Substance Use & Misuse, 48:943–953, 2013

ISSN: 1082-6084 print / 1532-2491 online
DOI: 10.3109/10826084.2013.797722

informa
healthcare

ORIGINAL ARTICLE

Stakeholders' Role in Contemporary "Substitute Drug" Prescribing Policies in Italy

Franca Beccaria[1] and Sara Rolando[1,2]

[1]*Eclectica, Research and Training Institute, Turin, Italy;* [2]*University of Helsinki, Helsinki, Finland*

This article, part of a comparative research project (WP2) funded by FP7 ALICE RAP, is based upon a review of literature and documents and 18 individual interviews with Italian national stakeholders (SHs) conducted in 2012. The goal was to identify the main shifts in opioid "substitution drug" treatment policies and understand the role played by different SHs during the last 30 years. The study confirms that opioid "substitution drug" treatment is a particularly suitable theme for improving knowledge in the field of SH analysis, even if results show that changes in policies are mainly due to external factors rather than to the action of SHs.

Keywords: agenda-setting, policy window, stakeholder analysis, "substitution drug" treatment, "substitution drug" treatment policies

INTRODUCTION

Political analysts have become more and more aware of how interests and power distribution impact on decision-making during the last decades; the importance of actors and interests groups in the policy making process has clearly emerged (Brugha & Varvarosky, 2000). Drug use(r) intervention policies constitute a particularly complex and interesting arena for stakeholder (SH) analysis as it "involves different types of practices: legal, social, and medical, which are carried out by different institutions and each in their own way contribute to the creation of social order and the distribution of risks and resources" (Houborg & Bjerge, 2011, p. 16). Political rationalities (Rose, 1996), meaning views about how government should address drug-related problems, conflict and follow one another over the years; they can and do involve moral judgments and many risks and costs for society and for health (Houborg & Bjerge, 2011).

The changes in Italy's drug user substitution treatment policies, described in this article, can be better understood from the perspective of Kingdon's (1984) classic contribution about the agenda-setting process. He posited that the process through which an issue get on a policy-making agenda entails three factors:

- problem stream (an issue is recognized as being important and significant and attracts the attention of policy makers),
- policy stream (effective policy ideas or proposals are developed)
- political stream (the wider political environment of elections, government changes, and public opinion, . . .).

In certain situations, the coupling of these three independent processes led to a policy window. This is an opportunity for the introduction of new views about the problem and/or of new policies: "a problem is recognized, a solution is developed and available in the policy community, a political change makes it the right time for policy change, and potential constraints are not severe" (p. 174). Policy windows occur mostly, because of a change in the political stream or because a new problem has arisen, and they offer an opportunity for policy entrepreneurs or SHs to influence new policies (Kingdon, 1995).

Substitution treatment represents an emblematic subject to be discussed looking at the role of SHs on policies, since it is one of the most widely discussed intervention-related topics in Europe and constitutes a matter of considerable political and public interest (EMCDDA, 2000). Notwithstanding that substitution treatment has developed progressively in Europe since its introduction in the 1960s (EMCDDA, 2000) and is currently quite widespread and accepted, the political debate about it has been cyclically very intense. It moved into the spotlight during the mid-1990s and clearly presented the different involved

Participant organizations in Addictions and Lifestyle in Contemporary Europe—Reframing Addictions Project (ALICE RAP) can be seen at http://www.alicerap.eu/about-alice-rap/partner-institutions.html

Address correspondence to Franca Beccaria, Eclectica, Training and Research Institute, via Silvio Pellico 1, 10135 Turin, Italy; E-mail: beccaria@eclectica.it.

interests, their SHs, their (inter)-relationships and their sources of influence as well as lack of.

In Italy opioid substitution treatment became permissible in 1975, in parallel with the institution of specific addiction treatment services, which became law and regulated from 1980, albeit with a great variation through the country (EMCDDA, 2000). Italy' current national system is organized through 1630 structures or programs. These include 563 "Servizi per le dipendenze" or SerD, local drug user services operating on an outpatient basis and 1067 sociorehabilitation units. The latter include, mainly, therapeutic communities (TCs) which represent 66.4%, semiresidential services (17.9%) and outpatients services (15.7%) (Dipartimento delle Politiche Antidroga, 2012). There are also a minor number of private organizations, mainly of religious orientation, which run private TCs independently from the public health system and are not always included in the official statistics (Coletti & Grosso, 2011). An effort to standardize the information system is ongoing, but in fact there are still no official data on the number of patients treated by these private services; a consequence, perhaps because some of them operate independently of the public service. The number of pharmacological based-treatments provided by local public drug user treatment addiction units (SerD) has grown steadily over the past 20 years, reaching 186,073 deliveries of services-care in 2010 (which represent the 66.6% of the total treatments), divided into methadone (75.1%), buprenorphine (13.6%), other non-opioid-substitute drugs (10.4%), naltrexone (0.5%), and clonidine (0.4%) (Dipartimento delle Politiche Antidroga, 2012).

Regional governments in Italy are in charge both of the health system as well as the organization of the addiction treatment system. National coordination is the responsibility of, and is monitored by, the Conference of Regions, and the Anti-Drug Policies Department, which is part of the Presidency of the Council of Ministers. This constitutes an example of a "cross-cutting" policy structure which attempted to integrate policy responses to the "drug problem."

The main aim of this Italian study is to provide an account of the role of different SHs from the 1980s until the present, highlighting the policy windows and the factors and the necessary conditions that have influenced the political agenda-setting process (Kingdon, 1995). SHs based upon the position of Varvasofsky & Brugha (2000), are "actors who have an interest in the issue under consideration, who are affected by the issue, or who—because of their position—have or could have an active or passive influence on the decision-making and implementation processes. They can include individuals, organizations, different individuals within an organization, and networks of individuals and/or organizations" (p. 341).

An historical background of substitution drug user treatment in Italy during the last 30 years has been retraced in order to better understand the role(s) of relevant SHs within the context and the culture in which the analysis is conducted. This is based on bibliographical and documentary research, which means mostly medical and legal literature. Relevant sociological studies are not available on this specific topic. The secondary sources have been integrated with opinions by the same SHs, in order to identify and analyze policy windows which have determined shifts in drug policies. Thus, the article describes the history of Italian SHs' in Italy's "substitution drug" treatment policies and provides a description of influences, alliances and conflicts as they have been noted in the literature and perceived and described by the interviewees. It also highlights how some SHs seized the opportunity given by policy windows to improve their roles and their approach to substitution treatment.

