember this friend and master of the art.

It will nor be easy to go forward along our chosen path, but we will do so in the name of that extraordinary man. He will live in our memories.

Icro Maremmani
In Memory of Vincent P. Dole, MD

Vincent P. Dole, MD, Dies at age 93, August 2, 2006

Dr. Dole (an internist) and his late wife, Marie Nyswander, MD (a psychiatrist), began their collaborative research with methadone with a handful of long-term heroin-dependent individuals in 1964. They did so in the face of overt threats of harsh criminal and civil action by federal narcotics agents. Their courageous, pioneering work demonstrated that methadone maintenance is a medical treatment of unparalleled effectiveness, a superlative description that is as applicable today as it was four decades ago. As a result, well over three-quarters of a million people throughout the world are able to lead healthy, productive, self-fulfilling lives - over 200,000 in the United States, an estimated 530,000 in Western Europe, and many tens of thousands more in Eastern Europe, Middle East, Central Asia, Far East, Australia and New Zealand.

After the remarkable transformation they observed in their first few patients, Dr. Dole and Dr. Nyswander went on to provide direct supervision of the first methadone maintenance treatment program at Beth Israel Medical Center in New York. In so doing they demonstrated that it was possible to replicate on a large scale the therapeutic success they achieved in the small, controlled, research environment of the Rockefeller Institute (now Rockefeller University). Dr. Dole was also responsible in the early 1970s for convincing the New York City Department of Corrections (at the time headed by Commissioner Ben Malcolm) that detoxification of heroin-dependent inmates in the city's main detention facility at Rikers Island was imperative to save lives and lessen suffering (there had been a wave of suicides at the time that had been attributed to severe opiate withdrawal). The detoxification program continues to this day, and has become a model for enlightened corrections officials in other countries.

Dr. Dole and Dr. Nyswander's contributions, however, transcend the life-saving clinical impact on patients and the enormous associated benefits to the community as a whole. They had prescience to hypothesize, years before the discovery of the morphine-like "endorphine system" in the human body, that addiction is a metabolic disorder, a disease, and one that can and must be treated like any other chronic illness. What was at the time brilliant insight on their part is today almost universally accepted by scientists and clinicians alike, and remains the foundation upon which all rational policies and practices in the field rest.

In his mid-80s Dr. Dole travelled to Hamburg to be present at the naming ceremony of the "Marie Nyswander Street"; in less than ten years Germany moved from methadone being illegal to having over 60,000 patients in treatment! His efforts during recent years were devoted to fighting the stigma that, tragically, remains so widespread against the illness of addiction, the patients and the treatment.

Robert G. Newman
Forty Years of Methadone Maintenance Treatment
Around the World: Past, Present and Future

Icro Maremmani

This year is the 40th anniversary of the implementation of the first methadone program in New York City. Last June in Manhattan the Beth Israel Medical Center organized the conference “Forty Years of Methadone Maintenance Treatment: Touching Lives Around the World..... Past, Present, Future ” remembering this event.

I was honoured to participate and my presentation was basically a reflection on the development of methadone programs in the USA, in Europe and in other parts of the world. The objectives of the treatment of heroin addicts are, of course, the same all over the world, but substantial differences can be found between the American practical experiences and those of Europe.

The organization of the medically assisted treatment of heroin addiction in the European Union is varied. In some parts of Europe the treatment is entrusted to general practitioners as in Austria, Belgium, France (for buprenorphine treatment), Germany, Ireland, Luxembourg, and UK. In other parts there are specialized centres as in Denmark, France (for methadone treatment), Italy, the Netherlands, Portugal, and Spain. In a small number of European countries there are specialized centres, but the number of treated patients is very limited as in Finland, Greece, Sweden, and Norway compared to those. So, the European method of treating heroin addiction is a little different from the American one. In Eastern-Europe there isn’t a long history of treatment and, at present, there is a strong discussion about the kind of treatment preferred. Unfortunately, "harm reduction” and “specific treatment” are often opponents in public policy.

From the epidemiological point of view, the prevalence of heroin addiction in Europe is comprised between 0.6 and 0.9 percent. The mortality of heroin addicts is 13 times higher in comparison with a matched age group (predominantly young men). 75% of the European heroin addicts have hepatitis C. The comorbidity with affective disorders
Heroin Addiction and Related Clinical Problems

is very high, more than 50%. We estimate that only 25% of heroin addicts are in a treatment system. More and more heroin addicts are inhaling the heroin. Surprisingly, the highest represented modality of treatment in Europe is still methadone treatment (> 90%). Despite the wide acceptance and diffusion of buprenorphine in France and in Italy, the use of buprenorphine is still limited. Anecdotal reports show us little use of slow-release morphine.

The European view in treating opioid addiction

The major points of interest in the European view regarding the treatment of Heroin Addiction are: a) the debate between “Short term vs Long term detoxification” b) the debate between “Harm reduction vs specific treatment”; c) the possibility of “Treating the addiction to treat other illness”, especially mental illness.

The first step we had to take in Europe in the 80’s, like the US in the 60’s, was to implement a policy of a long-term detoxification as opposed to the short-term methods previously used. Unfortunately, we see these short term methods still in use today in some parts of Eastern Europe, and especially in the Russian Federation in which Medically Assisted Rehabilitation is still forbidden.

We have, in Europe, a major commitment to harmonize “harm reduction” philosophy with “specific treatment” philosophy giving the precedence to the implementation of the “specific treatment” philosophy. This is quite different from that in the US, where “harm reduction” and “specific treatment” must compete for funding and so, it becomes an arbitrary choice and not a unified policy. Where we in Europe are looking to form an integrated policy between the two philosophies we now find the same problem in Eastern Europe and in Russia that exists in the US today.

An exciting prospect which we are now studying is the possibility of using a slightly modified methadone treatment to treat heroin addicts with psychiatric comorbidity.

The first problem we coped with in the past was having to choose between short-term and long-term detoxification. In the 80’s, not only the majority of public opinion, but also the majority of physicians asked us: Why detoxification? “It’s fundamentally a bad idea to give addicts an opiate (methadone), something that they can enjoy; complete abstinence must be the goal”.

We spent a lot of time explaining the scientific reasons for our choice. And now, in Europe there is a pervasive opinion that heroin addicts need an opioid medication as a man in the desert needs water. Or, if you prefer, that to deny an opioid medication to heroin addicts is like denying water to a man in the desert.

From the scientific point of view it is important to remember that, for heroin addicts, there is high mortality in a) patients who finished successfully short-term (28 days) detoxification b) patients who remained longer as “in-patients” in the hospitals c) patients with high psychiatric comorbidity; c) after prison discharge; d) after Therapeutic Community discharge. Who survived? Patients who were in long term detoxification programs.
Unfortunately, the vision which prefers short-term detoxification to medically assisted rehabilitation is still prevalent in groups which are not scientifically oriented, such as the Catholic Church. This view is also present in some Eastern European countries and especially in the Russian Federation.

Therefore EUROPAD still has some work to do in order to bring these countries around to the proven, and correct, vision regarding medically assisted rehabilitation.

The best approach to heroin addiction treatment

What is the best approach: harm reduction, office-based prescription, or comprehensive treatment?

What should be the present role and target of Harm Reduction? Currently, “harm reduction” and “specific treatment” tend to divide addicts into two categories: highly impaired ones and those addicts fitting high-threshold approaches who can achieve a satisfactory and stable degree of control over their disease. As a consequence, “harm reduction” and “specific treatment” tend to resort to different instruments, so that they differ in treatment strategy.

We do not deny the need for “harm reduction”. In fact when high-threshold treatments take precedence over “harm reduction”, the most severely ill addicts are destined to meet their death while outside any form of care, and this is not in line with the spirit of a civilized country. On the other hand, when “harm reduction” is dominant within a clinical setting, no effective therapy for addiction is possible, either on personal or on social grounds. Thus, although addicts may not die of drug related causes, thanks to successful “harm reduction”, they will die as heroin addicts. In fact “harm reduction” works through a low-threshold approach; it gives everyone a chance to temporarily improve their condition and lessens the risk of addictive practices. It focuses on the social and personal needs of the addict but it does not reverse craving and behavioural reinforcement and it does not have an impact on the natural course of addiction.

Generally clinicians (such as myself) prefer a high-threshold methadone treatment strategy, but there are several clinical points of interest regarding the “harm-reduction” strategies. Here there are new possible targets for harm reduction. The controlled administration of sub-therapeutic dosages of agonists (as opposed to therapeutic dosages) may decrease the severity of addiction behaviour and psychopathology. It may also reduce the craving related urgency, such as impulsiveness and acting out. The insight of the patient after reduction of the severity of the psychopathology can improve.

The psychopathological symptoms of heroin addicts are mostly fictitious due to withdrawal or intoxication states or masked by agonist high-threshold treatment. The controlled administration of sub-therapeutic dosages of agonists makes possible identification of psychiatric disorders before full-dose agonist treatment.

It is, in any case, reasonable to work for the recognition of harm reduction as a level of intervention sharing the same strategy as specific approaches, and therefore using the same instruments. As this is the authentic role of “harm reduction”, an unbroken
transition from “harm reduction” to high threshold settings becomes possible.

