Evaluating the effectiveness of the "Individual Assistance Plan" for Italian chronic patients

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***Abstract*—The aim of this work is the evaluation of a relatively new intervention for chronic patients in Italy, namely the PAI, i.e., "Piano Assistenziale Individuale" (Individual Care Plan). It is a service based on the paradigm of the personalised medicine, which should optimize several aspects of the individual care, such as patients' compliance to therapy, ease of access to care delivery, and a tighter monitoring of the patient's status on the long run. The expected outcomes from the PAI introduction are both the improvement of the patients' status and reduction of costs for the care provider. A case-control study has been performed, involving more than 20000 patients, and preliminary results seem to confirm the effectiveness of the new service, in particular by reducing patients' access to hospital and emergency room.**

Keywords—personalised medicine, careplan, public health

I. INTRODUCTION AND BACKGROUND

Healthcare revolves around the needs of people and families. During the years the strive to make health services more personalized and closer to their users has been constant. The main goal has always been the creation of a modern system capable of being efficient and in line with the most relevant international experiences and the evolution of the demographic situation: due to the ageing of the population, advanced countries have about 1/3 of their inhabitants suffering from chronic pathologies, whose care processes absorbs more than 70% of the resources [1].

Treatment of chronic illnesses requires patients to undergo periodic follow up visits, cyclic drug therapies and constant monitoring of compliance to treatments. Faced with the task of managing complex and often boring clinical and bureaucratic routines, an already clinically frail individual can feel inadequate and unable to withstand the required effort. This can lead to a drastic reduction of compliance, and consequently health level and life quality [2] [3].

For this reason, the asymmetry in the relationship between the patient and the Healthcare System must be balanced as much as possible. In particular, the latter must take responsibility to help and accompany the former through the whole care process. It is clear how overcoming the current fragmentation of services is essential to optimize this complex care process. The assistance model must shift from a disease-centered approach to a patient-centered one, personalized on individual needs and considering of social and familiar context. The process of analysis, planning and management of the process must be carried out in a way that is rational and, as much as possible, understandable for patients.

There are examples of such interventions in the literature showing that several countries are moving in that direction. For example, Brixner et al [4] show that participation in personalized care plans improves outcomes for patients with chronic diseases (in the specific case those treated with adalimumab) by helping them to manage a complex treatment regimen, and also lower health care costs. Freund et al [5] shows that 43% of hospitalizations for ambulatory care-sensitive conditions are potentially avoidable with more personalized healthcare plans. However, healthcare systems must carefully monitor the effectiveness of their interventions. As a matter of fact, Lewy et al [6] discuss on how different patient populations benefit in different ways from personalized care plans, and thus "continuous evaluation, service adaptation in a real-life environment set with clear outcome measures, is required for best results". Also the review by val Loenen et al. [7], while showing positive findings with better longitudinal continuity of care, highlights a lack of evidence for the positive effects of many other organizational primary care aspects, such as specific disease management programs.
In this paper, first we describe a personalized healthcare service recently introduced in Italy by the national healthcare system, and then we describe a preliminary evaluation study aimed at assessing its effectiveness.

II. THE NEW ITALIAN SERVICE

Following the above described paradigm of the personalized medicine, Regione Lombardia introduced the

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Presa in carico (literally, "taking charge") of the chronic patient, thoroughly regulated by ad hoc Regional Resolutions drawn up between 2017 and 2018. [8][9][10][11][12]

The first step of the implementation of this integrated model required the setting of the target, through the mapping of the entire regional population of chronic patients (about 3.5 million individuals) according to their clinical situation and consequent care needs. These subjects have thus been stratified into 3 levels:

1) the most clinically frail patients, with a main pathology and 3 or more comorbidities.
2) patients with a total of 2-3 pathologies;
3) patients with one chronic pathology and no comorbidities.