METHOD AND SAMPLE

An initial list of Italian key SHs was developed through a preliminary research literature search of books, scientific articles, and grey literature[1]. A snow-ball method was used to identify other key-informants (KIs) in the area of opioid dependence treatment until the data saturation was been reached (Gleser and Strauss, 1967) and interviewees began to suggest the same KIs who were already in the sample.

Two of the planned interviews were not implemented because these SHs stated they did not have the time to do so: a representative of the DPA and a priest responsible for a Catholic TC. The 18 final interviewees represent a broad range of "actors" and interests active in the Italian drug user treatment-intervention field (Table 1).

Qualitative semistructured interview methods were used. They were modified and adapted over time in order to more accurately understand SHs' opinions, intentions, interrelationships, and agendas about substitution treatment. Interviews were conducted face-to-face, by telephone or by Skype and lasted about 1 hr each. All of the interviews were audio taped and transcribed, and then analyzed with Atlas.ti 5.0, a qualitative analysis software package. Confidentiality and anonymity were guaranteed to the participants and it was agreed with each one the way in which they prefer to be quoted, without their being recognized, or at least minimizing that possibility of. No major ethical issues were encountered.

All the interviews were conducted between February and April 2012.

RESULTS

The materials from these interviews were analyzed using the three sets of process categories suggested by Kingdon (1984). At "critical times" the independent streams come together and are coupled, that is some proposal "floating" in the policy stream enters in the governmental agenda because it is seen as being a solution to a pressing problem. In the past in Italy one major pressing problem pushed the policy window to open, the HIV/AIDS epidemic, and more recently the economic crisis is pressing the system again. Times of crisis often give policy entrepreneurs the

[1] For example, official reports, guidelines, and ministerial newsletters.

TABLE 1. Stakeholders' sample

Stakeholders	No. of interviews	Role
Treatment providers: public addiction services (SerDs)	2	Heads of two local addiction departments of different regional capitals (metropolis)
TCs (national upper organizations)	2	Presidents of two II national level organizations of CTs
Therapeutic communities/ONGs	4	Presidents of different TCs or NGOs which provide different services, including TCs
Scientific societies (professional groups)	3	Presidents of the three main Italian scientific societies representing, mainly, public addiction services professionals and employees
University/scientific community	2	Clinical and epidemiologist researchers
General practitioners	1	A pioneer of a local model of outpatient treatment
Pharmaceutics industry	1	Head of a clinical research unit
Advocacy organizations	2	Member of a national association against prohibition and for the rights of consumers (responsible for a informative magazine). Member of one of the (few) Italian groups of drug users.
Criminal justice system	1	Magistrate, President of a court

opportunity to raise and express their ideas and/or policy about confronting the problem. Figure 1 schematized this process.

The Role of SHs in the First Policy Window: The Nineties

In order to better appreciate, and understand, the heated debate which arose during the 1990s it is necessary to consider what the problem stream and the policy stream were during the 1980s.

At that time, the prevalent culture considered heroin dependence as being, and as representing, sociopathy that had to be treated primarily in TCs, which appeared in Italy during the 1970s, using educational and/or psychosocial methods in combination with religiosity (Coletti & Grosso, 2011). Religious leaders were the major SHs in this process. Staff usually consisted of volunteers and peer educators often without any specific training and no professionals. This "phase of uncritical de-medicalization" (Gatti, 2004) has also been defined as "the myth of TC", in which the community was considered to be the indicated and consensualized, "invariable prescription" for addiction and drug user treatment; even by Italian medical doctors and societies. The number of TCs increased exponentially during the 1990s, reaching its peak (1372) in 1996 (Coletti and Grosso, 2011). At that time, TCs were clearly against the use of substitute medicines for treating addicts. Most of the public opinion, influenced by the media, thought that segregation and coercion were necessary for recovery (Montecchi, 1999).

TCs, and in particular the Catholic ones, have been criticized by the interviewed KIs of SerDs for having

	PRE 1993		POST 1993		SINCE 2006
Stakeholders (grade of influence)	SerDs ● TCs ●●● Policy makers ●●● Church ●●● Researcher/scientist ● Advocacy organizations ● Pharmaceutical industry ●	***Turning point*** *- AIDS epidemic* *- introduction of the concept of "harm reduction"* *- referendum*	SerDs ●●● TCs ● Policy makers ● Church ● Researcher/scientist ●● Advocacy organizations ● Professional/scientific associations ●●● Pharmaceutical industry ●●	***Turning point*** *- 49/2006 law (repressive)* *- reduction of resources* *- new type of consumers* *- decline of the public debate*	SerDs ●● TCs ● Policy makers (DPA) ●● Church ● Researcher/scientist ● Advocacy organizations ● Professional/scientific associations ●● Pharmaceutical industry ●●
Conflicts	TCs/ SerDs		SerDs /TCs		National/local policies Policy makers (DPA)/treatment services Health workers/social workers
Partnership	Policy makers/TCs		Pharmaceutical industry/SerDs Pharmaceutical industry/scientific community		SerDs/TCs TCs priv/policy makers Pharmaceutical industry/SerDs Pharmaceutical industry/scientific community
Treatment aims	Abstinence (rehabilitation)		Harm reduction		(Questioning of) harm reduction
Treatment methods	Psycho-social methods (short-term)		MMT Integration of pharmaceutical and psycho-social treatment		MMT Less integrative treatment

● grade of influence, range: 1to 3

FIGURE 1. Changes in stakeholders' positions and power in the field of drug-substitution treatment policies

demonized the MMT treatment and for causing great damage to addicts. They have been also depicted as being *"enterprises dealing with business more than addiction" (KI from a professional/scientific association)*. According to some key informants belonging to the scientific world, there was at that time—and it continues to exist—"*a very direct connection between politicians and these communities"*. Some groups had more relevance with regard to drug user treatment policies depending on the make-up of Italy's different governments[2]. The influence of TCs is also attributed to their economic power—they were well funded—to the point that the interviewed magistrate has compared them to *"theocon"* organizations.