This European strategy which we are now constructing should be accepted by the US as well. Unfortunately, in the US, it is my opinion that humanitarian and governmental organizations, although having the same end-goal, have not been able to fully collaborate because of financial and political differences. It is my fear that the same situation could happen in Eastern Europe and also, even more likely, in the Russian Federation.

Another important topic we are discussing in Europe is the role of general practitioners (GPs) in the treatment of heroin addicts. Certainly the first phase of the treatment, the induction phase, would be better conducted through the methadone clinics. In fact the daily attendance of the patients in the clinics would ensure the secure ingestion of the medication that would not be possible only by giving a prescription. Beyond that, it would be possible to modify the dose on a daily basis depending on the clinical assessment of the patient at that time.

When the patients reach the stabilization phase the role of GPs becomes crucial because they represent a re-entry into the “normality” of the general health care system therefore limiting the “stigma” of methadone clinic attendance.

Unlike the US, and also in the majority of the European Union, we in Italy are trying to maximize the integration of these two systems - methadone clinics with general practitioners. In this way more patients can take advantage of the closer and more friendly interface with their general practitioners. This idea is also a good one, from my experience, when treating heroin addicts with buprenorphine.

Lastly, there is a long string of research studies which indicates the use of long-acting opioid medications in treatment of double-diagnosed heroin addicts. We must remember that for many years these patients were excluded from methadone treatment because it was commonly thought that they would not respond. Instead if we treat double-diagnosed patients with long-acting opioids not only the addiction to heroin will decrease, but also associated psychiatric comorbidity will improve. We have found that the dose of methadone must simply be over-standard or combined with small doses of antidepressants, neuroleptics or mood stabilizers.

The need of an international collaboration

To improve the quality of the treatment of heroin addicts, certainly, we need an international collaboration. The best example of this collaboration is the friendship between EUROPAD and the American Association for the Treatment of Opioid Dependence (AATOD). EUROPAD requested that Russian scientific authorities introduce Methadone Treatment in Russia during a congress of the International Society of Addiction Medicine (ISAM) in St Petersburg in June 2004, but they explained that government restrictions (making methadone illegal) prevented them from participating. We repeated our requests in many international congresses. Finally, a Russian military officer of the narcotic control police visited my clinic in Pisa to begin a collaboration
with EUROPAD. At the same time Dr. Mark Parrino, President of AATOD, was working with American authorities to promote Medically Assisted Rehabilitation in the Russian Federation. Dr. Parrino contacted the president of the League of the Health of the Nation of the Russian Federation. So when the League invited AATOD and EUROPAD to organize a scientific meeting in Russia we were happy to collaborate. Dr. Parrino and I visited Moscow twice and explained to our Russian colleagues the scientific rationale regarding methadone treatment and how it would be possible to organize a network of methadone clinics in Russia, which is in accordance with our motto “from science to public policy”.

Of course in Russia there was some resistance not only against “harm reduction” but also against methadone treatment. A group of Russian psychiatrists published a memorandum, “Say no to methadone treatment in Russia”. And we answered with a scientific publication explaining the reasons for the necessity of Methadone Treatment in Russia. Dr. Parrino and I signed this publication together with the President of the Italian Society of Addiction Medicine and the President of EUROPAD-Italia.

The conference was a success and now the situation in Russia is improving.

This collaboration between AATOD and EUROPAD is a good example of how Science can change the world, and I want to underline that together we can make the difference not only in Russia, but also in the US, Europe and all over the world.

Acknowledgements. I would like to thank Juliette Cowdin, RN-BSN, for her support in the preparation of this paper and for giving me a heightened awareness of the perspectives of the American Health Care System and its attitudes.

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Methadone and Treatment Quality.  
The EFQM Excellence Model

Andrea Flego

Summary

In the technologically advanced world, providers of products and services have been dealing with the problem of quality, of how to assess its level, and of how to improve it continuously and systematically for many years. Therefore, this aspect cannot be eluded when scientifically planning and practically organizing a methadone treatment program. The treatment with methadone, although it is safe and relatively easier than others, is still at the centre of a great controversy. This is mainly due to the fact that the controversy lies in the basic reasons of the treatment with methadone rather than in the effectiveness of this treatment. The search for quality is a never-ending, dynamic process, and excellence itself is not definitive. It is a circular process that has to progressively improve the performances but also to defend itself from the natural entropy of not-managed situations (it has to continually introduce “negative entropy”). This process has to continually take into consideration innovations and new knowledges or ‘scientific evidences’.

Key Words: Methadone Maintenance - Treatment Quality  
- EFQM Excellence Model - ISO model

Introduction

In the technologically advanced world, providers of products and services have been dealing with the problem of quality, of how to assess its level, and of how to improve it continuously and systematically for many years. Therefore, this aspect cannot be eluded when scientifically planning and practically organizing a methadone
treatment program.

The treatment with methadone, although it is safe and relatively easier than others, is still at the centre, at least in Italy, of a great controversy. This is mainly due to the fact that the controversy lies in the basic reasons of the treatment with methadone rather than in the effectiveness of this treatment.

For this reason, in a quality manual, this second aspect cannot be analysed without fully understanding the first.

**Quality in the treatment of the addictions: search for a method.**

What do we mean when we speak about ‘quality’? The word suggests the concept of ‘doing something better’ or more precisely ‘at the best’. It also suggests the concept of ‘doing something better than before’ or ‘better than other people’.

There is a term more and more used that calls to mind this concept. It is the word ‘benchmarking’. The word means to evaluate by comparison with a point of reference. Thus, we can compare different things to know which is the best or which performs better, but we can also see which is the lowest point – and this is very important when we speak about quality - under which a product or service is of unacceptable quality.

To decide whether the quality of a product or a service is acceptable or not means to ‘plunge’, as Cicourel says (1), in the ‘study of the obvious’. It means to analyse what is taken for granted in the common sense, ‘the whys’ of an action. This concept calls to mind that of ‘rationale’ in pharmacology, which does not only mean how to prescribe a drug but also why the drug is prescribed and why with such modalities.

A product or a service is of good quality if it corresponds to the purposes for which it has been realized and if it meets the user’s requirements.

Nowadays, a car going at a maximum speed of 30 km/h and consuming 1 litre/km would be considered of unacceptable quality. One of the reasons is that it would not meet the driver’s expectations with regard to medium speed and fuel costs. Moreover, it could not compete in a market where competition is based on different cost-performance ratios. However, the most important reason is that our daily living has elected as common ‘value’ – and has founded an epistemology on it – the choice of going at a speed between 100 and 130 km/h consuming 8 to 12 l/km. Finally, this habit is possible because the roads and highways can support such performances (although car accidents occur) and because a road code exists that regulates the matter and possible controversies. The benchmarking for the production of cars is based on these parameters and not on other ones. However, this epistemology – attribution of meanings – with regard to cars did not exist or was different in other times and nowadays it is different in other places.

Similarly, when considering illicit drug addiction, it is not possible to speak about quality without analysing the ‘obvious’ of the purposes of drug addiction treatments, that is, before founding a common epistemology. And in Italy, there is an epistemology chaos with regard to drug addiction.
For example, a treatment for heroin addicts that does not use methadone or uses it only at low doses and for short periods is still considered of good quality. The objection that this does not correspond to any scientific-based evidence does not weaken this position, because it relies on an epistemology other than that commonly defined as ‘scientific’. Not only this epistemology is allowed but it is also part of the common feeling of the society and is sustained by the media.

For this reason, in our work, as well as in a quality manual, it is necessary to explicit some unbreakable assumptions on which to found a method to interpret events and interventions that can support quality assessment.

The assumptions are as follows:
1. Illicit drug addiction is a chronic and recurring disease, as pointed out by Mannaioni (2).
2. It produces physical and psychological suffering, in addition to social suffering, and part of it has a strictly biologic pathogenesis.
3. As in other medical fields, this suffering has to be treated on the basis of scientific evidence.

Thus, the scientific method becomes the model for clinical practice, as well as for benchmarking, which means that the conceptual model of choice is evidence-based medicine (EBM).

Continuous quality improvement (CQI).

The first operative concept regarding the quality assessment of a product was the ‘quality control’ concept. Initially, a product was checked at the end of the productive cycle and the defective items were eliminated before putting them into the market. Obviously, their costs were charged on the good items. However, this first attempt to evaluate quality was ineffective and expensive in the results and was soon replaced by a more rational action aiming at checking the ‘process’. In this case, the causes of the defects were analysed and the intervention was on them in order to reduce or eliminate the defects. Thus, it was possible to save money and to sell at more competitive prices. This intervention mainly improved the use of the resources, thus reducing the number of reject items.

Soon it was clear that this process was neither punctual nor linear but circular, as shown in the following diagram (figure 1).

This model is based on the concepts by Deming (3) that define the cycle “plan-do-check-act” (plan the actions, implement the actions, assess the effects, correct the actions) as a continuous cycle that constitutes the process of “Continuous Quality Improvement” (CQI). This model can be successfully adopted also in the sector of services production, including health care services. CQI has progressively replaced the previous, and perhaps more known, expression of “Quality Assurance”, which was introduced in Italy by Perraro and Gardini (4) many years ago under the denomination of “VRQ – Verifica e Revisione della Qualità”, in Italian language.

An important contribution to the theory of quality in health care services was made by Avedis Donabedian (5). He defined the four basic dimensions on which quality analy-
sis was to be performed: input (human, instrumental and financial resources), process (modalities to produce services), output (provided services) and outcome (results of services in terms of health improvement of the end users - individuals or, as in the case of prevention, population).