Subjects accepting the invite by ATSs (local Agencies for Health Protection) to adhere to the new assistance service, choose an ATS-accredited *care manager,* tasked with accompanying them in their care process.
The PAI ("Piano Assistenziale Individuale", literally "individual care plan") is the tool used by care managers for the personalized year-long planning of all the interventions (visits, exams, drug prescriptions, prosthetics, vaccines) needed to manage the chronic illness of the patient, freeing him from the burden of self-managing the bureaucratic aspect of the care process.

During the first visit the plan is laid out and all the aforementioned interventions are planned according to existing "reference sets" that list all the exams and visits deemed appropriate, according to the best practice, for the treatment of a specific chronic illness. [13]

The patient is also required to provide information about his medical history and lifestyle, to better tune and personalize the plan. In particular, items regarding his smoking habits, alcohol intake and physical activity, as well as the body mass index (BMI) value, are included. [14].

One year later (or earlier if needed) the care plan is re-assessed.

Considering its contents, the PAI is an invaluable source of information that can be analyzed to extract knowledge about the care process.

The work described in this paper exploited data from ATS Valpadana, that introduced the service in the beginning of 2018. The management of the process is entrusted to the IRISS software, developed by the IT company DSPSolutions [15].

The expectation for the introduction of this process is the improvement of the patient's status and the reduction of costs for the care provider. As a matter of fact, the advanced personalized planning of health interventions should allow reducing the number of accesses to the Emergency Room and the number of hospitalizations. Those were the two main statistical indicators considered in this paper.

III. Materials and Methods

A. Sample Extraction

Considering that the introduction of PAI happened in January of 2018, it was agreed to only take into consideration patients starting their plan in April of the same year, to be reasonably sure to avoid the clinicians' "learning curve" months, during which it is fair to expect sub-optimal PAIs to be created [16].

Two datasets were provided for analyses: one regarding patients undergoing PAI (from here on, "PAI patients" or "PAIs"), including 1890 subjects, and the other listing patients not undergoing PAI (noPAI patients or "noPAIs"), made of 18984 records.
The two groups have been paired based on their sex, age group and pathology level (1 to 3, according to the stratification described in section I).

Beside these, both the care plan detail file, listing every care intervention prescribed to PAI patients during the first visit, and the ATS-generated logs of actual interventions executed are available. The latters include logs of hospital discharge form, describing the main diagnoses and interventions made during hospitalization, and of accesses to the Emergency Room.

B. Data Cleaning

Data cleaning represented an important part of the analysis, which was necessary mainly for refining the pairing process: the control group had to be filtered to exclude unpaired records (noPAIs not corresponding to any PAIs), as well as noPAI patients which were dead before the start of their associated PAI.

Besides, the initial pairing was m-to-n, i.e., each PAI patient was associated with multiple noPAIs (that could be acceptable for our analysis), but also some of the noPAIs were paired to multiple PAIs. In order to be able to work under the assumption of independent samples, only one noPAI-to-PAI pairing was maintained in the end, making the PAI-noPAI matching 1-to-n. Since the initial pairing had been created based on pathology level, sex and age class, this refinement was based on the age similarity of the two subjects involved. Thus, each originally multi-paired noPAI was only kept paired with the closest PAI in terms of age. By doing so the initial dataset of 1890 PAIs and 18984 noPAIs was reduced (see section IV-A).

Also, the time window for the observation of each patient was reduced to a maximum of one year (the cycle duration of a PAI plan), beginning, for both PAIs ad noPAIs, from the start date of the yearly plan. Exceptions to the 365-day duration exist, due to two main reasons: unavailability of data (logs are currently available only until Jul 31, 2019, so monitoring of yearly plans started after Jul 31, 2018 last less than 365 days) and death of a noPAI patient (no deaths were recorded for PAIs during the observation period).