Since opioid dependence was defined, mainly, as being a moral failing, methadone was used during this period *only* for detoxification in hospitals and specialized centers. Relapses to drug use were very high. Furthermore, the synthetic opiate methadone, created to relieve physical pain, was used as sort of a reward and punishment by care givers, who excluded the relapsed patients from the treatment (Mannaioni, 1980). Even if scientists tried to disseminate MMT American studies (Dole & Nyswander, 1965, 1967) and to re-define the problem of "heroinism" as a chronic relapsing disease (Mannaioni, 1980), the role of neuropharmacology and clinical toxicology was quite marginal in planning and implementing Italy's drug user treatment. The Ministry of Health established laws and regulations restricting methadone dosage. For example the maximum doses—40 mg/die (Strepparola, 2005)—were based more on ideological/bureaucratic consensus than pharmacological scientific principles of titration (Fogaroli, Agnelli, & Cicciò, 1999).

Indeed, also local and national politicians, sensitive to public pressure, exploited the topic.

> In the past many SHs increased their power through their fight against the use of methadone and some [politicians] have built their electorate (KI from private/accredited TCs).

Many interviewees remember the slogan "methadone, State's drug" as being effectively used by the right wing parties and movements and as a good advertisement for TCs. The TC's, at that time, had most of the drug user treatment resources and visibility and were organized into national organizations (FICT—Italian Federation of TCs, of Catholic orientation, founded in 1981, and CNCA—National Coordination of TCs, with a more secular orientation, founded in 1982), while Italy's public services were not yet well structured during this period and did not have a clear identity (doctors had temporary contracts and there were no real multidisciplinary teams).

Notwithstanding this "stable" context, especially between 1986 and 1996 when the HIV/AIDS epidemic exploded (Coletti & Grosso, 2011) there was a big impact on Italian public opinion and "national mood" (Kingdon, 1984) regarding drug user treatment, which effected the political stream. All KIs agree on the major role played by the HIV/AIDS epidemic on substitute drug treatment policies, since HIV/AIDS involved mainly drug users, killing thousands of them. This soon became part of the "problem stream", (Kingdon, 1984). It was recognized by influential SHs and required attention by policy-makers. It also unchained a series of other events which pressed methadone maintenance treatment (MMT) to be placed on the agenda. As a result of this infectious and contagious health problem, and ensuing social pressure, the practice known as harm reduction began to spread during this period, mainly regarding methadone use, until MMT become an available viable solution within the policy stream. How was this change enabled to occur?

During this period the public debate about MMT treatment became heated and reached its peak. In 1988, the Radical Anti-prohibitionist Coordination[3] and in 1989 the International Anti-prohibitionist League[4] were founded. They played the role of democratic lobbies whose aims were to organize demonstrations, especially in Italy's public institutions. During 1989–1990 some antiprohibitionists candidates were elected to the Parliament with the declared aim to bring the harm reduction treatment ideology into the political agenda. During this process consensus developed and increased around this concept even among other politicians as a reaction to the punitive and prohibitive climate which culminated in 1990 with Law 162 (formalized by DPR no. 309/90); also known as the Iervolino–Vassalli law. It was introduced by right wing parties, which delegated the Ministry of Health to regulate opioid substitution treatment. Following this, during the same year, the Dpr 445/90 ruled that methadone could *only* be used for detoxification procedures and that methadone self-administration was forbidden (Cibin & Guelfi (ed.), 2004).

However, according to many interviewees the politicians' position about substitution drug user treatment has always been ambiguous since its introduction, and the differences between substitute and psychosocial treatment were and are "more ideological than real", as

> while denying the substitutive drug from the ideal point of view, they have greatly appreciated it in practice, because it has helped to make the addicts disappear from the squares (KI from a private/accredited TCs).

Equally,

> even if SerDs have been often criticized, they have been very important to all the politicians since they represent control instruments (KI from advocacy organization).

In the meanwhile, the local public addiction services were reorganized in 1990, establishing their current multidisciplinary structure. During the same period a number of universities, some of them were linked to the British school (e.g., Universities of Cagliari, Padova and

[2] Italy, governed by stakeholder coalitions, has had more than 50 shorter term as well as longer term governments since WWII–more than any other country in the modern world.

[3] Association of Radical Party

[4] Association of Transnational Non-Violent Radical Party (NGO)

Bergamo), became interested in this area. They assumed role of SHs and began to provide scientific evidence which were disseminated (Maremmani, Nardini, Daini, Zolesi, & Castrogiovanni 1992; Tagliamonte, 1992). The majority of the KIs referred to the influence of specific scientific personalities who have promoted and contributed to the spread of MMT treatment. They belong to three main disciplines that have been interested in the issue; pharmacology, epidemiology, and clinical medicine.

As a result of all of these interacting factors and systems during early 1990s—the AIDS epidemic, the spread of a harm reduction approach also among politicians, the reorganization of SerDs and the influence of Universities—there was a major change in the guidelines and protocols for substitution therapy. The validity of MMT, and the harm reduction treatment ideology and model was affirmed and recommended, even as most Italian TCs continued to oppose this practice.

The "policy window" described—enabling an opportunity for SHs to restore their roles and for new models to come into the treatment arena—was subsequent to the alignment of the three "streams" when MMT was coupled with the problem of the number of heroin addicts' AIDS deaths. This culminated in 1993, when a national referendum abrogated some articles of law regarding procedures and limits of methadone use and repealed the possibility for the Minister of Health to establish, by law, the limits and conditions of substitute drug user treatments (Figure 1)[5]. Since then, during the last two decades, no other laws or ministerial decrees on this subject have been created. The Minister of Health did, however, enact some circular letters aimed at limiting the use of "substitutive drugs"[6]. These were largely criticized and considered illegitimate, in addition to being challengeable by both national and international authoritative scientific guidelines (Cibin & Guelfi, 2004).