Because of their different nature, these four dimensions need different approaches during assessment and different means to assess them. However, a process of continuous quality improvement implies a continuous intervention on and monitoring of all the four dimensions because each can influence the final result or invalidate the improvement brought by the others.

The fourth dimension (outcome) deserves a particular attention because it implies the translation or not of efficient performances into efficacious interventions. The efficacy of an intervention is also guaranteed by factors external to the organization and related to environmental and social conditions on which health care workers cannot always act. From the methodological point of view, the assessment of outcome implies research models, such as Randomized Clinical Trials (RCT), which are not always feasible in normal health care organizations.

Therefore, while all health care organizations should implement a CQI process that takes into consideration the dimensions of input, process and output, the assessment of outcome is reserved only to some of them. However, all of the organizations can refer to the literature, in particular to that conducted according to Evidence-Based Medicine (EBM), of which the Cochrane Centres are an example in Italy.

A further development called “Total Quality”, introduced by Deming and by Japanese
A. Flego: Methadone and treatment quality. The EFQM Excellence Model

Researchers, has paid attention to the human factor as the main productive factor. The fundamental principle of this approach is that the best quality (or excellence) is achieved when all people participating in the production process are involved and motivated to pursue it. Thus, excellence is achieved when every employee of an organization does his/her work in a creative manner. This concept, as well as that of CQI, has merged into the more recent European Foundation for Quality Management (EFQM) model 1.

The EFQM excellence model.

The EFQM model represents a novelty in the panorama of approaches to quality. The novelty is not only temporal, the model is a recent one, but also of content because it introduces new concepts compared to the previous models. This innovative model perhaps can be better implemented in the sector of health care and social security than more traditional models.

At present, it has been adopted by some important European businesses such as British Telecom, Volkswagen, Rank Xerox and Philips, and by some Dutch health care organizations, among which the Jellinek Zentrum (Amsterdam) for pathological addiction.

Some years ago, the European Commission started a research project called “ExPeRT Project” to make a critical review of the most used models to guarantee quality in health care organizations in Western Europe.

From the study, it emerged that four models were widely used in Europe:

1. ISO approach
2. Accreditation of health care services
3. Peer Review
4. EFQM

The ISO model defines the characteristics or standards to which an organization and its functional procedures should conform to be considered of ‘good quality’. Such standards represent a sort of norms, which sometimes are very detailed and mandatory. Based on these norms, a number of certification agencies will be able to grant a certification of quality.

Similarly, in the Accreditation model, a public actor (or a private one acting on behalf of the Government) assesses and checks the features and functioning of an organization. Then it issues an Authorization to Operate followed by and Accreditation, to be verified at fixed deadlines, that recognizes the organization and allows it to obtain public or insurance funding. This is the case of the American Joint Commission for Accreditation of Health-Care Organizations (JCAHO) which, on behalf of the Federal Government, recognizes hospitals and other health care organizations.

Peer Review means that an organization is assessed by experts from another organization who have the same professional competences and experience in the specific field. This model is more dynamic, more concerned with ‘professional competence’, and it is lesser bound to specifications or regulations.

The EFQM model has a more ‘general’ approach in that it deals with all the aspects of an organization, even those not usually standardizable. Moreover, it emphasizes
‘quality management’ at all levels as an integral and necessary part of the overall organization management. Finally, it favors the processes of ‘organizational development’ and CQI.

The EFQM Excellence Model is a model for quality management that has been formulated by the European Foundation for Quality Management and was revised in 1999 in Geneva.

EFQM is a non-profit, membership-based organization created in 1988 by the presidents of 14 leading European businesses such Bosch, BT, Bull, Ciba-Geigy, Dassault, Electrolux, Fiat, KLM, Nestlé, Olivetti, Philips, Renault, Sulzer, Volkswagen, with the support of the European Commission. By January 2000, it included 800 members from most European countries (38 countries) and most sectors of activity, including public administrations and health care organizations.

EFQM helps European businesses to improve their products and to provide better services by means of efficacious and state-of-the-art management techniques.

From the very beginning, the ‘vision’ of EFQM was to contribute to the creation of strong European organizations that applied the principles of Total Quality Management in their economical activities and in their relationships with the employees, stakeholders, customers, and communities in which they operated.

The mission of EFQM is:

1. To stimulate and help European organizations to participate in improvement actions aiming at excellence in terms of clients and employees’ satisfaction, impact on society and economical results;
2. To provide support to the managers of European organizations to accelerate the process that sees total quality as a determinant factor to reach a global competitive advantage.

The introduction of Total Quality Management programs can result in important benefits for the organizations, such as growing efficiency, reduced costs, and greater satisfaction, which means better economic results.

The EFQM model is based on the concepts by Deming with regard to the continuous quality improvement through the cycle “plan-do-check-act”, which constitutes the process of continuous quality improvement. As for the description of the organization, the EFQM model is similar to the model of Donabedian, which distinguishes structure, process, and outcome.

The EFQM Excellence Model was introduced in 1992 as a reference model to award the European Quality Award. It is the most used model in Europe to evaluate organizations. While the Quality Awards are limited to few users, the real measure of the efficacy of the EFQM model is its wide use as a management system and the associated growth of managerial capacities in organizational self-assessment.

Independently of the sector, dimensions, and structure or maturity, to be successful an organization has to define an appropriate management system. The EFQM model is a good tool to do this because it allows an organization to evaluate at what point it is in its way to excellence, it helps to understand the causes of failure, and it stimulates
adequate solutions.

The innovations of this model are many compared to the previous models. Some of them are of particular interest for the health care and drug addiction therapy in Italy.

First, the EFQM model is European, which is not only a geographical connotation. One of the aim of EFQM is “to stimulate European organizations to achieve global competitive advantage, aiming at the satisfaction of the clients and employees, and at a positive impact on the society”.

Secondly, the EFQM model is not ‘normative’. The attention is not focused on conformity to specifications that are continually redefined. In fact, this model recognizes that there are many efficacious approaches and it fixes only few Fundamental Concepts, which can be implemented in different manners.

Moreover, EFQM updates the model taking into consideration the outcome of ‘good practices’ assessed in thousands of European and non European organizations. By this way, the model remains dynamic and reflects the present trend in management. The last revision was initiated in January 2003.

The approach with which an organization pursues and achieves its goals may vary and the assessment of the procedures and approaches is not based on conformity to standards but on the efficacy in achieving the results.

In fact, the EFQM model recognizes that there are many approaches to achieve sustainable excellence. Within these non prescriptive approaches, there are some Fundamental Concepts. They are non exhaustive and can be changed or integrated based on the improvements of the organizations that have reached excellence. At present, the fundamental concepts are:

1. Results orientation. Excellence is achieving results that delight all the organization’s stakeholders (consigners, suppliers, employees, and final customers).
2. Customer focus. Excellence is creating sustainable customer value.
3. Leadership and Constancy of Purpose. Excellence is visionary and inspirational leadership, associated with constancy of purpose.
4. Management by processes and facts. Excellence is managing the organization through a set of interdependent and interrelated systems, processes and actions.
5. People development and involvement. Excellence is maximizing the contributions of employees through their development and involvement.
6. Continuous learning, innovation and improvement. Excellence is challenging the status quo and effecting changes by using learning to create innovation and improvement opportunities.
7. Partnership development. Excellence is developing and maintaining value-added partnership.
8. Corporate social responsibility. Excellence is exceeding the minimum acceptable level of functioning of the organizations and striving to understand and respond to the stakeholders’ expectations.

Thirdly, the model has fully adopted the principles of Total Quality, i.e. it tends to
emphasize the quality of people rather than procedures. If the goal of every single person of the organization is to provide a product or service of quality and if everyone can develop his/her creativity in pursuing quality, this will become a necessary value.

The EFQM excellence model is based on nine Criteria. Five of these - leadership, personnel management, policy and strategy of the organization, partnership and processes - are Enablers, and they enable an organization to implement its ‘mission’ and pursue its objectives. The other four criteria – customer results, people results, society results, key performance results - are Results, and they are the real object of quality assessment. The Result criteria cover what an organization has achieved. Results criteria are caused by Enablers and feedback from the Results help to improve the Enablers criteria.

The model, which recognizes different approaches to achieve sustainable excellence in all aspects of services, is based on the following assumption:

“Excellent results with respect to Performance, Customers, People and Society are achieved through Leadership which leads Policy and Strategy, that is delivered through People, Partnership, Resources and Processes”.

The diagram of the EFQM model is as follows: (Figure 2)

The arrows indicate the dynamic nature of the model. They show how Innovation and Learning support the improvement of Enablers, which in turn improve Results.

The nine boxes represent the Criteria with which to assess the progression toward excellence. For each of the nine criteria, a definition explains what it means to achieve a high level in that Criterion.

Among Enablers Criteria, Processes and Leadership are considered the most...
A. Flego: Methadone and treatment quality. The EFQM Excellence Model

important; among Result Criteria, Customer Results and Key Performance Results are the leading.

Each of these criteria can be investigated taking into account the 32 sub-criteria, 24 for the Enablers and 8 for the Results. These sub-criteria are used as areas of ‘assessment’, which are tools to assess, through clear and comprehensible examples, the ‘status’ of an organization.

