Community Outcome Project
San Patrignano Community

Final Research Report - SUMMARY
October 2018

with the friendly collaboration of
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1. INTRODUCTION

1.1. Origins of this research

This research report, drafted by Explora with the friendly collaboration of Ce.P.Ci.I., Department of Sociology and Economic Law at the University of Bologna, presents the statistical and sociological results of a long-term study. The report currently focuses on the retention factor for a group of users who entered San Patrignano during the 12 months from 1 March 2013 and 28 February 2014. The second and much broader part of the study will be a comprehensive follow-up, targeting former residents of the community over an extended period of time.

Entitled Community Outcomes, the research project originated in 2011-2012 as the result of a project run by the Italian President of the Council of Ministers’ Department for Anti-Drug Policies. Said project involved a national sample of 30 communities and it aimed to measure the long-term effectiveness of the treatments received by the individuals hosted in the communities. The research tools, as we will describe in more detail later, were a) sociological and b) toxicological. The former were needed to assess the life and health conditions of the people who had submitted to the various treatments and how well they had readjusted to life in society afterwards. The latter, on the other hand, were used to accurately measure the degree of abstinence or otherwise from drug use, as appropriate.

The national study commenced in December 2011, promoted and funded by the Italian President of the Council of Ministers’ Department for Anti-Drug Policies, who assigned it to the Department of Sociology and Economic Law at the University of Bologna (Coordinated by: Professor Giovanni Pieretti).

The project ran until 16 June 2015. From that date, the planned extensions needed to continue the project in the 30 national facilities (in accordance with the timescales laid down in the original GANTT) and for which an application was made to the Department for Anti-Drug Policies, were not granted and neither were the relative funds. The study therefore came to an end in Italy in late 2015 insomuch as it was no longer materially possible to continue the research (the sociological and toxicological parts).

San Patrignano is the only community to have succeeded in continuing the study, having taken the decision to invest its own resources in it. The combined endeavours of the community’s own staff and Ce.P.Ci.T researchers assured that the sociological research, albeit requiring a huge amount of effort, continued in the intervening periods without any gaps in data collection.

1.2. Research characteristics

San Patrignano, in addition to being the world’s largest drug rehabilitation community, started, in 1992-3, to promote follow-up research projects to understand how the lives and health of former residents, in other words, the people who had spent time in the community to tackle, and potentially resolve, their problems of addiction, had progressed. There was a desire to understand, using scientific research, what the “results” were of the work that had been done. The approach San Patrignano took, as extensively illustrated in several of the studies carried out, can be very concisely termed Mileu Therapy.

Since its foundation in autumn 1978, San Patrignano has always adopted a long-term approach (originally around a year now at least three years) to the treatments offered to individuals dependent on drugs entering the community but taking great pains to assure the pathways offered are tailored to
the individuals embarking on them. As the founder of the Community, Vincenzo Muccioli, once wrote, “men are not skittles” referring to the need to respect the personal characteristics of each individual and to map, with almost sartorial precision, the treatment pathway (not programme) to the unique features of each person and their life histories.

Moreover, to this day San Patrignano has never taken money from the families of residents, from the Italian government or from Regional Councils. It has always believed that the work done in the community's many workshops and areas of operation gives residents the opportunity to become self-sufficient and overturn the widespread image of drug addicts as marginalized individuals with presumptions of entitlement to welfare assistance.

These and other characteristics make San Patrignano a singular type of community: not only does it fight drug addiction, it has also made turning around the lives of the people it hosts a central part of its mission.

It has to be underscored that this document is not the actual outcome, which will be perfected when the subjects currently being studied have all left the community. It is predominantly a study of the retention factor, in other words, the community’s ability to continue to engage individuals who have decided to embark on a pathway out of drug addiction. The higher the retention factor, the fewer the drop-outs and the more likely the treatment is to be successful over time, as international literature on the subject has shown.

It also has to be underlined that the very high retention factor of the group studied will provide a strong foundation on which to base the subsequent follow-up.

In addition to the retention factor, the study described herein also explores the personal “growth” of individuals during the pathway and their perceptions of the service received, offering an important value-added opportunity to compare their perspective with that of their case workers.

If the community’s ability to retain users during the treatment pathway is notable, the residents’ success over time will be equally notable, meaning their ability to leave their pathological addictions permanently behind them and resume their place as fully-functioning members of civil society. At that stage, an all-round, fully effective outcome will have been achieved.
2. OBJECTIVES

2.1. General and specific objectives

The primary outcome of the “Community Outcomes” project is to assess the outcomes of therapeutic/rehabilitation interventions carried out in the therapeutic community (during and after treatment). Therefore we will focus more on effectiveness in practice than theoretical efficacy, comparing it constantly with the clinical conditions of the individuals at commencement (severity index), with the processes used and with the characteristics of the facility itself.

The three main areas of assessment were:

1. Access methods of people with drug addictions (selection criteria, no. of applications received/no. of people accepted, severity index on admission, types of substances detected in toxicological tests, where applicable).
2. Period of treatment/rehabilitation within the community (variations in severity index, length of stay, drop-out rate, time before drop-out, reason for drop-out, level of training and professional skills acquired, life skills).
3. Post-treatment/rehabilitation period (keratin matrix toxicological tests twelve months after leaving the community, in parallel with assessment of quality of life and degree of reintegration into society and employment.)

2.2. Value-added expected from this research project

The “Community Outcome” study has at least three innovative features:

- A research methodology that combines sociological research tools (administered at different times during the therapy and after its completion) and purely medical tests. Forms used to record the biographical, family, social and occupational aspects of each individual’s life were used in conjunction with tools of a more medical nature to reveal anamnesis and clinical history (like the short severity index file which provides a snapshot of the severity of the resident’s mental and physical health on their admission to the facility) as well as a toxicological report (keratin matrix testing) which measures with incontrovertible accuracy the extent of drug use of each user involved in the study. Taking this approach makes it possible to assess the results and effectiveness of the therapy not only on the basis of the final outcome but also in relation to the user's profile when they entered the rehabilitation community, to their experience of the rehabilitation pathway and, on its completion, to what happened to them afterwards.