New SHs appeared on the scene after the referendum. General Practitioner (GPs), as well as SerDs were permitted to prescribe methadone in 1993 which enabled the patient to take his legally prescribed medicine by himself in pharmacies. However, the number of doses and prescriptions were limited (Ministero della Sanità, 1993). In 1994, the COMBATT[7] program was developed in Trieste. This was the first group of GPs in Italy who developed and practiced the treatment of heroin addicts in their consulting rooms. This innovative treatment program in Italy remains a local experience, along with a few others (Michelazzi, Leprini, Cimolino, & Maremmani, 2000). In 1995 "Forum Droghe", the most relevant national association for the rights of consumers, connected with the most left wing political parties, was created with the aim of reforming the drug use(r) treatment-intervention policies.

At the end of the 1990s, when MMT had become a recognized and viable solution in the "policy stream" and had gained a central role in the public addiction treatment system, at least in the metropolitan areas, public treatment services were increased in their visibility and resources. In addition a network of low threshold facilities has also been developed since the late 1990s. These have mostly been administered by NGOs, ranging from drop-in centers (open during the day time), night shelters, street units, and outreach work in entertainment settings.

According to the available data and to the key informants, other SHs lost their power. Indeed the decade closed with the Agreement between State and Regions signed in 1999 that developed criteria for accreditation and authorization of private treatment services, professional staff, etc. The number of religious/voluntary CTs began to downsize, and they had to rethink their organizations (Coletti & Grosso, 2011). Many CTs began to also accept patients into opioid substitute treatment, at least for short periods of detoxification, within this changed treatment reality.

New Roles and Alliances: The First Decade of 2000

The debate about substitution treatment became less active and new alliances have been settled during the 21st century. While the long-term MMT has been progressively increased in the first decade (Dipartimento delle Politiche Antidroga, 2012)[8], SerDs, according to the interviewees, have gained a position of being "core SHs". Their "power" is not described by themselves and by the other KIs during the interviews in terms of an ability to influence policies. It is, rather, identified by a wide margin of discretion in practice, and thus by a certain autonomy from the political level.

At the same time, more importance has been granted to empirically informed evidence and to international guidelines. Research in this area in Italy has been improved starting from the first large cohort study on the Italian population relating to addiction treatment public services which dates back to 2000 (Bargagli, Piras, Faggiano, & Versino, 2000). The relationship between the scientific world and public services became closer. In 2001, FederSerD, a national interdisciplinary organization of professionals working in the public addiction services, was founded and in 2001 a Consensus Panel was organized which was signed by numerous physicians coming from different universities and SerDs. According to the international literature, it emphasized the importance of long-term and individualized treatment and the integration with other treatments such as counseling and psychosocial rehabilitation (Maremmani et al., 2002).

[5]The referendum promoted by the Radical party was primarily aimed at the decriminalization of the personal use of drugs. It achieved that the purchase and possession of drugs for personal use was punished by a fine. According to the Italian Constitution, the referendum has to be proposed by 500,000 citizens with the aim of repealing a law or a part of a law.

[6]See for example, Ministero della salute (1994). Circ. n. 20 in 1994—Guidelines for the treatment of opiate addiction with substitution drugs.

[7]Coordinamento Medici di Base per l'Assistenza Territoriale alla Tossicodipendenza (GPs Coordination for drug addicts local assistance).

[8]According to the last Report on Addiction to the Parliament (2012), in 2011 the process of substitution treatment was: short-term (16.3%), medium-term (23.5%), long-term (60.2%).

Buprenorphine was also introduced in Italy in 2000 and two years later the first National Consensus conference on buprenorphine was held in Palermo (Lucchini, 2002). It became part of clinical practice within a few years.

The fact that all of the above mentioned events, as well as other scientific conferences and meetings, were funded by pharmaceutical industries[9], seems to suggests that the relationship between addiction treatment services and industry became closer. Many interviewees think that industry has had and has a significant influence on the treatment system (more than on policies) mainly through their relationship with the professional/scientific associations. From the point of view of TCs, financing studies, publications, and conferences, pharmaceutical industries make sure of having an influence on the operational level:

> some professionals or managers have been almost included in the payroll of these industries (KI from SerD).

Some interviewees have also pointed out that over time industries have sought a more institutional alliance, finding it in the National Health Institute and in the scientific community. As the same scientists recognize, the evident "coincidence" of similar health and marketing targets; both of these systemic SHs are interested in medicalizing the problem of addiction and in the dissemination of standards and guidelines. It is reasonable to consider that it is just a "chance" outcome that the interviewed researchers in some way try to defend the industry's resizing its influence. They note, and emphasize, that in the particular moralistic and restrictive Italian context, in which clinical influence is also limited, the effective SH role of industry has been lower in Italy when compared to other countries. But a distinction has been made between the two main involved industries in Italy, since the collaboration with the Italian industry (described by a KI as *"fair and aware of the ethical dimensions"*) seems to be more appreciated by different interviewees than the one with the multinational company, which *"show more resolute pushes aimed to the development of its product"*.

An alliance between public services and TCs was also established. In 2002, a working group called "High Integration" was set up by major associations of public and private workers (FederSerD, FICT, CNCA) to identify joint work practices and to create a unique treatment system, within which each one has its own specialty; that is pharmacological or psychosocial treatment. For example, the anti-MMT TCs of the past are no more "drug free" even if their psychosocial rehabilitation model is still dominant (Dipartimento delle Politiche Antidroga, 2012; Coletti & Grosso, 2011). According to some interviewees from this sector, there has been a real change in the TCs' views of addiction. Similarly, KIs from SerDs think that the traditional dualism that in the past opposed the use of methadone and the concept of *"salvation"*, remains today only an ideological opposition, *"a political discourse"*. SerD and TCs operators collaborate and work together in everyday practice. A different speech emerges about *nonaccredited TCs*, mostly linked to the Church, which continue to operate independently in the belief that addiction must be addressed with education rather than medicine, toward which the other SHs continue to be quite critical.