Unlike others models, the EFQM model is not based on a definition of quality. In contrast, it considers quality management as an integral part of the management function, as well as of the professional functions present in an organization.

However, the real novelty of the EFQM model is that it allows and legitimate self-assessment, whereas one of the principles of the previous models was external assessment (certificate of conformity by external agencies in the ISO model, review by public organizations in Accreditation, review by external professionals in Peer Review).

Self-assessment can be applied to small and big organizations, in the public and private sectors. An increasing number of organizations is using data from self-assessment in the planning of their activities and use the EFQM model to review them.

The EFQM model can also be used as a diagnostic tool to assess the present ‘status’ of an organization. By this process, an organization is able to better balance its priorities, allocate its resources and define a realistic activity plan. In doing this, the process of self assessment is important. EFQM gives the following definition:

“Self-assessment is a comprehensive, systematic and regular review of an organization’s activities and results referenced against the EFQM Excellence Model. This process allows the organization to discern clearly its strengths and areas in which improvement can be made. Through this process of evaluation, an organization improves the balance of its priorities, the allocation of its resources and produces a realistic plan of its activities”.

It is clear that this model which allows self-assessment of all nine dimensions (Criteria) and throughout all the organization at almost no cost is preferable to external assessment, when the results are the same. Moreover, with an internal review there are fewer controversies between professional workers and management.

Implementation of the EFQM model at Jellinek Zentrum - Amsterdam.

The Jellinek Zentrum - Amsterdam is an organization with 500 health care workers that cure and care for 5,000 patients with addiction problems, distributed in 24 different programs of medical, psychosocial and rehabilitative treatment. The quality model adopted by this centre is based on the EFQM model and its results have been recently published (7-9).

The most interesting characteristic of the Dutch variant of the EFQM model is that five different phases of organizational development have been defined: Product Orientation, Process Orientation, System Orientation, Chain Orientation, and Total Quality.

Product Orientation is when the attention of the organization is on providing correct performances. For example, to define what is a good medical and toxicological assessment and a good pharmacological protocol.
However, the most important processes are Process Orientation, System Orientation, Chain Orientation, and Total Quality, which could be defined as ‘meta-processes’ because they integrate the interventions of different knowledges and disciplines.

At one meta-level, the management (e.g. the director of an Addiction Department) can maximize the probability that the services provided are correct without caring for them personally if the people are in the right place and if there are rules of collaboration and responsibility that are scientifically validated and accepted. The actors of these performances will guarantee the quality, especially if they are gratified with what they do. This is an example of process-oriented organization.

Considering the next meta-level, the organization can focus on the interactions between different areas of activity. In other words, it can study how different segments of intervention, which follow different logics and scientific knowledges, can integrate to meet the user’s needs. Addiction departments offer a good example of system-oriented management in that different professionals interact, each with his/her own competence, to develop a multidisciplinary therapeutic and rehabilitative program. A system-oriented organization tries to govern these complex interactions on the basis of the context in which it works and monitors their effects on the end user.

In a chain-oriented organization, the attention of the management is on the problem of “therapy and assistance continuity”. In other words, the attention is on the chain or sequence of events, some of them within the organization, which can produce a good therapeutic result if governed or can introduce bias and distortions if not. Some examples? The family doctor who prescribes buprenorphine while methadone is administered; the therapeutic community that accept addicts without agreeing a therapeutic program with Addiction Facilities; a hospitalization which has failed because it was decided by the family without an agreement between health care workers of Addiction Facility and the hospital; a sudden release from prison without a program.

Because it implies non-hierarchical – i.e. partnership - relations, the chain-oriented management has to use new tools, ranging from external credibility for its workers to budget management in a therapeutic sense, for example negotiating funding to the communities in exchange of quality assessment of the services provided, formulation and assessment of operative protocols which, to function, have to consider the convergence of motivations and interests among all the organizations involved. In some ways, this action is diplomatic and can be synthesized as follows "to make a constant effort to orient all resources towards the health of the end user”.

The last process is Total Quality. Every worker can work well if he/she is in the condition to do it. Many of these conditions do not depend on external factors or on top management. There are some organizational conditions that depend directly on the operative management.

The motivation of the workers distribute in a Gaussian curve; this means that, considering the good and the very good workers, there are high probabilities to comprise more than 80% of workers from the start. Moreover, it is known that money does not motivate people, and this applies also to people working in Addiction Departments.
They are much more motivated when they feel their work as “their own”. Leadership also consists in having a direct or indirect relationship with all workers. In this relationship some messages should be clear: what is expected from the worker and why (i.e., the benefits for the end user), which are the margins of autonomy and creativity of each person (each person must benefit of such margins and they must be proportional to what he/she can give), and finally to whom, when and how to refer in order to work better and to present his/her own results (maybe also to obtain a reward).

The Jellinek Zentrum has been subjected to various assessments based on the EFQM model and different changes have been introduced in its organization in these years.

**Methadone and quality**

Until now I briefly exposed a new interesting quality assurance model. But how can it be applied to Methadone Maintenance Therapy Programs (MMTP)?

First, the planning of a treatment with methadone too can be divided in different components: mission, vision, enablers criteria, result criteria and self-assessment. All these components are essential but should be analysed and defined separately. In fact, every process to improve quality implies a clarification of its components, a sort of ‘declaration’ of how they should be, followed by a circular evaluation of how they are in reality in order to introduce changes leading to excellence.

**The “mission” and “vision” of a methadone treatment program.**

Because of the existence of more than one epistemological model on methadone treatment and of the confusion between them, as previously mentioned, it is necessary to make a choice. Thus, starting from the three assumptions of the second paragraph, which are arbitrary for some people but which we consider fundamental to implement a scientifically evidence-based MMTP, it is possible to formulate a precise definition of the ‘mission’ of MMTP:

1. To reduce and eliminate heroin use, minimizing the risks of relapse and promoting such a state for a long period (months or years).
2. To stabilize as far as possible the psychic state of the patients without severe psychic diseases, eliminating craving and preventing hypophoria.
3. To promote and favour, eventually in association with other therapeutic interventions, a change in the life of drug addicts, sometimes resulting in a long drug-free condition.

Such a general “mission” can be personalized according to the physical conditions, the whole diagnostic picture and the response to treatment of the patients. In fact, not all patients can achieve the above-mentioned goals to the level, but methadone should not be used systematically to pursue goals other than those, or else the intervention will be inefficacious and non scientific.

The “vision” of MMTP is a component that deals with the context in which one acts. In other words it forecasts the scenarios within which the treatment interacts and studies the impact of treatment on the health of the patient, in order to maximize it.
Heroin Addiction and Related Clinical Problems

To define the “vision” adequately it is necessary to ask oneself some questions. These can be summarized as follows:

1. Questions concerning the epidemiology of the phenomenon investigated. For example, which is the prevalence of heroin addiction among our patients? Which is the rate of psychiatric comorbidity? Which is the rate of patients with complex organic disease?

2. Questions concerning the attitude of the health care workers. For example, which is the degree of acceptance of MMTP epistemology? How much are the health care workers convinced of its efficacy? Which interactions exist between operators with different professionalities with regard to methadone treatment?

3. Questions concerning the opinion of the society on methadone treatment, especially of the community in which one works. A greater social acceptance favors the treatment, also because it has a positive influence on the users and their families. If there is a scarce acceptance, some informative-formative interventions should be planned that modify the culture in a more favourable sense.

The great difficulties encountered by addiction treatment services to properly administer methadone in a hostile environment demonstrate how an intervention, although conducted following the state of the art, can have a greater or a minor impact on the target population according to the context. Moreover, hostile environmental conditions may lead to an inappropriate use of the drug. In Italy, for example, methadone have been used inappropriately for many years on the basis of ideological motivations.

It follows that the “mission” is associated with scientific knowledges that are recognized and codified in the literature, whereas the “vision” is associated with the context in which one acts. Thus, the “vision” is the interface between acquired scientific evidence and its transferability to a real context. It consists in an analysis of the situation and actions aiming at improving the feasibility of the mission in accordance with the above-mentioned circular process.

Some years ago, the Strategic Plan 2000-2005 of NIDA, the federal organization in USA dealing with drug addiction, started Clinical Trial Network aiming at increasing the use of scientific knowledge in the clinical practice by services for drug addiction. This because the transferring of acquired knowledge into clinical practice was contradictory and poor. Probably, this also occurs in Italy, although the issue has not been raised yet.

This can be due to an inadequate definition of the “mission”, but also to a “vision” which is insufficient to efficaciously transform knowledge into adequate services.

As previously mentioned, methadone has proven inefficacious in contexts where people think that a heroin addict should not be treated with drugs and think that methadone is not therapeutic. Thus, a different epistemology of the context makes scientific evidence less efficacious in the practice.

From this, it is clear that the definition of “mission” is essential to plan an efficac-
Enablers Criteria

As previously mentioned, the Enablers Criteria of the EFQM model are Leadership, People, Policy and Strategy, Partnership, and Processes. What do they mean with respect to MMTP? Here are some examples.

1. The Leadership defines the “mission” and “vision” for all health care workers (see previous section). Moreover, it supports the principle that “there is always something which can be improved” in MMTP by introducing a periodic process of comparison and evaluation. It also makes sure that clear and univocal messages are received by the user as to the finalities and modalities of the service. Finally, the leadership identifies and promotes the changes that may be necessary while continuing pursuing the finalities described in the “mission”.