- The project uses a methodology which, more than ever before, focuses attention on the individual with drug addiction, not just as a user of the community but also as a human being with rights, one of which is the right to express an opinion or judgement on the facility and the therapy experienced within it (using the user satisfaction form, for example).

- The project represents a combined “research-training” opportunity: assessing the effectiveness of treatment requires the active participation of staff working in Rehabilitation Communities who, once trained to fill in the survey forms drawn up by the research team, become the initial facilitators of the assessment process. One of the underlying aims of the
project is to disseminate an assessment culture among staff in Therapeutic Communities, with a view to building, over time, permanent systems based on systematic data linked to processes and results. There is a clear need for such systems and they represent a potential value-added to be obtained from effective treatments.
3. TOOLS AND METHODOLOGY

The “Community Outcomes” study aims to generate a set of indices to be used:

- to reconstruct the selection criteria of individuals with drug addictions applying to enter the community, with a particular emphasis on exclusion criteria in relation to any co-morbid conditions (diseases/infections, psychiatric disorders, etc.);
- to assess the clinical severity index of individuals admitted to and resident in the community, in relation to the main clinical toxicological parameters (severity index) to determine any differences in the severity of individuals undergoing treatment/rehabilitation in each community, a condition which could affect (in conjunction with the type of treatment) the prognosis (as a result of differing responses to the treatment) over the medium and long term;
- to measure the length of the stay in the rehabilitation facility, being careful to look at variations in the severity index in relation to this variable;
- to calculate the drop-out rate, namely the number of individuals abandoning their rehabilitation pathways prematurely and to also attempt to identify the reason why;
- to reveal the life skills acquired during the treatment/rehabilitation period;
- to reveal the salient features of the delivery facility (user density, dedicated rehabilitation areas and services, internal rules for users, etc.) and the treatment/rehabilitation processes used (service profile and density, meaning the types of services delivered and the average number delivered over time to each individual user, methods used to assess treatments and rehabilitation processes, customer satisfaction, case worker to user ratios, case worker motivation levels, case worker turnover, level of professionalism);
- measure abstention from drug and alcohol use by administering keratin matrix tests after users have left the community. Informed agreement to this measurement will be obtained ahead of time by asking users to sign a consent form. They will then be subsequently contacted by telephone and in writing to ask them to allow a hair sample to be taken and to answer a simple questionnaire/interview. In this context, the individual’s quality of life will also be determined, focusing in particular on the degree of reintegration into both society and the occupational environment.

3.1. Measurement tools and functions

The “Community Outcomes” study therefore aims to create numerous measurement tools, in an interdisciplinary perspective, and with the aim of covering as comprehensively as possible all aspects of the facility and of the user's pathway, starting from their initial contact with the facility to after they have completed their treatment within it.

First and foremost, the study features seven paper tools (Figure 1):

1. Short Severity Index: filled out at the beginning of the study to reveal the clinical severity of each individual entering the facility;
2. Individual User Service Sheet (Output): this tool assess the services the facility plans to offer the individual on their admission, and it is progressively completed during their stay, until the time of their departure;
3. Internal Outcome Monitoring Sheet for Individual Users: the aim is to collect data on each individual resident's substance use, their attitude towards therapy, levels of aggressiveness, participation in community life, project-building skills, handling of family relationships and
any relapses. This tool is also compiled bit by bit, as the resident progresses along their pathway in the community.

4. User Life Skills Sheet – case worker: this form is completed every six months during the user’s stay in the community, it is compiled by their assigned case worker and requires a personal judgement to be made regarding the skills the case worker things the user has acquired;

5. User Life Skills Sheet - user: completed every six months during the user's stay in the community, asking them to assess the life skills they think they have acquired;

6. User Satisfaction Sheet – case worker: completed every six months during the user's stay in the community, aimed at case workers and used to calculate satisfaction levels and, from their perspective, how the user perceives the services received;

7. User Satisfaction Sheet - user: completed every six months during the user's stay in the community, aimed at users to determine their satisfaction regarding the quality of the services received at the facility.

The “Community Outcomes” study also looks at abstinence from drug and alcohol use by carrying out keratin matrix toxicological tests (hair) twelve months after the user has left the community. Informed consent from the user to submit to this test is obtained in writing on their departure from the community.
### Figure 1. “Community Outcomes” study measurement tools

<table>
<thead>
<tr>
<th>TOOL</th>
<th>ADMINISTRATION STAGES AND TIMINGS</th>
<th>SUBJECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short Severity Index</td>
<td>During first month at facility</td>
<td>Case worker</td>
</tr>
<tr>
<td>Individual User Service Sheet</td>
<td>During stay and when the user leaves the community.</td>
<td>Case worker</td>
</tr>
<tr>
<td>(Output)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal Outcome Monitoring Sheet for Individual Users</td>
<td>During stay and when the user leaves the community.</td>
<td>Case worker</td>
</tr>
<tr>
<td>Life Skills Sheet - Case worker</td>
<td>Every six months during the user's stay in the community</td>
<td>Assigned case worker</td>
</tr>
<tr>
<td>Life Skills Sheet - User</td>
<td>Every six months during the user's stay in the community</td>
<td>User</td>
</tr>
<tr>
<td>User Satisfaction Sheet - Case worker</td>
<td>Every six months during the user's stay in the community</td>
<td>Assigned case worker</td>
</tr>
<tr>
<td>User Satisfaction Sheet - User</td>
<td>Every six months during the user's stay in the community</td>
<td>User</td>
</tr>
</tbody>
</table>

3.2. **Dataset quality analysis**

Before the data was statistically analysed, the quality of the dataset was first evaluated. This analysis allowed us to check the comprehensiveness of the information obtained and any incongruence. When the information obtained on hard copy questionnaires was input digitally, quality control procedures were applied; in fact, in order to compare the data uploaded to the software application against the information indicated on the relative measurement tool, an initial quality control was carried out on the first twenty sheets uploaded by each data entry operator. Subsequently, quality control was carried out randomly on the next fifty sheets entered and no particular problems were encountered in the digitalization of information contained in the completed questionnaires.

