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The diversion and/or non-therapeutic use (misuse) of drugs and in particular opioids is a well-known phenomenon, which is also present in the clinical management of addiction. In fact, for methadone and buprenorphine, as well as for other opioids used as analgesics, the phenomenon of diversion and use outside of their therapeutic uses, including the use of non-prescribed drugs, arbitrary modification of objectives and means of administration, dosages and other variations, is extensively documented.

For several years, the scientific community on one side and the pharmaceutical companies on the other have developed techniques that offer formulations of opioids called abuse deterrent formulations (ADF), characterized by a low degree of potential for non-therapeutic use/diversion. The various ADF have shown their effectiveness, although alone they cannot constitute definitive answers to a problem that has both pharmacological and clinic implications. This is the strategy behind the development of the combination buprenorphine/naloxone. The stated aim is to deter intravenous misuse associated with buprenorphine. Similarly, more recently, as a result of a growing intravenous misuse of methadone, a formulation of methadone/naloxone in a stoichiometric ratio of 50 : 1 has been developed and tested.

Often, the clinical efficacy of a drug or some improvement of its clinical use are evaluated through the conduct of randomized double-blind controlled trials. This methodology is the most rigorous, scientifically, but it is easily understandable that, in the case of the evaluation of the reduced potential for non-therapeutic use and/or diversion of a new pharmaceutical product, such methodology proves to be impractical because the control group would be exposed to unacceptable risks both from a clinical and ethical point of view.

The purpose of this contribution is to provide an overview of the major works carried out under the Italian Public Services for Addictions, Ser.T, which have focused their attention both on the phenomenon of diversion and non-therapeutic use of buprenorphine and on the clinical evaluation of the therapeutic transfer (switch) from a treatment with buprenorphine alone to a treatment with the drug combination buprenorphine/naloxone. This latter aspect has an important clinical relevance because there are currently still few data in the literature, especially in Italy, regarding the clinical aspect and the outcomes of the switch from buprenorphine alone to buprenorphine/naxolone in an outpatient settings.

Evaluating the efficacy of a drug to solve a complex problem such as the diversion or non-therapeutic use of treatment with opioids, without

taking into account all of the contributing factors, is not a suitable method of analysis. In the case of buprenorphine/naxolone, many published studies recognize that this drug has different levels of efficacy, while showing that alone it cannot resolve the universal and permanent phenomenon of non-therapeutic use/diversion, considering that consumers have different degrees of tolerance and dependence. Buprenorphine/naxolone, however, is like the new association methadone/naloxone, because the premises had the initial goal of deterring and/or rendering less attractive the intravenous use of these drugs by facilitating their home administration. In this sense, recent studies conducted widely, show a lower trend for the intravenous use of buprenorphine/naxolone compared with buprenorphine alone. Finally, it should be noted that the role of the therapist and the setting of therapy cannot be delegated solely to the characteristics of the drug. The clinical evaluation ex-ante and long course of treatment, the established therapeutic alliance, the conditions for administration, monitoring and management of take home drug treatment, the building of a path to promote entrusting, represent essential and binding elements, being the foundation for good clinical practices that can be made more efficient thanks to ADF.

Lorenzo Somaini

Addiction Treatment Center Cossato, Local Health Unit, Biella, Italy