2. People are crucial in the management of MMTP. Because the MMTP is a very wearing out component of our work, the staff must be in a sufficient number. Considering that a good service has to administer methadone every day, including Sundays and holidays, the minimum number of health care workers should be of one doctor and two nurses. The presence of other professionals is recommended. However, this is not always possible because the resources are few, but a good program for quality improvement should consider that the lower is the number of workers, the greater is the risk of workers’ “burn-out”. The problem is not only ethical (people working in unacceptable conditions) but also arithmetical. Fewer workers means an increasing “burn-out”, which results in greater turn-over, which results in difficulty in finding new workers, which finally results in even fewer workers. A sufficient number of workers for the administration of methadone prevents this vicious circle and at the end it is a good investment. Moreover, the workers administering methadone should have access to accurate clinical and organizational protocols and should be trained to manage aggressiveness, violence and incongruous behaviours. These aspects are often left to the common sense and to the sensibility and abilities of the health care workers. A good quality manual for addiction services should contain protocols or procedures for these situations too.

3. Policies and strategies are the modalities with which the “mission” is oriented to the interests of the stakeholders. There are two types of stakeholders: the users and the consigners. In methadone treatment, the main interest of the users is to take the maximum advantage in terms of health, in the present and future time. Thus, the effect of methadone on users should be monitored at short, medium and long term in order to select those clinical and organizational behaviours that better pursue the goals of the “mission”. The consigner is in this case the public administration because methadone is also used for the public health. Thus, strategies will be defined in order to reduce social
problems (petty crime, hanging about the out-patient room) but also to reduce the spreading of transmissible diseases. Policies and strategies should be explained to the health care workers through a “key processes scheme”. In this way, those processes that are determinant for the success or the failure of a strategy are emphasized. For example, the management of the external space of the out-patient room (when the resources exist) can influence the correct use of methadone and in the outcome of the therapy. The modalities to implement such a strategy should be made clear through a scheme of behaviour or protocol to be used by the health care workers.

4. External partnership and internal resources should be planned and managed. In the case of methadone treatment, possible partnerships are those with voluntary workers, and private or voluntary groups. These relationships should be codified in the framework of the so-called Enlarged Department. Such partnerships can strengthen the efficacy of MMTP, especially in the rehabilitative sector. Another strategic partnership is with the police. The management of an out-patient room for MMTP implies security risks for the workers and the public order. For a correct collaboration with police, the privacy of the patients should be respected and the patients should be warned that no disturbances to the services are allowed, to defend both the workers and the rights of those users who behave adequately. This should be defined and advertised within the out-patient room activities. With regard to the internal resources, there is the problem of the continuous re-definition of the adequacy of the rooms and the furniture of the out-patient room, which must follow health care norms for security. A periodic review of these specifications by the health care workers should be a component of a good quality plan.

5. The processes are the heart of the added value of the service. The clinic of MMTP, according to the criteria of evidence-based medicine, is probably the most important process to manage systematically. The supply and custody of methadone and the thematic of giving the methadone to take home, the so called “entrusting”, are other important processes to codify, to manage daily, and to review systematically. ‘Entrusting’ (how much methadone can be taken away, for how many days, and according to what criteria) risks to be the weak point of every service delivering MMTP. In relation to this matter, the differences between health care professionals should be minimized through a process of consensus conference, so as to offer to the other workers, starting from the nurses, and to the users themselves, a point of reference which is certain and rigorous. “Entrusting” practice can also lead to aggressive behaviour. In these cases, a change in the rules and behaviour should be planned and implemented in a progressive manner, informing the workers and the police, if necessary. The communications regarding the adopted procedures should be clear for the users.
So far, much has been said about quality, but anything is fixed and immutable. Indeed, in the search for quality—especially total quality—all the interested parts are involved in a continuous re-definition and elucidation of the above-mentioned contents.

**Result Criteria**

A good elaboration and definition of the Enablers Criteria allows a correct planning of the Result Criteria: customer results, people results, society results and key performance results.

The continuous monitoring of the results is the most important aspect of the EFQM model. For all result criteria, two features are monitored: performance and subjective perception.

In the case of customers, the measurement of performance can be conducted through the identification of a set of clinical indicators which should continually monitored, such as the negativity rate of urine analysis, the degree of reliability of the patient (in this regard, the judgment should not be only a subjective one of the worker but objective and shared criteria should be defined), and the rate of “retaining in treatment”.

In the case of people, each worker should be given precise objectives and the achievement of these is assessed according to the policy of the organization. However, the assessment is efficacious if two indications are respected: 1) it should be clear what is expected from the worker; 2) the evaluation modality should not be inquisitional or inspectorial, but colloquial and aiming at finding actions to improve performance.

In the case of society, the social perception of the activity of the service should be monitored. Sometimes, the society only sees the negative aspects of drug addiction (the presence of drug addicts in the streets near the out-patient service is often the object of animated discussions in population’s meetings). In some way, this is physiological in that the existence itself of drug addicts is not appreciated. However, this aspect should not hide other aspects such as improvements or worsening of the disturbance caused by drug addicts, which can be associated with precise and identifiable causes. In the case of worsening, corrective actions can be identified to be effected inside and outside the health care structures.

Finally, to monitor key performances, these should be first identified. In a service providing MMTP, key performances are few. For example, the identification of indicators for each of the three processes identified in the previous section: evidence-based medicine of methadone, supply and custody of methadone and the thematic of ‘en-trusting’ with associated list of reliability criteria and flow-chart of assignment to the different phases and modality of treatment.

The dimension of subjective perception is more complex to monitor. However, it allows the identification of tools that can be adequate to: 1) give voice and visibility to the perception that users have of the given service; 2) give voice and visibility to the perception of the workers; and 3) monitor social perception.

Because the EFQM model is not prescriptive, the ways to implement these actions are various. Each person should identify the problems considered so far and should find solutions adapt for his/her context, placing them at others’ disposal in a forum
In the EFQM model, each criteria is associated with sub-criteria. These consist of questions that must be considered. Finally, for each sub-criterion, there are guidance points. They are neither mandatory nor exhaustive, but they exemplify the meaning of the sub-criterion. The guidance points can be found in the publication of the EFQM Excellence Model. The Jellinek Zentrum has elaborated a specific Excellence Model, unfortunately not translated from the Dutch, which can be adopted for programs for addiction treatment, among which MMTP.

**Self-assessment**

As previously said, the EFQM model, unlike others, is not based on a definition of quality; thus, it does not assess the conformity to precise norms, but it assess the efficacy in the achievement of the goals. Moreover, unlike other models, it makes use of a process of self-assessment of the organization. Self-assessment is carried out on all nine dimensions – or criteria - through a tool called RADAR (acronym for Results – results with respect to the mission -, Approach – approach to the problems -, Deploy – use of resources -, Assess – assessment of the effects of the action -, Review – periodic review).

The RADAR system is the heart of the EFQM model. The above-mentioned elements represent five moments of a process of self-assessment that is built according to the following logic:

1. To determine the Results to be achieved as part of a process of definition of its policies and strategies. These results include organization performance, from the financial and operative point of view, and the perception of it that the stakeholders have.
2. To plan and develop an integrated set of Approaches to highlight the results.
3. To make these approaches explicit and available (Deploy) in a systematic way to guarantee their implementation in the organization.
4. To Review the approaches used through analysis and monitoring of the results achieved and through activities of continuous learning. Based on this, identify the necessary improvements and decide their priorities, planning and introduction.

When the model is used within an organization, the elements of Approach, Deployment, Assessment and Review have to be used for all Enablers sub-criteria, and those of Result for all Result sub-criteria.

The RADAR is used as follows:

**Results**

This aspect is concerned with the results achieved by an organization. In an excellent organization, the results show a positive trend and a good performance, the goals are appropriate and in line with or superior to what is necessary, the performance can be compared with that of others and depends on a good approach to the problems.

**Approach**
This aspect is concerned with the plans of an organizations and the reasons for them. In an excellent organization, the approach has a clear rationale and well defined and developed processes, it focuses on the necessity of the stakeholders, it is consistent with the policies and strategies, and it is appropriately connected with the other approaches used.

**Deployment**

This is concerned with how much an organization is able to make the approaches visible to and usable by the workers. In a good organization, the approaches are used in a systematic way and in areas which are strategic for the organization.

**Assessment & Review**

These aspects are concerned with what an organization assesses and reviews both in the approaches and in the deployment. In an excellent organization, the approaches and their deployment are periodically reviewed, actions are activated based on the review results, and these are used to identify possible changes, to establish their priority and to plan their introduction.

Self-assessment of an organization can also be carried out through a tool called “Pathfinder Card”, which helps identify the opportunities of improvement and plan the action of improvement. There is no score but a list of questions which can be answered in a short time. The logic is the same as that of RADAR, but it is simpler and less rigid. One or more Criteria, or any sub-criteria associated with them, and the corresponding questions of the card are selected. The questions are not mandatory prescriptions, but an occasion to reflect on each of the examined aspects: they provide indications on the critical aspects of the organization and on the possible actions of improvement.