3.3. **Methods of analysis**

A number of preliminary descriptive analyses were conducted for the following tools (Short Severity Index, Life Skills – user/case worker, User Satisfaction - user/case worker) regarding the response methods to the individual questions set in the measurement tools. Following this, profiles describing respondent characteristics were generated, cross-referenced with variables revealed by other paper tools (Internal Outcome Monitoring Sheet for Individual Users, Individual User Output Service Sheet).

Based on the results of these descriptive analyses, specific multivariate procedures were conducted to compare respondent characteristics across the different aspects of the subject under study. The information was then analysed to generate patient profiles (User Life Skills - User/Case worker, Satisfaction - User/Case worker) with respect to the severity of the pathology diagnosed at the start of the pathway (Short Severity Index).
All statistical analyses were carried out using SPSS, version 18, or R statistical software, to generate descriptive indices and tables. Summary graphs were produced using Microsoft Office Excel.

For the purposes of comparison, the measurement scales used in each tool to give a total score in each aspect were standardized and converted to a 0-100 scale. The following formula was used to normalize scores:

\[
\text{Normalized score} = \frac{\text{Total score} - \text{minimum value}}{\text{Maximum value} - \text{minimum value}} \times 100
\]

Based on the types of variables analysed, appropriate statistical tests were applied to look at the association/correlation with the variable being studied. The following statistical tests were run for the various objectives of the study:

Objective 1 - check the difference in score obtained on a given tool between two groups: the T test was applied after the normal distribution of scores had been verified or, in the event of a non-standardized score distribution, the Mann-Whitney U nonparametric test.

Objective 2 - check the difference in scores obtained by three or more groups on a given tool: ANOVA variance analysis was used after the normal distribution of scores had been verified or, in the event of a non-standardized score distribution, the Kruskal-Wallis nonparametric test.

Objective 3 - assess the association between two scores: Pearson’s correlation coefficient was used after the normal distribution of scores had been verified or, in the event of a non-standardized score distribution, Spearman’s rank correlation coefficient.

Objective 4 - assess the association between a nominal qualitative variable (like gender, for example) and an ordinal qualitative variable (like education): Pearson’s chi-squared test or the Fisher Exact test were used.

Objective 5 - assess the association between two nominal qualitative variables (gender and nationality for example): the contingency coefficient was used (Kendall's K-test).

Objective 6 - assess the association between two ordinal qualitative variables (education and score categories, for example): Goodman and Kruskal’s Gamma Coefficient, which measures the two-way association between two ordinal variables and varies from -1 to +1, was used.

Objective 7 - assess a significant change in value between time T0 and time T1 for the same individual (longitudinal data, paired): the paired sample T-test was used, after normal distribution had been verified, otherwise the Wilcoxon nonparametric test.
4. SAMPLE

The sample in the Community Outcomes study comprised 290 individuals, 238 males (82.1%) and 52 females (17.9%). The average age was approximately 29 years and ranged from a minimum age of 16 to a maximum of 59 years. The average age of female users was significantly lower (p-value<0.001) than the male population (24.7 vs. 29.8). We must specify that 4 of the 290 users were minors when they entered San Patrignano: the Short Severity Index was calculated but for the purposes of privacy no further measurement tools were administered nor was the follow-up scheduled for 12 months after completion of the pathway. In other words, this group of users is useful to describe the profile of individuals entering San Patrignano from March 2013 to February 2014, but not for the subsequent steps in the Community Outcomes project.

89.3% of participants in the study are Italian nationals and there are no significant gender differences (89.5% males, 88.5% females) Only 3.1% of users are from Southern Europe and 2.3% from Eastern Europe.

As regards the educational qualifications of users (Table 1), around 2 out of 3 (61.0%) stated they had completed their lower secondary education (64.3% males and 46.2% females). In comparison, 33.5% of users stated they had completed higher or further education (14.3% vocational secondary school and 19.2% senior secondary school) with higher percentages for females (42.3% of females compared with 31.5% of males). In general, the distributions of the educational qualifications of users were significantly different between genders (p-value=0.004).

<table>
<thead>
<tr>
<th>Educational qualifications</th>
<th>Male</th>
<th>Females</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No educational qualifications</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Primary school</td>
<td>8</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>Lower secondary school</td>
<td>151</td>
<td>24</td>
<td>175</td>
</tr>
<tr>
<td>Vocational secondary school</td>
<td>31</td>
<td>10</td>
<td>41</td>
</tr>
<tr>
<td>Senior secondary school</td>
<td>43</td>
<td>12</td>
<td>55</td>
</tr>
<tr>
<td>Degree</td>
<td>1</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>235</td>
<td>52</td>
<td>287</td>
</tr>
</tbody>
</table>

* Figures not available for 3 users

The majority of users were unmarried when they entered the community (83.2%) and the percentages were fairly similar across the genders (83.4% for males and 82.4% for females). Conversely, 10.5% stated they were married or living with a partner (10.2% males compared to 11.8% females).

A little more than half of the users in treatment stated they did not hold stable employment (51.8%) and the percentage was greater for male subjects (53.3% vs 45.1% of the females).

Almost all users stated their mothers were around (96.5%); all female users said their mothers were still alive compared to 95.7% of males. Conversely, 15.1% of users said their fathers were absent (15.9% of males compared to 11.5% of females). In general, the vast majority of the participants in the study said their mother and/or father was around.
57.4% of participants in the study said their parents lived together (58.9% of males, 51.0% of females), 27.0% said their parents were separated, 15.6% said they came from a one-parent family. More of the female group had parents who were separated (37.3%) than the males (24.7%). Almost all users were the natural child of their parents (96.4% of males, 96.9% of females) compared to 3.7% of users who were adopted (3.6% of males, 4.0% of females). In terms of their own parental status, the majority of the users stated they did not have children (81.2%) and there was no significant difference between the genders (81.2% males, 80.8% females).