In this situation in which agreement about MMT and alliances prevail, in the view of scientists, ministerial guidelines have continued to be based on a "socio-psycho-moral vision of addiction" (Gessa, 2002). Indeed during the same year of the Consensus Panel a Ministerial Decree (Ministero della Salute, 2002) reaffirmed that the goal of treatment should have been the recovery—abstinence from drug use—including from using medicinal, "substitute drugs". Furthermore, under the Berlusconi's governments[10], Italian drug policy has returned to being a more punitive approach. Drug possession above certain quantities is once again considered to be a criminal offence according to the 2006 law (n. 49) restoring, in a way, the situation to what it was before the 1993 referendum (Scivoletto, 2011). There has been a significant increase in rates of imprisonment for drug-related crimes and the imprisonment of addicts as unintended consequences of the 2006 punitive shift (Zuffa, 2011). Interviewees gave many examples about how the Health Ministry has continually attempted to limit methadone therapies with various measures even *after* the referendum (Fasoli, 2005, p. 9). They all agreed that these various attempts have not succeeded to effect daily treatment practices. Indeed the progressive transfer of jurisdiction from State to Regions in the field of health (so called devolution which started in 1990s) has led to a lack of both a general framework and national unified objectives also with regard to opioid substitute treatment policies. Many attempts to individuate common guidelines have been made but these kinds of initiatives did not have the power to replace local regulations and practices[11]. According to someone "*it is not even possible to speak about national drug user substitutive treatment policies since there are no national guidelines, not about common training courses nor about control on the quality of treatment" (KI from the scientific community)*.

The power of the Health Ministry in the drug use(r) treatment-intervention field has been further reduced by the creation of the *Anti-drugs Policies Department (DPA),* in 2008, as a branch of Government and crosscut Ministries, mandated to counteract the drug "phenomenon" by: (1) coordinating Regions, (2) defining the national action plan, and (3) collecting data about drug use and the treatment system. Positive views on the necessity for this institution have been expressed mainly by private TCs; according to whom it performs the tasks of coordination and direction. But the majority of KIs, belonging mainly

[9] In Italy the two basic sources are, one national producing methadone (Molteni) and the latter multinational producing buprenorphine (Reckitt Benckiser).

[10] 2001–2005; 2005–2006; 2008–2011.

[11] For example, the diffusion of the WHO Guidelines by the Istituto Superiore di Sanità (National Health Institute) (2009), or the Guidelines disseminated by the DPA (2009),

to SerDs and the scientific field, have expressed a critical view. According to them, the DPA is an ambiguous institution in itself since

> often it has been a political instrument of the government in charge, more than a vehicle of scientific practices (KI from private/accredited TCs).

Some of the interviewed researchers have highlighted that a conflict of interests exists; a body delegated to monitor "the phenomenon" and the intervening response system should not be directly employed by the government. Nevertheless, according to the KIs involved in the treatment system, both public and private, the DPA has neither the power to guide and coordinate the Regions nor to really influence the addiction services' ordinary activities. A Consulting Board formally exists in the DPA, but it has been criticized by the interviewees, both public and private, in that it has not functioned as a consensus building instrument. The majority of respondents claimed that in recent years the Consulting Board has very seldom been convened and only on marginal issues; its role is *"almost zero"* and it represents a *"meaningless and unheard organ" (KI from SerDs)*. The treatment sector and the scientific community are also quite critical of the DPA Scientific Committee because it is composed mostly of American researchers[12]. For this reason, it is considered, by most of KIs, to be an outlier institution engaged in transmitting propaganda, that has neither connections with nor influence on the Italian addiction treatment system.

A major change has occurred in the contemporary Italian drug use(r) intervention-treatment SHs' map; two of them seem to have disappeared. The GPs and the consumers. The few addiction outpatient treatment efforts by GPs which were developed during the early 1990s have remained limited at a few local places. The majority of interviewees interpret this fact to a flaw within the treatment culture. They highlighted that not only are GPs not trained about addiction but they also continue to be influenced by prejudices and stereotypes. In addition, there are also suggestions by interviewees that opioid treatment of drug users by GPs has not been developed because the law has made prescribing very complicated and has led to many legal sentences against medical doctors.

The actual absence of drug user treatment consumers, as drug policy SHs, has been considered to be a major problem by KIs from the SerDs, since, because of economic crisis, *"they will be increasingly discriminated"*. Advocacy organizations were quite active during the 1990s. They currently have almost disappeared and the few that are still active operate only at local level. According to a magistrate this flaw, or weakness, is due to a general *"Italian vice, in the sense that human rights advocacy has always been very weak"*. Other reasons are mentioned by different KIs, among them: (1) the persistence of stigma and shame−-related to the fact that the moral view of addiction in Italy has never fully disappeared, (2) the decline of the general public debate, and (3) the decrease of the political and social commitment of new generations.

[12]The scientific committee is actually composed of 11 members of which 6 are foreign and in particular from USA (5). http://www.politicheantidroga.it/organismi/membri-comitato.aspx

The Impact of the Current Italian Economic Crisis: Toward a New Policy Window?

Despite the general acceptance of the effectiveness of drug user substitution treatment—from a harm reduction perspective— some ongoing changes once again raise a number of relevant questions and could lay the groundwork for a new policy window.

The main problem stream represented by Italy's contemporary general economic crisis has determined a progressive reduction of all of the SHs' power, in terms of resources and recognition (Figure 1). In this context, new opposing positions have emerged, even internal to the same SHs.

The role of contemporary SerDs, when compared to 1990s, has been weakened mainly by the reduction of human and economic resources. This has also occurred with their main traditional competitors, the TCs, which are trying to reinvent their aims and treatments.

According to some interviewees from the scientific field, the current *"suffering"* of SerD and *"the impoverishment of their role"* is also linked to a lack of recognition of a professional role and a lack of investment in professionalization. Specific training for addiction professionals has not been developed nor has "the habit" of evaluating the effectiveness of interventions been consensualized and "normed". Moreover turn-over and burn-out are increasing among SerD professionals and workers.

Many different KIs point out that the resources' reduction has resulted in a parallel favoring of the spread of substitute drug user treatment. It is a less expensive treatment. They agree with the literature on the fact that the economic crisis increases the risk that it becomes the *only* treatment offered by public services, while other psychosocial therapies are often neglected (Renda, 1999; Strepparola, 2005; Strepparola & Di Carlo, 2005). This risk is also exacerbated by the significant reduction of resources for social and occupational reintegration of addicts, such as employment grants and housing facilities. For this reason, substitute maintenance treatment is now more fully appreciated even inside SerDs, even if, according to KIs from the research field and based on scientific literature, it should still be improved (Salamina et al., 2010; Schifano et al., 2006). However, recent research involving public and accredited services employees has documented some critical aspects about how these treatments are applied (Tassinari & Volpi, 2012). Consistently, according to many interviewees, there is the risk of excessive medicalization that has subordinated the use of psychosocial interventions. Some professional categories, such as social workers and professional educators, have, as a consequence, lost their motivation to treat drug users. They feel more like control agents than care providers and change agents. Negative images about MMT have emerged not only among the professionals but also among services users, especially

related to the risk of institutional dependency and chronicization (Volpi & Cira Rivelli, 2010).