Self-assessment of MMTP can be performed following the above-mentioned model, using the set of indicators described in the previous section. However, the model has to be adapted for drug addiction and obviously this can be done only by professionals working in that field. So far, the Jellinek Zentrum is the only organization that has developed a model specifically for addictions, which unfortunately is not yet available. In the future, the directions to follow are two: 1) to adopt the Dutch model; and/or 2) to elaborate an original model based on the specific context.

**Quality in clinical practice: excellence**

The EFQM model, and in some way also the other models, tends to trigger a virtuous circle in which every detail is considered. Excellence means to have achieved, by continuous adjustments following periodical assessments, ‘the best possible’ or ‘sustainable quality’.

However, the change from a situation in which quality is not considered (or of pre-contemplation as Prohaska would say) to one strongly quality-oriented is only the start. All organizations tend to entropy and all open systems (an organization is an open system) has to continuously work on homeostasis to maintain their identity in the interchange with the environment. Thus, Excellence also means 1) to maintain and
progressively improve the level of all the dimensions and 2) to continuously change to adapt to new realities and new scientific evidence.

**Quality of the pharmacological and non-pharmacological aspects and their integration.**

The use of methadone in the treatment of drug addicts has been considered for a long time, in Italy as well as abroad \((11-13)\), a ‘minor evil’ in which methadone was justified if the dose was increased and/or if it was associated with consultations, more or less psychotherapeutic, and social or rehabilitative activities, thus stimulating instrumental or ‘liturgical’ attitudes \((14)\). That is, attitudes in which the patient was forced to accept things that he/she did not consider necessary in order to obtain methadone from the health care worker.

If methadone has to be used, this should be done in the best way possible. This means that, for the therapeutic teams of addiction departments, the drug should be “at the centre of the therapeutic program”. This means that the drug, as main intervention, has to be measured in the clinical practice also in the absence of other interventions.

This point, which may seem obvious to some people, is still a cause of controversy which risks to feed an old problem. How can a tool that is not trusted by the therapeutic team be used at the best? \((15;16)\)

In fact, as proven by the literature, a well managed MMTP may by itself eliminate the use of other opiates and modify the life style and quality of life of many heroin addicts. Evidence also exists \((17)\) that interventions of psychosocial support have a good cost-benefit ratio if they are of modest entity, such as generic counselling. More intensive interventions are more expensive than useful where the diagnosis is of drug addiction not complicated by comorbidity, psychosocial situations particularly compromised, or severe polyaddiction.

Some patients present heroin addiction associated with one or more of the above-mentioned conditions. They are the so called “non responders”, for whom MMTP does not produce the expected results \((18-20)\).

Most of quality clinical practice is concerned with these patients, who represent a minority of the users but who have complex and severe clinical pictures.

An important quality goal in MMTP programs should be the identification of the problems of these patients and the development of tools to improve the services provided. For example, there are cases in which the dose of methadone has to be increased for pharmacological or clinical reasons, such as in the case of contemporary administration of nevirapina \((21)\) in patients with AIDS-related pathology, or in the case of severe psychiatric comorbidity \((22)\). In other cases, complementary treatments such as counselling, psychotherapy, and social or rehabilitative interventions are necessary to cope with specific problems of the patient and to improve the prognosis and the outcome of MMTP \((23-26)\).

Finally, there are situations in which the improvement of the rate of ‘responders’ is associated with organizational or communication factors. The cultural reference system – that is the epistemology with respect to methadone treatment – is important not only
A. Flego: Methadone and treatment quality. The EFQM Excellence Model

for the workers but also for the patients and their environment. The influence of the peers, also with respect to the credibility of the service, can be important to improve or not the outcome of MMTP.

Similarly, to give a picture of definite and reassuring rules to the patients with greater motivation or to strongly prevent patients from breaking a positive environment with a critic or instrumental attitude may increase the rate of the “responders”.

The problem of the “non responders” should be dealt with according to an algorithm that can be formulated as follows:

1. To identify pharmacological causes (inadequate dosage, necessity of greater doses for particular problems) and corrective actions.
2. To identify organizational causes (relationship and communication with the patient) and introduce corrective actions.
3. To identify particular problems of the patient, such as comorbidity (organic or psychiatric), stress or situations of social discomfort, or presence of poly-addiction and activate other medical, social, and psychiatric interventions (intensive if necessary).

If none of the above-mentioned problems exists or if corrective actions has been successfully activated, the remaining cases of “non responders” represent, maybe, the not eliminable part of the phenomenon. However, at the end of the circular process of quality improvement, their number could be much more lower than the initial one.

The diachronic study of “non responders” in a service providing MMTP can offer an important representation of the characteristics of the customers and of the functionality of the service, and represents a crucial element for benchmarking.

**Conclusions: state of the art and open issues**

The search for quality is a never-ending, dynamic process, and excellence itself is not definitive. As it has been demonstrated, it is a circular process that has to progressively improve the performances but also to defend itself from the natural entropy of not-managed situations (it has to continually introduce “negative entropy”). Finally, this process has to continually take into consideration innovations and new knowledges or ‘scientific evidences’.

In my opinion, the EFQM model is more functional than others to the activities of addiction services, in particular those providing MMTP. In fact, these activities are at high rate of methodological uncertainty (the human factor is always dominant with respect to specifications and procedures) and require creativity and team spirit.

Moreover, this model shows the directions to follow and the goals to achieve, while allowing great freedom in the choice of the modalities to act. It is evident that an organization has to harmonize individual initiative in a common project. Therefore, there will not be individual paths to quality but paths of an organization, and the benchmarking will be based on the results achieved rather than on procedures adopted.

In our case, the “state of the art” identifies the organizational and operative modali-
ties that achieve the higher rate of responders to MMTP and /or greatly reduce the rate of non responders among the more problematic patients (27-40).

Obviously, it is not a static and universal definition, but it is subject to continuous evolution. It is the result of the comparison of “the state of the art” of several organizations that measure themselves in a continuous action of benchmarking and choose as point of reference scientific literature. It is, as stated by the EFQM model of excellence, a definition of “good practices” continually proposed to other people working in the same field.

In this continuous search for quality, many issues remain open. In particular, three problems greatly influence the daily work of addiction services.

The first problem is the little flexibility of methadone, which continues to be the drug of choice, but which requires a daily administration, with the consequent organizational problems. With regard to this, it should be pointed out that the real or presumed superiority of LAAM has not been tested in Italy (41). If LAAM is effective even in a small number of patients in MMTP, the fact that it has not yet been introduced means an increase of costs, in human, organizational and financial terms.

The second problem is the need for research, innovation and experimentation in the management of non responders, the number of whom has to be progressively reduced.

The third problem is the problem of ‘entrusting’ methadone. The degree of reliability of the patients should be better defined and better procedures, flow charts and protocols should be planned to decide how much methadone can be taken away, with what modalities and to whom.

In fact, from the therapeutic point of view, it is disadvantageous not to give a patient the possibility to responsibly manage its therapy. However, it is equally detrimental to trust a patient who is not able to responsibly manage his own therapy.

In the prayer of the anonymous alcoholics, they ask the ‘superior being’ for help to face what they can face, to accept what they are not able to face and to distinguish between the two situations. We, therapists of drug addiction, need help in this “understanding” and “distinguishing” action. And our superior being can be represented in part by a good model of continuous search for quality, scientifically based and shared among the professionals.

References

52(3):183-192.


(Footnotes)

All shareware documentation on EFQM can be found at: www.efqm.org, verified in October 2003.

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Treatment of Chronic Hepatitis C Virus Infection in IntravenousDrug Addicts: State-of-the-Art

Vincenzo Guadagnino¹, Maria Paola Trotta², for the “Nocchiero” Study Group

Summary

Injection drug users (IDUs) are the largest group of people infected with the hepatitis C virus, and the group among whom most new infections occur. Treating chronic hepatitis C in IDUs is important at an individual level and from a public health perspective. Treatment with a combination of pegylated interferon and ribavirin eradicates the virus in a high percentage of patients depending on the HCV genotype. Unfortunately, HCV-positive IDUs are rarely offered this treatment because of their assumed lower compliance with treatment, psychiatric comorbidities, social discomfort and the risk of reinfection. However, there is increasing evidence that IDUs treated for HCV infection can achieve a sustained virological response comparable to that of non-IDUs. It has also been shown that drug addicts with HCV infection can benefit from anti-HCV treatment if it is given within the framework of a multidisciplinary standardized model of care. In this scenario, prospective clinical trials are warranted to establish new guidelines for the treatment of HCV infection in patients with drug dependence.

Key Words: HCV infection - Treatment - Clinical Issues - Drug Dependence

Introduction

Chronic HCV infection is the leading cause of chronic liver diseases, including cirrhosis and cancer; 170 million people worldwide are infected. Injection drug users (IDUs) are the largest group of people infected with hepatitis C virus, and the group among whom most new infections occur. Moreover, IDUs represent a particular challenge in the management of chronic HCV infection because of their assumed lower compliance with treatment, psychiatric comorbidities, social discomfort and the risk of reinfection. However, there is increasing evidence that IDUs treated for HCV infection can achieve a sustained virological response comparable to that of non-IDUs. It has also been shown that drug addicts with HCV infection can benefit from anti-HCV treatment if it is given within the framework of a multidisciplinary standardized model of care. In this scenario, prospective clinical trials are warranted to establish new guidelines for the treatment of HCV infection in patients with drug dependence.
degree of adherence to treatment, their psychiatric comorbidities, social discomfort and risk of reinfection. However, treatment of chronic hepatitis C in IDUs is important both at an individual level and from a public health perspective. The National Institutes of Health recognized that drug addiction should not qualify as an *a priori* criterion for HCV-treatment exclusion, and stressed that management of HCV-infected IDUs is more effective if the patients are enrolled in drug treatment programmes ¹. Given the large body of evidence that IDUs affected by HCV can benefit from treatment ², prospective clinical trials are warranted to verify this observation and to establish treatment guidelines for this specific population.