With regard to the 51 users who provided information about the status of their children, 64.7% said the children were their dependents (65.9% males compared to 60.0% of females), 21.6% were fostered (17.1% of males compared to 40.0% of females) and the remaining 13.7% had been removed. Almost all children of the 51 users with children were minors (92.6%) but with higher percentages among male users (95.5% males vs. 80.0% females).

Again regarding the group of users with children (51 users), around half (46.3%) stated their children lived elsewhere and/or were in care (21 male users, equal to 47.7% compared with 2 female users, equal to 40.0%); in parallel, 22 users with children, equal to 40.7%, said their children lived with them and/or were not in care (18 male users, equal to 40.9%, compared to 4 female users, equal to 40.0%).

More than half of the participants in the study and members of the community said heroin was their primary drug of use at admission (58.8%), with higher percentages among female users (56.3% of males compared to 70.0% of females) (Table 2) In comparison, 39.4% of users had been taking mainly stimulants (cocaine, amphetamines, hallucinogens, ecstasy) when they entered the community (42.4% of males, 26.0% of females). Only 1.8% of users had been taking cannabis as a primary drug.

Table 2 Distribution of users by type of primary drug taken and gender

<table>
<thead>
<tr>
<th>Primary drug</th>
<th>Males</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Cannabis</td>
<td>3</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>1.3%</td>
<td>4.0%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Cocaine, Amphetamines, Hallucinogens, Ecstasy</td>
<td>97</td>
<td>13</td>
<td>110</td>
</tr>
<tr>
<td></td>
<td>42.4%</td>
<td>26.0%</td>
<td>39.4%</td>
</tr>
<tr>
<td>Heroin</td>
<td>129</td>
<td>35</td>
<td>164</td>
</tr>
<tr>
<td></td>
<td>56.3%</td>
<td>70.0%</td>
<td>58.8%</td>
</tr>
<tr>
<td>Total</td>
<td>229</td>
<td>50</td>
<td>279</td>
</tr>
<tr>
<td></td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>
5. RESULTS: SHORT SEVERITY INDEX

5.1 Severity scores by area of interest

Average severity scores, normalized and calculated as described in paragraph “3.3 Methods of Analysis” for the five areas making up the Short Severity Index vary from a minimum of 13.3 in the medical area to a maximum of 58.9 in the toxicological area which appears, therefore, to be on average higher than the other areas (Figure 2).

![Figure 2. Average scores in each area of interest in the Short Severity Index](image)

5.2 Analysis using relevant stratification variables

Using a number of relevant variables of interest to stratify the analysis (Figure 3), we observed a greater presence of social hardship in foreign users (p-value=0.025) and users with low levels of education (p-value=0.046). The toxicological severity scores were higher among unmarried users compared with those who were married/living with partners (p-value=0.001), and greater social hardship was seen in the group of separated/divorced/widowed users (p-value=0.009) compared to those who were unmarried (p-value=0.009 or married/living together (p-value=0.012).

![Figure 3. Average scores for each area of interest by relevant stratifications](image)
A higher severity score was found in the medical and social areas for users whose parents were separated or who were from one-parent families (p-value=0.018 and p-value=0.001 respectively); users without children had higher toxicological severity scores than those with children (p-value=0.001). More health issues and more recourse to multiple treatments were seen in heroin users (p-values of 0.014 and <0.001 respectively) and in those injecting (p-value<0.001 for both areas).

5.3 Means of access to facility

When we looked at how users access the facility (directly, brought by family members, via local self-help and health groups, doctor’s referral or by another health organisation dealing with drug abuse, sent from prison or other means of access), no significant differences were found between the latter factors and user severity scores. Anyway, a few trends did emerge, such as higher toxicological severity scores for users coming from prison or brought by family members, greater medical severity for users accessing the facility themselves, and greater social, psychological, psychiatric hardship and multiple treatments among users sent from prison.

5.4 Treatment and discharge methods

The majority of users with experience of multiple treatments had also underdone previous treatments in other facilities. The small number of users who had already experienced the pathway in the therapeutic unit being studied had a higher severity index score than the others (Figure 4).
There were no statistically significant differences in how users were discharged, with respect to their severity profile on admission. Generally speaking, critical users in toxicological terms and with previous treatment history are later engaged in a pathway to get them back to work while users with the most critical profiles in medical, social, psychological-psychiatric terms on admission are discharged to their homes.

5.5 Contact with facility

With reference to the user's contact with the facility after treatment has ended (regular, at least monthly contact, occasional contact once or twice a year, no direct contact but indirect contact with relatives and/or friends, no contact, either direct or indirect) no significant differences in behaviour were found between users with different severity scores. Anyway, users who did not remain in contact with the facility after discharge tended to have a higher severity score in all areas on admission.
6 RESULTS: USER LIFE SKILLS

The longitudinal analysis of life skills scores (difference between first and last measurement taken) highlighted significant improvements in all areas (physical and mental health, behaviour, emotions and relationships, training and work) for the users studied; in particular, more significant improvements were found in the relationship and emotions area (Figure 5).

**Figure 5.** Average scores for each area of interest

With respect to area A - physical and mental health, significant improvements were seen on all items observed (lifestyle, mobility, cognitive abilities, recognizing and avoiding risk); in particular, substantial improvements were found in cognitive abilities.

Significant improvements were found on all items in area B - behaviour (communicating effectively, management of daily tasks, caring for others, respect for ethical values). In particular, more significant improvements were seen in communicating effectively and respect for ethical values. Significantly lower values were observed for “caring for others”.

In area C - emotions and relationships, significant improvements, of the same size, were seen on both items (relationships with others, “managing” emotions).