A significant fragmentation has been highlighted among "policy communities" made of the specialists of the problem or issue being focused on (Kingdon, 1995). Interviewees have confirmed that the reduction of the multidisciplinary and integrated treatments has further amplified the power differences between physicians and nonmedical staff, mainly psychologists, educators, and social workers which, in recent years,

> have matured a feeling of otherness and opposition against this [substitutive] treatment (KI from professional/scientific association).

This medical model domination arises again within Italy's *professional/scientific associations*. Some KIs have reported about the internal power-game dynamics even within the group of medical doctors because of the prevailing neurobiological approach and because of the presence of "first ladies", that is, self-centered leaders. According to the same members of professional/scientific associations and to other KIs, even if they can orient and influence the treatment system, they are unable to impact drug policies, since the *"politicians are completely separated by technicians"*. They confirm what Kingdon said: "forces that drive the political stream and forces that drive the policy stream are quite different: each has a life of its own, independent from the other" (1984: 124)

Still, some scientists are quite critical toward the role of professional/scientific associations, since

> they are more interested in defending their own corporate interests than in supporting the scientific principles (KI, magistrate).

It is also necessary to note that within the scientific community there are different ideas about how the "addiction", a complex, highly politicized, SH-bound, and multidimensional area, has to be addressed according to the specific discipline. What they share in common is their belief about: (1) their being powerless in regard to initiating, changing and sustaining policies, and their (2) perception of being more acknowledged and appreciated in the international context than in the national one. Indeed, even if some of the Italian scientists occupy important positions in European or international institutions[13], none of them, to date, have been invited to be part of the DPA Scientific Committee.

Another important phenomenon exists that in some way questions the use of substitute medicines. According to the interviewees there has been a gradual reduction of heroin addicts and an increase of polydrug users and dual-diagnosis patients during the last few years, for whom the "substitute treatment" is inappropriate. It is possible that the reduction in long-term opioid substitute treatment during the very last year (Dipartimento delle Politiche Antidroga, 2012) could be also related to this trend.

[13] For example, for many years the UN Office on Drugs and Crime (UNODC) was directed by an Italian; an Italian professor has been President of the European Opiate Addiction Treatment Association (EUROPAD) since its foundation in 1994 and is president of the World Federation for the Treatment of Opioid Dependence.

Given the documented change in contemporary Italian "addiction", public services are more and more useless, according to an interviewee from a nonaccredited private service. Nevertheless, as one KI belonging to one of the few advocacy organizations remaining complained, this *"doesn't seem to lead to a political debate"* and services managers just *"adapt to changes of government and economic blackmail"*. Recently, there has also been a renewed interest by the media in the subject. The media's interest, which had a great influence during the 1990s, has almost disappeared. The problem of addiction treatment was withdrawn from the public discourse and was less likely to get into the politicians' agenda. Although new problems have arisen during recent years in Italy they have not yet been considered in the problem stream and seem to be far from entering into the national political agenda.

CONCLUSIONS

Since the spread of drug consumption in Italy, during the 1970s, drugs use was seen as being a vice and a sin, under the Church influence, and, the recovery of addicts, or rather their salvation, was related to as being a moral problem and a matter for priests. This view about the problem, and the solution, was consensualized, reinforced and sustained with enabling policies and practices. Necessary SH politicians, public opinion and even medical doctors supported TCs, that were mainly administered by Catholic associations. The AIDS epidemic that emerged at the end of the 1980s represented the major factor that led to a "policy window", creating the necessary conditions for new SHs to gain power in the addiction treatment field, acting as policy entrepreneurs (Kingdon, 1995). In fact during the two decades in which the public addiction services (SerDs) organized and affirmed their role in drug user treatment, with the support of the scientific community, both interested in affecting the problem stream spreading the concept of chronic disease and the need for pharmaceutical treatment. Further support came from the pharmaceutical industry, which financed studies, informative meetings and training events. From this point of view, scientists have helped to build the "consensus" around the MMT and industry has funded this action through the dissemination of generalizable evidences and guidelines. This change in drug use substitution drug policies has been determined more by the treatment services, scientists and industry that have ridden the wave of the moment, than by national institutions or politicians. The conflict between SerDs and TCs reached its peak during this period. Later TCs, and even policy makers, lost much of their power in the field of drug user treatment. This was because of the referendum, which forbade the regulation of drug users treatment by law, and because of devolution, which made it impossible to develop and spread consensualized national guidelines.

During the last decade SerDs have consolidated their position. Operative partnerships have been created with TCs, which have partly revised their point of view. The positions of the different SHs and treatment practices

have been settled and the ideological conflict has been smoothed out. General interest about "substitute treatment" is no more in the problem stream or in the political agenda. It no longer seems to be a current problem that requires attention by politicians (Kingdon, 1995). Ideologies relative to opioid "substitute treatment", which are still sometimes appealing to a few politicians and religious leaders, seem to be both distant and disconnected from current treatment practices in Italy.

Nevertheless, some factors have recently occurred which, more or less directly, are bringing "substitute treatment" again into question in Italy. The first factor is the current economic crisis. On the one hand it has served to increase the use of substitute treatment, while on the other hand it has revealed its limits and risks when used as the *only cure*. The latter consideration is due to the significant change in drug users' patterns of drug use; more and more of them are polydrug users for whom heroin is not their drug of choice. Both these factors seem to have weakened the power of all the SHs. This changed reality has increased the conflict within the same treatment services, between the different professional areas, and within the scientific community, between the different disciplines. Although not yet configured as such, this period could in the near future open a new policy window.

Looking at the SHs dynamics (Figure 1) some conclusions can be drawn from this analysis. First of all, as claimed by Kingdon (1995), the main shifts in Italy's "substitute drug user treatment" seem to originate from external events rather than from the internal SHs' actions. This is so even when different SHs, during different time periods, benefit or lose from these crisis situations.