**Prevalence and Natural History of HCV Infection among IDUs**

The overall prevalence of HCV infection in the general population is estimated to be between 1 and 2.4%, but this rate increases to 40-95% among IDUs in developed countries ³. The risk of infection is extremely high among IDUs who share needles or other equipment: the percentage of those who become infected is between 50% and 80% after one year of drug use, and nearly all IDUs have become infected after 8 years of drug use ⁴.

Active drug users are therefore the primary source of new HCV infections, both within this category of individuals and in the overall population (sexual partners, household contacts, etc.). Moreover, it has been demonstrated that IDUs tend not to change their behaviour after disclosure of HCV infection and continue to be a risk to others ⁵. Thus, people with current or past substance abuse should be informed about HCV infection and should be screened for it.

There are very few studies about the natural history of HCV infection in people who pick up the infection from injection drug use, mainly because of methodological concerns. Firstly, IDUs are not usually treated for HCV infection in academic centres, where most natural history studies have been conducted. In addition, IDUs rarely undergo liver biopsy to monitor the stage of liver fibrosis and can be difficult to monitor longitudinally ⁶. Rai and colleagues ⁷ studied the incidence of end-stage liver disease and the clinical expression of cirrhosis in a cohort of 1667 IDUs in Baltimore, and found that severe liver disease is uncommon, especially in young people. Even though HCV infection generally progresses slowly in young IDUs during the first 10 years of infection ⁷, its prognosis could be unfavourable because of poor nutritional status, alcohol abuse, multiple infections and superinfection with known or unknown viral agents ⁸. Additional research is needed to identify markers of liver fibrosis and to elucidate the mechanism of fibrosis progression in HCV-infected IDUs.

**Treatment of HCV Infection Among IDUs**

Up to 1998, interferon (IFN)-α was the only effective treatment for HCV infection. In 1998, the combination of IFN-α (administered three times a week subcutaneously)
and ribavirin (in a orally twice a day dose) was found to improve the rate of sustained virological response (defined as negative HCV RNA 6 months after treatment completion) \(^9,10\). At a later stage, two types of pegylated interferon (INF-α-2a, and INF-α-2b) with a longer half-life became available, and subcutaneous administration was cut down to once a week. Combined therapy with pegylated interferon and ribavirin was reported to be significantly more effective than non-pegylated interferon; it resulted in a sustained virological response in 51-56% of patients with HCV genotypes 1 and 4, and in 76-82% of patients with HCV genotypes 2 and 3 \(^11,12\). Treatment duration differs according to genotype: 48 weeks are required in HCV genotypes 1 and 4, whereas 24 weeks is sufficient in HCV genotypes 2 or 3.

Although the combination of pegylated interferon and ribavirin seems to eradicate the virus in a high percentage of patients, it appears that few HCV-positive IDUs are offered this treatment \(^13\). Hagan et al. \(^14\) recently concluded that among 404 HCV-positive IDUs aged 18-35, only 4% would be offered treatment if those with problem drinking, moderate-to-severe depression, or recent injection drug use were considered ineligible \(^14\). It is feared that treatment efficacy among IDUs might be affected by various socio-demographic and behavioural characteristics, namely, a low level of willingness to enter treatment, a poor degree of adherence, adverse events (particularly psychiatric events), psychiatric comorbidities, social discomfort and reinfection \(^15\). As a result, almost 50% of HCV-infected IDUs do not receive any treatment, despite fulfilling medical criteria for antiviral therapy of chronic hepatitis C \(^2\). Indeed, in the late 1990s, directives for the management of HCV infection recommended not treating HCV-infected subjects who had a history of active drug addiction \(^16,17\). It was not until 2002 that the National Institutes of Health declared that drug addiction must not be adopted as an a priori exclusion criterion, and recommended that treatment of drug addicts affected by chronic HCV be associated with detoxification programmes \(^1\). Two years later, an American Association for the Study of Liver Disease practice guideline recommended that “treatment of HCV infection should not be withheld from persons who currently use illicit drugs or who are on a methadone maintenance program, provided they wish to take HCV treatment and are able and willing to maintain close monitoring and practice contraception” \(^18\).

These recommendations are based on growing evidence that HCV-infected IDUs can benefit from antiviral treatment. In fact, 36% of abstinent IDUs \(^19\) and 54% of patients on maintenance therapy for drug abuse \(^20\) achieved a sustained virological response with interferon alone or in combination with ribavirin. This is in line with reviews in which it was concluded that sustained response and acceptance of treatment in patients engaged in detoxification programmes were comparable to those in control groups and to those observed in representative clinically controlled trials \(^2,21\). Moreover, in the only prospective study of combined therapy with pegylated-interferon plus ribavirin among patients on methadone maintenance, Mauss and colleagues \(^22\) found no difference in sustained virological response to the treatment combination between patients on methadone maintenance and a control group. However, treatment discontinuation
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in the first 8 weeks of therapy was higher in patients on methadone maintenance (22%) than in controls (4%). After the first 8 weeks of therapy, discontinuation rates did not differ between the two groups, and 50% of patients prematurely discontinued treatment in the methadone group.

Although these studies provide evidence for treating HCV-infection in patients with drug dependence, prospective clinical trials are needed to establish anti-HCV treatment guidelines for IDUs that take into account the supposedly lower willingness to undergo treatment, the frequent presence of psychiatric disorders and the risk of reinfection.

**Willingness to enter treatment**

As is true of all chronic diseases, the success of chronic HCV infection treatment depends mainly on willingness to accept medication. Among patients with HCV genotype 1, adherence (defined as the use of at least 80% of the prescribed therapy for at least 80% of the expected treatment time) was associated with a greater probability of virological success: 63% of patients who complied with treatment versus 52% who were non-compliant. McHutchison et al. reported a direct relationship between adherence and virological response: adherence levels at least equal to 80% of the prescribed therapy determined an increase in the probability of sustained virological success, namely, from 44% to 52% for therapy with interferon/ribavirin, from 54% to 63% for therapy with pegylated-interferon/ribavirin, and from 61% to 72% for therapy with pegylated-interferon/ribavirin (with dose adjustment according to body weight).

Few studies have investigated the impact of non-adherence to anti-HCV treatment on therapeutic outcomes among IDUs. From the data available on adherence to medication in infectious diseases other than HCV, mainly HIV infection, IDUs were not more likely to refuse treatment than other groups of patients. In a review of predictors and correlates of non-adherence to antiretroviral medication in HIV infection, Ammassari and colleagues reported that a history of intravenous drug use was not consistently associated with non-adherence. This finding was confirmed on the acceptance of anti-HCV therapy. In a prospective study of 50 drug addicts included in maintenance programmes, Backmund et al. reported high percentages of response to therapy and that keeping of at least 2/3 of appointments, which is indicative of a higher degree of adherence, was a predictor of a sustained virological response. Moreover, the report of a good virological response in subjects with drug dependence suggests that good levels of adherence can be achieved in this subset of patients, particularly when medical care is well integrated with treatment for substance abuse.

Important issues include the correlates and predictors of non-adherence to anti-HCV treatment among IDUs. Non-adherence to treatment is now recognized to be an extremely complex phenomenon involving factors related to the patient, the disease, its therapy and the physician-patient relationship. Psychiatric comorbidities and depression disorders play a particularly important role in adherence to treatment among HCV-infected IDUs, because of their high prevalence in this setting and the implications at a behavioural level.

For chronic diseases other than HCV infection, it is well documented that depres-
sion is an important risk factor for non-adherence to treatment: in a metanalysis that examined the impact of depression on attitude and adherence to treatment, depressed patients had a risk of non-adherence that was three times higher than that of patients without depression. Various studies, including a cohort study of Italian patients, have demonstrated a correlation between depression and non-adherence to antiretroviral drugs. In addition, more severe depressive symptoms were associated with an increased risk of disease progression and death, independently of socio-demographic characteristics, drug abuse and other clinical variables. Nevertheless, because most of these studies were cross-sectional, we cannot draw causal inferences about the association between depression and non-adherence to treatment.