In area D - training and employment, significant improvements were observed for both items (training, employment), although more marked for training.
7 RESULTS: USER LIFE SKILLS - CASE WORKER

The longitudinal analysis of life skills scores recorded by the assigned case worker (difference between first and last measurement taken) highlighted significant improvements in all areas (physical and mental health, behaviour, emotions and relationships, training and work) for the users studied. In particular, more significant improvements were seen in the relationship and emotions area, although not as much as the user's own perceived improvement (Figure 6).

**Figure 6.** Average scores for each area of interest

With respect to area A - physical and mental health, significant improvements were seen on all items observed (lifestyle, mobility, cognitive abilities, recognizing and avoiding risk); Moreover, slightly more significant improvements were seen in cognitive abilities, although a little less than the user’s own perceived improvement.

As regards area B - behaviour, significant improvements were seen on all items (communicating effectively, management of daily tasks, caring for others, respect for ethical values). In particular, more significant improvements were seen in the respect for ethical values while significantly lower values were observed for “caring for others”, in line with the user's own perception.

Significant improvements, of roughly the same degree, were seen for both items in area C - emotions and relationships (relationships with others, managing emotions).

In area D - training and employment, significant improvements were observed for both items (training, employment), although more marked for training.
8 RESULTS: USER SATISFACTION

8.1 Importance of areas of interest

The longitudinal analysis of the scores users attributed to the importance of the areas of interest being studied (structure pre-admission “Territory association”, location, supervisors, case workers and therapeutic program) obtained by comparing the first and last values recorded (Figure 7) highlights a significant increase in the user’s perceived importance. The area of interest significantly increased are: territory association (p-value<0.001), location (p-value=0.005), health workers (p-value=0.045) and therapeutic program (p-value<0.001). The “relationships with supervisors” area, which tended to be rated as the more important of the two, was not found to be significant.

8.2 Satisfaction with the areas of interest

In a similar way, the longitudinal analysis of the scores users gave for their satisfaction with the areas of interest being studied obtained by comparing the first and last values recorded (Figure 8) highlights some significant increases in the user’s perceived satisfaction. These increases are observed for the territory association (p-value=0.026), the location (p-value<0.001) and therapeutic program (p-value<0.001). As regards relationships with case workers, although no significant variations were found, satisfied tended to develop from the first to the last questionnaire completed.
8.3 Analysis of importance vs. satisfaction

An association between the user's perceived importance and satisfaction was witnessed for all areas of interest. The comparison highlighted a positive association (directly proportional) between the two aspects being studied: the more users rated the areas of interest as important, the higher their perceived level of satisfaction (p-value<0.001).
9 RESULTS: USER SATISFACTION – ASSIGNED CASE WORKER

9.1 Importance of areas of interest

The longitudinal analysis of how the case workers rated the importance of the areas of interest, obtained by comparing the first and last values recorded (Figure 9) highlights a significant increase in all areas (p-value<0.007), with the exception of the relationships with supervisors area, which still tended to be the most important of the two but not significantly so.

9.2 Satisfaction with areas of interest

The user’s perceived satisfaction levels, according to the case workers, across the areas of interest (Figure 10) at the beginning and end of the measurement period highlights a significant increase in satisfaction in all areas studied (p-value<0.006).
9.3 Analysis of importance vs. satisfaction

An association between importance and satisfaction was witnessed for all areas of interest. The comparison highlighted a positive association (directly proportional) between the two aspects being studied: the more the case workers rated the areas of interest as important, the higher the user’s perceived level of satisfaction, according to the assigned case worker (p-value<0.001).
10 RESULTS: MULTIVARIATE ANALYSIS

10.1 Cluster Analysis Short Severity Index

Cluster analysis is a tool used to explore data and locate any natural groupings (clusters). Cluster models are normally used to identify groups (or clusters) of subjects with similarities on one of the variables examined, where the similarity between members of the same group is high but low between members of different groups. The Two Step Cluster Analysis used in this study works with both qualitative and quantitative variables. For exploratory purposes, this type of analysis was applied to short severity index data to find any groups of users diagnosed with pathologies of a similar severity at the beginning of the treatment pathway. The cluster analysis results highlighted the presence of two groups of users, the first comprising 83.5% of users and the second the remaining 16.5% of those assisted.