Politicians are interested in the "substitute drug treatment" as long as this is a matter that interests the publics' opinion and is therefore exploitable to canvass voters. In other words, policies are informed more from the public opinion and social alarm, than from available and accessible evidences or international guidelines. On the other hand, it is clear that it has been difficult for policy makers, and it still is, to have a real influence on treatment practices. This is also an outcome of the devolution, since legislative directions are often hampered in field practices, especially if the treatment services have not been consulted and engaged in the decision making process (Lenton, 2008). During the current period, in which the general attention to drug-substitution treatment is low, an ambiguous position seems to be the most useful option in order to balance current repressive and welfare policies, as have emerged in other countries (Houborg & Bjerge, 2011). The existing ambivalence is directly connected with the fact that drug addiction treatment is at a crossroads between health, welfare, and control policies, as well as being between social and individual medicine. As interviewees has stated, this ambiguity is deeply rooted in the nature of the Italian addiction treatment system, which is both responsible for the care of the users and also for their control. Ambiguities are also reflected in Italy's drug user treatment laws and guidelines. The usefulness of MMT has been affirmed for years at the same time that policies have stated that the main aim should be the recovery—which is a "code" for abstinence.

International guidelines and bodies seem to have a little influence on Italian drug user treatment policies. When they are related to, they are used by SHs that have an interest in secularizing the approach to the addiction treatment, since the Church influence has greatly affected the national story of substitute drug user treatment.

The same could be said about the influence of scientific evidence: they have been used and (mis)interpreted during different periods in Italy by different politicians and SHs in support of their own positions and agendas. It is interesting to note, and perhaps it is also somewhat ironic, that, while the scientific evidence, through different SHs, contributed to undermining the power of TCs in the first policy window, the representatives of these communities, during the interviews, have referred to the results of recent research about psychosocial treatment to reaffirm the effectiveness of their own approach.

Notwithstanding the limitation of the study's small number of interviewees, that is typical of qualitative research, the Italian case furthers an understanding of the complex, dynamic, and multidimensional relationships between SHs in the drug user intervention-treatment arena. This highly and systemic politicized and socially-constructed problem is subject to different alliances between a range of individual and systemic SHs over the time.

Declaration of Interest

Franca Beccaria is a member of Scientific Laboratory of Osservatorio Permanente sui Giovani e l'Alcool (Permanent Observatory on Youth and Alcohol) in Rome, an association which is mainly funded by the Italian Breweries Association. For this task she does not receive any honorarium, but the reimbursement for traveling expenses for one/two meeting/s per year. In 2012, she has received an honorarium from ERAB (The European Foundation for Alcohol Research, an independent alcohol research foundation supported by The Brewers of Europe) for participating at the project "Underage drinking. A report on drinking in the second decade of life in Europe and North America". They also reimbursed the traveling costs for a meeting in Montreal and a meeting in Brussels. Together with the University of Torino (applicant) she got a grant from ERAB for the research "Images of adolescent alcohol use and health in Italy. A study of teenagers' drinking and societal reactions to it" (2012–2013). Sara Rolando has no conflicts of interest. The authors alone are responsible for the content and writing of the article.

The research leading to these results or outcomes has received funding from the European Community's Seventh Framework Programme (FP7/2007-2013), under Grant Agreement no. 266813—Addictions and Lifestyle in Contemporary Europe—Reframing Addictions Project (ALICE RAP).

THE AUTHORS

Franca Beccaria, PhD, Sociologist, partner in Eclectica, a research institute in Torino (Italy), is a contract professor at the EMDAS, *European Masters on Drug and Alcohol Studies*, the Avogadro University (Novara). Her main research interests are alcohol consumption and culture, drinking styles, prevention, and the sociology of health. Last book edited "Alcohol and generation. Changes in style and changing styles in Italy and Finland" (Carocci, 2010), and "Alcol e giovani. Riflettere prima dell'uso" (Alcohol and youth. To think before using) has been published in 2013 by Giunti Editore.

Sara Rolando, Sociologist, PhD student at the University of Helsinki; has been working as a researcher in Eclectica (Torino) since 2007. She is involved in various national and international research about alcohol use and users, particularly on the topics of drinking culture and young people. She is interested in comparative qualitative methods.

REFERENCES

Bargagli, A. M., Piras, G., Faggiano, F., & Versino, E. (2000). *Vedette. Studio Nazionale per la valutazione dell'efficacia dei trattamenti per la tossicodipendenza da eroina*. Monografia n.1. Roma.

Brugha, R., & Varvarosky, Z. (2000). Stakeholder analysis: A review. *Health policy and planning, 15*(3), 239–246.

Cibin, M., & Guelfi, G. P. (2004). *Il trattamento con metadone*. Milano: Franco Angeli.

Coletti, M., & Grosso, L. (2011). *La comunità terapeutica per persone tossicodipendenti*. Torino: Gruppo Abele.

Dipartimento delle Politiche Anti Droga (2012). *Relazione annuale al parlamento 2012 – Sull'uso di sostanze stupefacenti e sulle tossicodipendenze in Italia* [Annual report to the Parliament 2012—On drug use and addictions in Italy]. Roma.

Dole, V. P., & Nyswander, M., (1965). A medical treatment for diacetylmorphine (heroin) addiction. A clinical trial with methadone hydrochloride. *Journal of the American Medical Association, 193*(8), 646–650.

Dole, V. P., & Nyswander, M., (1967). Heroin addiction. A metabolic disease. *Archives of Internal Medicine, 120*, 19–24.

EMCDDA (2000). *Reviewing current practice in drug-substitution treatment in the European Union*. EMCDDA, Lisbon.

Fasoli, M. (2005). *Informazioni sulle terapie di mantenimento con metadone per la dipendenza da oppiacei*. Retrieved from http://www.sdrogabrescia.it/documenti-scaricabili/documenti/metadone/metadone.pdf.

Fogaroli, C., Agnelli, C., & Cicciò, L. (1999). Valutazione di efficacia dei trattamenti farmacologici sostitutivi condotti secondo diversi protocolli terapeutici. *Bollettino Farmacodipendenze Alcoolismo, XXII*(4), 22–25.

Gatti, R. C. (2004). *Droga Architettura e materiali per le nuove reti di intervento*. Milano: Franco Angeli.