The relationship between depressive disorders and adherence to therapy has not been widely studied in the context of anti-HCV therapy. In a prospective study of therapeutic efficacy, adherence to treatment and neuropsychiatric side-effects, Schaefer et al. did not find any significant difference in the endpoints between a group of patients with previous psychiatric disease and control groups. Interestingly, the incidence of drop-outs and therapy discontinuation was lowest in patients with a psychiatric history; indeed, none had to discontinue treatment because of neuropsychiatric side-effects. We recently investigated the impact of depression disorders and self-reported adherence to treatment on the effectiveness of anti-HCV antiviral therapy. The investigation was conducted within the framework of the Nocchiero study, which is an Italian multicentre prospective cohort study on the efficacy and tolerability of the treatment of HCV-infection with pegylated-interferon alpha-2b and ribavirin in interferon-naïve drug addicts receiving opioid maintenance therapy. It was conducted in collaboration between 11 detoxification units (National Health Service Managed Drug Treatment Services; SerT), and 6 clinical centres for the management and care of infectious diseases and HCV. Out of 53 patients enrolled in the study, 43 patients completed a self-report questionnaire about depression symptoms (Centre for Epidemiological Studies–Depression Scale; CES-D). In this subgroup, 28.1% of patients reported attitudes of non-adherence; in 12.5% of these cases, non-adherence was directed to pegylated-interferon, in 21.9% to ribavirin, and in 6.3% to both drugs. The higher rates of non-adherence to ribavirin versus interferon may be because interferon was given weekly at the SerT, whereas ribavirin was taken by the patients themselves. We did not find that depression symptoms evaluated at the beginning of treatment significantly affected adherence, at least as far as the first quarter of therapy was concerned. This result is important, because good adherence in the first three months of therapy results in an early virological response, which, in its turn, is associated with a sustained response.

Taken together, these findings suggest that individualized programmes designed to address the particular needs of IDUs, and integrate medical care with treatment for substance abuse can achieve high rates of adherence.

**Tolerability and side-effects**

Combined interferon and ribavirin treatment for HCV infection is complex and is associated with adverse reactions. In the registration trial of pegylated interferon and
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ribavirin, side-effects caused treatment discontinuation in 10-14% of patients. The major side effects of the combination therapy are flu-like symptoms, haematological abnormalities, and neuropsychiatric symptoms. Up to 50% of patients receiving treatment with interferon may experience adverse neuropsychiatric effects, especially depression. Other adverse neuropsychiatric effects are anxiety, cognitive slowing, impaired concentration and insomnia, all of which are also symptoms of a major depressive disorder.

Neuropsychiatric disorders, especially depression, are the most challenging side-effects when treating IDUs because of the high prevalence of pre-existing or concomitant psychiatric problems in these patients and the potential for a detrimental effect on adherence to treatment.

Comorbid psychiatric symptoms and drug abuse are the most frequent reasons not to treat IDUs for HCV infection. These exclusion criteria were adopted because of concerns that interferon may worsen underlying psychiatric illness, which could result in premature discontinuation of antiviral treatment, non-adherence to treatment, suicide, and violence toward others. However, it is now recognized that patients with stable psychiatric illness who are engaged in mental health treatment can successfully complete treatment with interferon for HCV infection. In a prospective study of therapeutic efficacy, adherence to treatment and neuropsychiatric side-effects after HCV treatment in former drug addicts, methadone-replacement subjects, and patients with severe chronic psychiatric disorders versus an HCV-infected control group, there were no differences in the study endpoints between patients with previous psychiatric disease and the control group. Moreover, antidepressant treatment seems to be effective in preventing major interferon-associated depression in HCV-infected patients. However, larger, controlled randomized trials are required to verify if this strategy results in a better response to antiviral therapy.

In the Nocchiero Study, when we investigated the impact of self-reported depression disorders (through the CES-D scale) on the effectiveness of anti-HCV antiviral therapy, we found that the mean CES-D score at enrolment (17.3 SD ± 11.06) did not change substantially after 4 (mean: 19.1; SD+10.9) or after 12 (mean: 17.8; SD+10.4) weeks of HCV therapy, and did not impair the virological response to therapy during the first 3 weeks of treatment. Patients who clearly showed a depressive attitude had a significantly higher grading of symptoms and/or side-effects (mean: 14.2± 4.46 SD) than patients with a CES-D score below 16 (mean: 7.42 ±3.82 SD; t-test P <0.0001). Moreover, self-reported side-effects were associated with early discontinuation of anti-HCV treatment. Indeed, subjects reporting a higher symptoms/side-effects score had a greater probability of early treatment discontinuation (OR 1.33; 95% CI 1.02–1.71; P=0.03) than did subjects reporting a lower score. A previous study of IDUs affected by acute hepatitis C showed that patients experiencing or fearing side-effects were at a greater risk of treatment refusal and/or premature withdrawal.

These findings highlight the relevance of subjectively identified symptoms, regardless of their clinical importance, and suggest that the management of side-effects is
critical to treatment efficacy during the first weeks of therapy. A symptom checklist drawn up by patients would help to identify the onset of side-effects and be helpful to physicians in guiding their dialogue with patients regarding these symptoms, their causes, and possible treatment. This approach may be particularly useful for difficult-to-treat patients such as drug abusers.

**Risk of Reinfection**

A major concern about treating HCV infection among IDUs is that patients in whom the virus has been eradicated may become re-infected. HCV infection does not confer protective immunity, and cases of reinfection have been reported. Therefore, patients who continue to be exposed to the virus risk reinfection, and this risk is estimated to be the same as that for drug users who have never been infected. In a study of the frequency of superinfection among highly exposed IDUs, Herring and colleagues reported that HCV superinfection in IDUs, both intra- and inter-genotype, is a frequent event (20% in the cohort), with an incidence rate similar to that of first-time infections. This finding suggests that no cross-protecting immunity develops during the first year of chronic infection with HCV. Although the real prevalence and clinical consequences of HCV superinfection remain unknown, it should be stressed that infected persons and those whose viremia has been eradicated by antiviral therapy should protect themselves against subsequent HCV exposure.

**A Model Integrating Drug Abuse Detoxification and HCV-Treatment**

Previous studies and our own experience indicate that an effective strategy in the treatment of HCV infection in IDUs is to start treatment during detoxification or methadone maintenance, under the supervision of physicians specialized in hepatology and addiction medicine.

In this context, we devised and applied a strategic standardized model that integrates drug abuse detoxification and HCV treatment. We first identified multidisciplinary teams made up of specialists in infectious diseases from 6 reference clinical centres, specialists in the treatment of drug addiction (working in detoxification services: SerTs), a consultant psychologist or psychiatrist and at least one nurse from each reference site and from each SerT. Six teams were identified. Representatives of the clinical centres and SerTs drew up a standardized protocol for the management of antiviral treatment. After a preliminary phase in which the methodology was shared and regular meetings were scheduled to monitor teamwork, each SerT identified subjects engaged in addiction therapy programmes who had known for at least six months that they were anti-HCV-positive. These subjects were offered screening to confirm viral infection and to assess the severity of chronic HCV hepatic disease. Subjects identified in the preliminary screening received counselling about their health status, the characteristics and risks of the natural history of chronic C hepatitis, and the benefits and potential side-effects of antiviral treatment. They were then referred to the reference clinical centre for more detailed screening (HCV RNA definition, genotype analysis and assessment of bio-hu-
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moral and immunological parameters to verify treatment eligibility), for clinical evaluation and liver biopsy. When chronic hepatitis was diagnosed and counter-indications to treatment were excluded, the reference clinical centre prescribed anti-HCV treatment and the patient underwent pre-treatment screening for depression with the CES-D. The IDU was then referred back to the SerT and started treatment with pegylated-interferon, administered subcutaneously once a week at the SerT, and ribavirin treatment, which was taken daily at home. The SerT also monitored laboratory parameters, side-effects, treatment adherence and depression symptoms. The SerT referred subjects to the clinical reference site for clinical controls during treatment and follow-up.

In this multidisciplinary team setting, specialists with different types of competence promote good relations with the health care structure by helping drug addicts with their problems. The collaboration between specialists in infectious diseases and in addiction medicine, as well as psychologists, allows us to assess a patient’s “readiness” to start treatment and to ensure support for the patient throughout the treatment programme. Patients were informed about the rationale and terms of therapy, and about the potential for the onset of adverse effects. Moreover, the weekly consultation at the SerT provided an opportunity to monitor and reinforce motivation, and adherence to treatment.

Through this multidisciplinary approach, we treated 53 IDUs engaged in detoxification programmes. The results were very satisfactory, namely, 58.5% of patients had an end-of-treatment virological response, and 54.7% a sustained virological response.

In conclusion, based on previous studies and our own experience, it should be stressed that drug addicts with HCV infection may benefit from anti-HCV treatment if this is given within the framework of a multidisciplinary standardized model of care. Moreover, our results support the feasibility and efficacy of a multidisciplinary standardized model of care in treating chronic hepatitis C among drug addicts.

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Appendix

The participants in the “Nocchiero” study groups are listed below:

Benevento: Infectious Diseases Unit A.O. “Rummo” (G. Maio, G. D’Alessio) and Ser. T. (V. Biancolilli); Catanzaro: Chair of Infectious Diseases and Postgraduate School of Infectious Diseases, University “Magna Graecia” (V. Guadagnino, J. Carioti, B. Caroleo) and Chair of Pharmacology, University “Magna Graecia” (G.B. De Sarro) and Ser. T. (B. Grande, G. Audino); Civitacastellana: Ser.T. (A. Lagrutta); Corigliano Calabro: Ser.T. (A. Di Noia); Cosenza: Infectious Diseases Unit A.O. “Annunziata” (L. Guaglianone, S. De Santis) and Ser.T. (F. Magnelli); Crotone: Infectious Diseases Unit A.O. of Crotone (N. Serrao); Ser.T. (G. Paluccio); Enna: Infectious Diseases Unit A.O. of Nicosia (M. Sapienza) and Ser.T. (M. Parisi); Rome: National Institute
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