Table 3 lists the individual predictors (variables used to construct clusters) for each of the two clusters created (group 1 and group 2) in order of overall importance. Overall importance is shown in the table (Importance column), the darker the colour the more important the variable and the lighter colours the less important ones. From the table, the most important variables determining clusters are the presence of children (importance of 1) and the presence of minors (importance of 0.97). In particular, the first cluster contains all subjects who said they have no children, not even young ones (100% for both variables) while the second cluster contains all patients who said they have children (100%) and almost all subjects with young children, living with them or not (97.5%). For the remaining variables, the importance dropped drastically, reaching 0.48 for marital status (85.5% unmarried in the first cluster, 45% married/living with partner in the second cluster), 0.46 for children living somewhere else and/or in care, and 0.44 for children living in the same house and/or not in care (Table 3). Interestingly, scores in the areas included in the short severity index can be seen to have an importance score almost equal to zero (0.07 for the toxicological area, 0.02 for the social and medical area, 0.01 for the psychological-psychiatric area, and 0 for the previous treatment area).
<table>
<thead>
<tr>
<th>Variables</th>
<th>Importance</th>
<th>Group 1 (N=202 – 83.5%)</th>
<th>Group 2 (N=40 – 16.5%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children</td>
<td>1</td>
<td>No. (100.0%)</td>
<td>Yes (100%)</td>
</tr>
<tr>
<td>Presence of young children (minors)</td>
<td>0.97</td>
<td>No. (100.0%)</td>
<td>Yes (97.5%)</td>
</tr>
<tr>
<td>Marital status</td>
<td>0.48</td>
<td>Unmarried (95.5%)</td>
<td>Married/Living with partner (45.0%)</td>
</tr>
<tr>
<td>Children living elsewhere and/or in care</td>
<td>0.46</td>
<td>No. (100.0%)</td>
<td>No. (50.0%)</td>
</tr>
<tr>
<td>Children living in same house and/or not in care</td>
<td>0.44</td>
<td>No. (100.0%)</td>
<td>No. (52.5%)</td>
</tr>
<tr>
<td>Age</td>
<td>0.13</td>
<td>27.36</td>
<td>34.53</td>
</tr>
<tr>
<td>Toxicological area score</td>
<td>0.07</td>
<td>61.55</td>
<td>52.5</td>
</tr>
<tr>
<td>Education</td>
<td>0.03</td>
<td>Lower secondary school (61.9%)</td>
<td>Lower secondary school (50.0%)</td>
</tr>
<tr>
<td>Social area score</td>
<td>0.02</td>
<td>21.16</td>
<td>24.08</td>
</tr>
<tr>
<td>Medical area score</td>
<td>0.02</td>
<td>12.9</td>
<td>16.17</td>
</tr>
<tr>
<td>Child (Natural)</td>
<td>0.01</td>
<td>Natural (96.0%)</td>
<td>Natural (100.0%)</td>
</tr>
<tr>
<td>Occupation (Not stable)</td>
<td>0.01</td>
<td>Not stable (53.0%)</td>
<td>Stable (57.5%)</td>
</tr>
<tr>
<td>Psychological-psychiatric area score</td>
<td>0.01</td>
<td>25.51</td>
<td>22.62</td>
</tr>
<tr>
<td>Primary drug used</td>
<td>0.01</td>
<td>Heroin (60.4%)</td>
<td>Heroin (52.5%)</td>
</tr>
<tr>
<td>Parents (Together)</td>
<td>0.01</td>
<td>Together (55.9%)</td>
<td>Together (60.0%)</td>
</tr>
<tr>
<td>Gender (Male)</td>
<td>0</td>
<td>Male (81.2%)</td>
<td>Male (85.0%)</td>
</tr>
<tr>
<td>Presence of father</td>
<td>0</td>
<td>Yes (85.6%)</td>
<td>Yes (82.5%)</td>
</tr>
<tr>
<td>Nationality</td>
<td>0</td>
<td>Italian (88.1%)</td>
<td>Italian (92.5%)</td>
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<tr>
<td>Previous treatment area score</td>
<td>0</td>
<td>26.79</td>
<td>27.36</td>
</tr>
<tr>
<td>Primary method of drug administration Inhaling/per os</td>
<td>0</td>
<td>58.4%</td>
<td>57.5%</td>
</tr>
<tr>
<td>Presence of mother</td>
<td>0</td>
<td>Yes (97.5%)</td>
<td>Yes (97.5%)</td>
</tr>
</tbody>
</table>
10.2 Temporal Life Skills Analysis - User and Case worker

To further explore rehabilitation treatment outcomes, a detailed analysis was performed to determine the cut-off point after which significant improvements in life skills are witnessed. Changes in scores were assessed for each area (physical and mental health, behaviour, emotions and relationships, training and work) from the start of treatment (time T0) to T1, T2, T3, T4, T5, T6, T7 periods of time afterwards. Time T0 was set as when each user fills out their first questionnaire whereas the remaining cut-offs were set as follows:

- T1: time between T0 and filling out the nth questionnaire after 6 months;
- T2: time between T0 and filling out the nth questionnaire, between 6 and 12 months;
- T3: time between T0 and filling out the nth questionnaire, between 12 and 18 months;
- T4: time between T0 and filling out the nth questionnaire between 18 and 24 months;
- T5: time between T0 and filling out the nth questionnaire, between 24 and 30 months;
- T6: time between T0 and filling out the nth questionnaire, between 30 and 36 months;
- T7: time between T0 and filling out the nth questionnaire between 36 and 60 months.

Life skills scores calculated for users and also those perceived by case workers were analysed at the same time.

As regards the acquisition of skills in the user’s mental and physical health area, a gradual improvement in both measurements (Life Skills sheet compiled by user and Life Skills sheet compiled by case worker) was seen the longer the treatment lasted. A significant improvement (p-value<0.001) was observed 6-12 months after the start of treatment, both in the user’s perception and also according to the case workers (Figure 11). Interestingly, the extent of the skills perceived by users was always greater than that recorded by the case workers, although the difference gradually decreased the longer the treatment lasted.
Figure 11. Trends in average life skills scores, specifically mental and physical health, reported by users and by case workers.

The users’ acquisition of skills in the behaviour area gradually improved for both measurements (users and case workers) the longer the treatment lasted, as did psycho-social skills; nevertheless, according to the user's perception a statistically significant improvement (p-value<0.001) was seen 6-12 months after the start of treatment but only after 12-18 months in the case worker’s eyes (Figure 12). Again, the extent of the skills perceived by users was always greater than that recorded by the case workers, the difference gradually decreasing the longer the treatment lasted.

Figure 12. Trends in average life skills scores, specifically behaviour, reported by users and by case workers.

A gradual improvement, on both measurements (users and case workers) in users’ skills was also seen in the emotions and relationships area, the longer the treatment lasted. A statistically significant improvement (p-value<0.001) was seen 6-12 months after treatment commenced, both in the user's perception and in the opinion of the case workers (Figure 13). Again, the extent of the skills perceived
by users was always greater than that recorded by the case workers, the difference gradually decreasing the longer the treatment lasted.

Figure 13. Trends in average life skills scores, specifically **Emotions and relationships**, reported by users and by case workers.

The users’ acquisition of skills in the training and employment area gradually improved for both measurements (users and case workers) the longer the treatment lasted; according to the case workers, a statistically significant improvement (p-value<0.001) was seen 6-12 months after the start of treatment but only after 12-18 months in the user’s opinion (Figure 14). Again, the extent of the skills perceived by users was greater than that recorded by the case workers, the difference gradually decreasing the longer the treatment lasted, until they were equal around 30-36 months after treatment commenced.