Gessa, G. L. (2002). Lo strano caso del metadone in Italia. *Medicina delle Dipendenze – Italian Journal of the Addictions, 34*.

Glaser, B. G., & Strauss, A. (1967). *The discovery of grounded theory: Strategies for qualitative research*. Chicago, Ill: Aldine Pub. Co.

Houborg, E., & Bjerge, B. (2011). Drug policy, control and welfare. *Drugs: Education, Prevention and Policy, 18*(1), 16–23.

Istituto Superiore di Sanità (2009). *Linee guida per il trattamento farmacologico e psicosociale della dipendenza da oppiacei*. Italian translation of "Guidelines for the psychosocially assisted pharmacological treatment of the opioid dependence" WHO.

Kingdon, J. (1984). *Agendas, alternatives and public policies*. 1st ed. Boston: Little Brown.

Kingdon, J. (1995). *Agendas, alternatives and public policies*. 2nd ed. Boston: Little Brown.

Lenton, S. (2008). Working with windows: Translating drug research into drug policy. In D. Moore, & P. Dietze (Eds.), *Theory, evidence and context: Contemporary innovations in alcohol and other drug practice in australia* (pp. 179–190). Melbourn: Oxford University Press.

Lucchini (2002). *L'uso della buprenorfina nel trattamento della tossicodipendenza. Due anni di esperienze nei Ser.T*. Milano: Franco Angeli.

Mannaioni, P. F. (1980). *Le tossicodipendenze*. Padova: Piccin-Nuova Libraria.

Maremmani, I., Nardini, R., Daini, L., Zolesi, O., & Castrogiovanni, P. (1992). Il trattamento chemioterapico della dipendenza da oppiacei con agonisti. Stato dell'arte. *Quaderni Italiani di Psichiatria, XI*(3), 233–264.

Maremmani et al. (2002). Clinical foundations for the use of methadone. Italian consensus panel on methadone treatment. *Heroin Addiction & Related Clinical Problems, 4*(2), 19–32.

Michelazzi, A., Leprini, R., Cimolino, T., & Maremmani, I. (2000). Cronistoria di una pratica medica. *Alcologia, 12*(2), 95–98.

Ministero della Sanità (1993). Circolare 30 luglio 1993, n. 1100/11/D/F10/1862. Impiego dei farmaci sostitutivi nei trattamenti delle tossicodipendenze [Circular 30 July 1993 n. 1100/11/D/F10/1862. Use of substitute drugs in the treatment of drug addiction].

Ministero della Sanità (1994). Circolare 30 settembre 1994, n. 20. Linee-guida per il trattamento della dipendenza da oppiacei con farmaci sostitutivi, G.U. 14 ottobre 1994 [Circular dated 30 September 1994, n. 20. Guidelines for the treatment of opioid dependence with substitute drugs, G.U. October 14, 1994].

Ministero della Salute (2002). Decreto 14 giugno 2002. Disposizioni di principio sull'organizzazione e sul funzionamento dei servizi per le tossicodipendenze delle aziende unità sanitarie locali – Ser.T, di cui al decreto ministeriale 30 novembre 1990, n. 444 [Decree of 14 June 2002. Principle provisions on the organization and operation of drug services of local health units – Ser.T, of the Ministerial Decree 30 November 1990, n. 444].

Montecchi, L. (1999). Droga: Informazione e servizi [Drug: information and services]. *Psiconline 3*, 57–75. Retrieved November 11, 2012, from http://www.pol-it.org/ital/psichiatriaonline/montecchi.pdf.

Renda, E. (1999). *Droga. Immaginario e realtà*. Roma: Armando.

Rose, N. (1996). Governing "advanced" liberal democracies. In A. Barry, D. Osborne, & N. Rose, (Eds.), (*Foucault and political reason: Liberalism, neo-liberalism and rationalities of government* (pp. 37–64). London: UCL Press.

Salamina, G., Diecidue, R., Vigna-Taglianti, F., Jarre, P., Schifano, P., Bargagli, A.M., et al. (2010). Effectiveness of therapies for heroin addiction in retaining patients in treatment: Results from the VEdeTTE study. *Substance Use & Misuse, 45*(12), 2076–2092.

Schifano, P., Bargagli, A.M., Belleudi, V., Amato, L., Davoli, M., Diecidue, R., et al. (2006). Methadone treatment in clinical practice in Italy: Need for improvement. *European Addiction Research 12*(3), 121–127.

Scivoletto, C. (2011). La disciplina sugli stupefacenti e le misure amministrative. Profili di analisi normativa e giurisprudenziale. In F. Prina (Ed.), *Consumo di droghe e sanzioni amministrative. Un bilancio sull'applicazione dell'art.75 del PDR 309/90*. Milano: Franco Angeli.

Strepparola, G. (ed.) (2005). *Curare gli eroinomani*. Milano: Franco Angeli.

Strepparola, G., & Di Carlo, C. (eds) (2005). *Le Radici dell'innovazione*. Milano: Franco Angeli.

Tagliamonte, A. (1992). Trattamento della dipendenza da oppiacei con farmaci sostitutivi. In: E. Gori & E. Muller (Eds.), *Basi biologiche e farmacologiche delle tossicodipendenze* (pp. 279–288). Milano: Pythagora Press.

Tassinari, S., & Volpi, F. (2012). I trattamenti con farmaci sostitutivi nelle dipendenze da oppiacei: la percezione degli operatori. In M. Coletti, M. Ferri, & J. Di Stefano, (Eds.), (*I trattamenti con farmaci sostitutivi nelle dipendenze da oppiacei* (pp. 23–36). Roma: Alpes Italia.

Varvarovsky, Z., & Brugha, R. (2000). A stakeholder analysis. *Health Policy and Planning, 15*(3), 338–345.

Volpi, F., & Cira Rivelli, M.C. (2010). I focus group. Il punto di vista degli utenti sul tema del vissuto relativo ai trattamenti farmacologici protratti. *Itaca, 30*, 31–39.

Zuffa, G. (2011). How to determine personal use in drug legislation. The "threshold controversy" in the light of Italian experience. *Legislative Reform of Drug Policies* n.15. 1–11. Retrieved November 11, 2012, from http://www.druglawreform.info/en/publications?start=10.