Figure 14. Trends in average life skills scores, specifically **Training and Employment**, reported by users and by case workers.
11 RESULTS: DROP-OUT

Abandoning a course of treatment before it has reached its natural conclusion, also known as drop-out, is a huge, and intrinsic, risk when patients with substance abuse issues undergo a residential treatment programme. With respect to the participants of this study (290 people), you are reminded that four minors were not included, except for the Short Severity Index, in the current figures. Of the 286 remaining, at the time this data was collected 53 were still in treatment and 233 had completed it (Individual User Service Sheet Output form completed); of these, 61, equal to 26.2%, abandoned the therapeutic programme while it was still under way. At the time the data presented in this study was collected, 172 people out of 286 had completed the therapeutic rehabilitation pathway with the approval of San Patrignano (60.1%).

This made us curious, and we realized how important it was to compare the profiles of the user population in treatment with those of individuals who had completed their rehabilitation, in order to identify any potential predictors which would be useful in the development of specific measures to reduce drop-out.

Considering the large number of cases and the general similarity of the profiles of users being treated in the SanPa Community, the comparison of the two sub-groups rarely picked up statistically significant differences; nevertheless, the trends observed provided some interesting and useful insights.

An initial finding, perhaps to be expected, was that drop-outs almost always occur in the earliest phase of the rehabilitation pathway. 30% of users who abandoned the program did it in the first two months, and two thirds of this sub-population did it within the first four months; dropping-out after the first year of rehabilitation was only seen in 20% of those who abandoned their course of treatment.

Those who dropped out were on average older than the rest of the users (32.1 years compared to 28.4 years; p=0.003), were in treatment for addiction to both heroin and stimulants (49.0% of drop-outs compared to 35.4% of non-drop-outs) and more drop-outs had young children than those who completed their rehabilitation programme (Figure 15).

In terms of the severity scores on admission to the facility, even though there were no significant differences, it emerged that users abandoning their treatment tended to have a higher severity score in the medical, psychological-psychiatric and social areas (Figure 16).
Figure 16. Average scores for each area of the Short Severity Index for drop-out users and non-drop-outs.
12 FROM RETENTION FACTOR TO FOLLOW-UP. THE ROLE OF TOXICOLOGICAL TOOLS IN RESEARCH ON LONG-TERM ADDICTION TREATMENT OUTCOMES

In any discussion of treatment programmes for addiction, whether the addiction is to substances or to behaviours, and therefore not substance-related, the important point to remember, and emphasize, is that the real problem is how the results over time can be measured.

As widely documented in international literature on the subject, treatments are usually divided into short or long-term. The former tend to focus on substances or specific consequences of the addiction while the latter try to intervene and remove the causes of the addictive behaviour.

The two types of intervention are very different in nature: short-term treatments can easily be described in steps (stages, techniques, timings) whereas long-term treatments are difficult to describe accurately. The former do not usually foresee any measurement of outcomes over time unlike the latter which, despite being more difficult to decipher analytically, often attempt to measure long-term effects in follow-up studies.

Treatment programmes offered in Italian rehabilitation communities, described in international literature on the subject as among the best in the world, fall mostly into the second category. Since said treatments aim to achieve a degree of stability whereby the individual concerned not only “breaks free” from the addiction (chemical or behavioural) but also resumes his or her place in civil society as a fully-functioning member, able to work and exercise their rights, the treatments are inevitably never short-term.

As mentioned before, it's almost impossible to describe with any precision the particulars of each stage of the community treatment process, given that the residual self of each individual is profoundly different, although it’s equally difficult not to identify a number of general commonalities in the interventions. Outcomes, on the other hand, can be easily verified over time, as they are based on a number of indicators which are more or less beyond question:

1. health;
2. drug-free status;
3. recovered social role and employment;
4. exercising rights as a citizen.

The effectiveness of a treatment programme is usually measured 1-3 years after its completion.

Communities offer treatments which, despite their individual differences, share a common vision - all focus on restoring to full health and a normal life to the individuals accepting the treatment. It is inevitably a complex recovery, and frequently problematic, but it often produces results which are clear and measurable. None see pathological addiction as a permanent characteristic of the individual, and the outcomes of their interventions have proved them right.

The San Patrignano community was the first to promote follow-up studies and research among people who had been residents at the facility for long and significant periods (currently no less than three
consecutive years). It was also the first to embrace both socio-statistical follow-up studies and also toxicological ones. In other words, former residents were asked to provide a hair sample as a biological sample for toxicological analysis.

This aspect, in comparison to the equally important sociological research, allows the Community to assess, with absolute, scientific certainty, if the individual submitting to the hair test is drug free or not (for a period of more than six months prior to the sample).

We can safely assume that anyone entering San Patrignano to begin a pathway that will last several years will have no access whatsoever to any type of drug. Providing a hair sample for toxicological analysis of a biological sample therefore only makes sense as part of the follow-up proper which starts after treatment has been completed.

In the case of this study, which draws a distinction between the time spent in the community (retention factor) and the external follow-up, the decision was taken, to dispel any possible doubts, that a series of hair tests would also be done in an initial, preparatory stage of the research.

On 1 July 2014, as part of the national “Community Outcomes” study, 113 samples were taken from residents at San Patrignano, and all were negative.

On 11 November 2015, the tests were repeated on 144 residents of the community (76 of whom had been involved in the previous test) - as before, all biological samples tested negative in the toxicological analysis.

All samples (257) were from individuals who had been at San Patrignano for at least six months and up to 30 months - more or less in the middle of their treatment.

It can be said, therefore, that while the toxicological analysis of a biological sample within the context of the retention factor research is a self-fulfilling prophecy of sorts, it becomes absolutely vital to the follow-up proper which starts once the pathway in the community has ended and represents the natural evolution of the research carried out during the course of the treatment.

Needless to mention that the toxicological tools used during the retention factor stage and the subsequent analysis have helped fine-tune tools for the next stage of the study, currently in its inception.
13 CONCLUSIONS

The purpose of the therapeutic community outcomes study, commenced in March 2013 and follow-up phase still under way, was to assess the effectiveness of the various therapeutic and rehabilitation processes, by constantly cross-referencing them with the clinical conditions of users at the start (severity index), the processes used and the facilities implementing them. The following areas were considered:

1. Access methods of people suffering drug addiction (selection criteria, number of applications received/no. of people accepted, severity index on admission, substance types detected in toxicological tests);
2. Period of treatment/rehabilitation within the community (variations in severity index, length of stay, drop-out rate, time before drop-out, reason for drop-out, level of training and professional skills acquired, life skills);
3. Post-treatment/rehabilitation period (keratin matrix toxicological tests twelve months after leaving the community, in parallel with assessment of quality of life and degree of reintegration in society and labour market, assessed using a questionnaire/interview.)

As regards the information collected and analysed to date, the results presented in this document helped to build a detailed profile for the first two areas of interest.

As regards the first area, and in particular the severity scores of users on admission which were measured using the Short Severity Index tool, a medium-low severity profile on admission was broadly found for participants in the study. This confirmed the access criteria respected by admissions staff when determining who to admit to the facility.

The area with the highest severity score (58.90 where the maximum severity score possible was 100) was the toxicological area, while the average severity profile in the other areas studied (medical, social, psychological-psychiatric and previous treatments) did not exceed 30 (out of a maximum of 100).

When the characteristics of users with higher severity scores were analysed, more problems in the social area were found for foreign users, with medium-to-low levels of education, mainly separated/divorced or whose parents had separated. Higher severity scores in the toxicological area were seen for younger users, those who were single and had no children, whereas higher severity scores in the medical area were predominantly associated with the types of drugs taken and method of administration.

In the same context, analysis of severity scores on admission did not appear to be associated with how the facility was accessed (directly, brought by family members, via local groups, doctor/hospital referral or sent from prison) nor the way users were discharged (to a private home, or engaged in a pathway to get them back into work, or to a private home AND engaged on a pathway to get them back into work). The type of post-treatment contact was also not associated with the severity score on admission.

It was interesting to note that the multivariate analysis to find groups of users with common characteristics highlighted the presence of only two groups, confirming the overall homogeneous nature of users at the time of admission.

The distinctive feature of the two groups emerging from statistical analysis of the data was the presence or absence of children, especially younger ones. The group without children was, on average, younger, the majority were single and had a medium-low level of education, no stable occupation and a higher severity score in the toxicological and psychological-psychiatric areas than
the other group of users. Conversely, the second group had a higher average age, half were married or living with a partner, the same proportion had a medium-high level of education, a less severe toxicological profile, but a more problematic social and medical one, in light of the difficulty in caring for their children.

These results were confirmed in an analysis which took a different approach. It aimed to pin down the characteristics of the “less severe” and “more severe” categories for each area of the Short Severity Index.

Users with a less severe score in the toxicological area were found to have children, especially young children, who lived in the same house and were not in care, thereby explaining their “greater sense of parental responsibility”. A less severe profile in the medical area was observed for users with a milder toxicological profile (where inhalation was the main method of drug administration, for example) and who did not come from a broken home. A less problematic profile in social terms was observed in users with a stable job and who grew up with both parents, whereas there was a higher probability of repeat treatments for users who injected opiates, a group which was also found to have a higher average age.

As regards the second area of interest in the study, trends in user life skills during the rehabilitation and re-education pathway were analysed. A comparative criterion was introduced to the methodology to allow the users’ perceptions of their developing skills to be compared with the assessment of the same skills by their case workers.

The results pointed to a significant improvement in life skills during the rehabilitation/re-education pathway across all areas studied (mental and physical health, emotions and relationships, training and employment) and in particular with respect to cognitive abilities in the mental and physical health area.

An additional finding which emerged from the comparison of the two different points of view (user and case worker) was that the life skill profiles were worse when reported by the case workers, who tended to assign lower scores than those the users perceived for themselves. Interestingly, the longer the treatment pathway the less difference there was between the two points of view, to the extent that by three years after treatment started, the scores assigned by case workers equalled those perceived by users.

One of the questions the study aims to answer concerns the length of treatment required before a significant improvement can be seen in life skills. For improvements in physical and mental health, emotions and relationships, from 6 to 12 months was needed from both perspectives (user and case worker); for significant improvements in behaviour (communicating effectively, management of daily tasks, respect for ethical values, caring for others) 6 to 12 months were needed according to users but a longer time, from 12 to 18 months, in the case worker’s opinion. Conversely, the significant acquisition of training and employment skills was obtained after 6-12 months according to the case workers but only after 12-18 months in the users’ minds.

The results generated in this study are distinctive, not just on a national Italian scale but internationally. They give us an interesting breakdown of San Patrignano residents reflecting both the practical perceptions of case workers and the admission criteria for those entering the facility.

The multi-dimensional nature of the severity score seems to hinge primarily on the presence/absence of young children who live with the user; this seems to be key factor in both types of user, who are otherwise mostly similar.

Another important aspect is the length of treatment needed to observe improvements in the life skills of residents; with respect to the standard duration (roughly three years), a significant improvement
can be seen in almost all areas studied (mental and physical health, emotions and relationships, behaviour, training and employment) by the end of the first year, which confirms the effectiveness of the multidisciplinary rehabilitation programme offered to the type of users entering the facility. 
In conclusion, the salient results of the study can be summarized as follows:

- Substantial similarities, in terms of the severity of the social and health issues witnessed in the participants in the study;
- Separation of participants into two groups depending on whether they had children, particularly younger children, but otherwise homogeneous in terms of toxicological, medical and social severity;
- Significant improvement in user life skills and satisfaction during the rehabilitation pathway; in most areas studied, significant improvements in life skills were seen as early as 6 to 12 months after commencing treatment.
REFERENCES


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