C. Analysis

First of all, a descriptive analysis has been performed, in order to identify the characteristics of the target cohorts. Since, as already mentioned, the pairing was made based

on pathology level, sex and age class, these were the first aspects to be taken into consideration for the study.
Once the similarity of those variable values in the two cohorts has been verified (and thus their comparability assured), the statistical indicators have been calculated and inferential statistics have been performed to test if they significantly differ between the two populations. As mentioned, the analysis has been focused on ER accesses and hospitalizations, both of which are very well-documented aspects of the care process, thanks to the ATS-generated intervention logs provided for the analysis. Two calculation methods for those indicators have been used. First, an overall statistic measuring the number of events per man-year of observation was performed. The

resulting rates were compared using Chi-square test. Moreover, the yearly number of hospitalizations and accesses to the ER *per patient* were calculated, in such a way to perform also a statistic for paired data. Since we have more than one noPAI paired to every PAI, the first step was to make the samples comparable. For each group of noPAIs paired with the same PAI, their average parameter value was calculated, thus obtaining a new array with the same length of the PAI one.
In order to identify the appropriate statistical tests for pair data analysis, we investigated data normality using the Kolmogorov-Smirnov test. When the normal distribution hypothesis was rejected, making the t-test inadequate for the task, the non-parametric Wilcoxon test was applied.
Multivariate regression analysis was also used to investigate the relevance of specific parameters as predictors of the indicators. The aim of this analysis was to determine the predictive value of belonging to the PAI/noPAI class after correction for other characteristics.
All the statistical analyses have been performed using the R package [17].

IV. Results

A. *Descriptive Analysis*

The transformation of the dataset from a m-to-n to a 1-to-n pairing entailed the reduction of the number of records for both PAIs and noPAIs. Thus after data cleaning, the usable patient dataset was composed by 1889 PAI observed for a total of 683564 days, and 14582 noPAI patients observed for 5274335 days. Their composition in term of severity of health condition is described in Table I, while Tables II and III describe the dataset in terms of gender and age class, respectively. Figures 1 and 2 further detail the age distribution.

TABLE I. DATA BY PATHOLOGY LEVEL

	Pathology level	number	%
PAI	1	37	1,96
	2	616	32,66
	3	1236	65,53
No_PAI	1	290	1,99
	2	4930	33,81
	3	9362	64,20

TABLE II. DATA BY SEX

	sex	number	%
PAI	F	1003	53.10
	M	886	46.90
No_PAI	F	7809	53.55
	M	6773	46.45

TABLE III. DATA BY AGE CLASS

	Age class	number	%
PAI	00-17	6	0,32
	18-64	624	33,03
	65-74	546	28,90
	75+	713	37,74
No_PAI	00-17	58	0,40
	18-64	5016	34,40
	65-74	4049	27,77
	75+	5459	37,44

Fig. 1. Age distribution of the PAI population

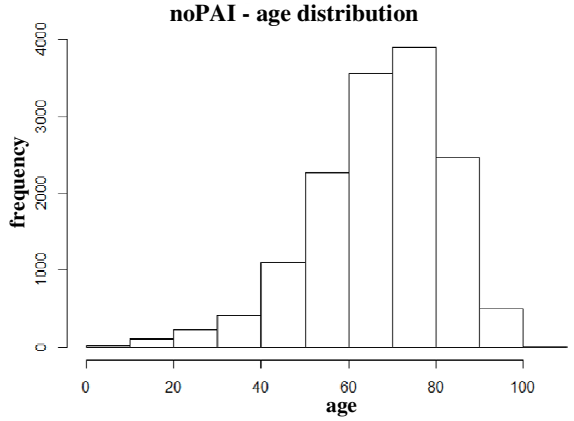

Fig. 2. Age distribution of the noPAI population

B. *Inferential analysis*

Regarding the intervention logs, the total number of ER accesses were respectively 146 for the PAIs and 5189 for the noPAIs.

Table IV shows data about ER accesses- specifically, for every Triage severity class (White, Green, Yellow and Red, in increasing severity order) the raw number of PAI/noPAI patients accessing the ER as well as their percentage on the total population (as mentioned, 1889 and 14582 patients). The difference between the rates is always in favor of our research objective and are statistically significant (Chi-square test p-value always <= 0.001).

TABLE IV. ER ACCESS ANALYSIS

TRIAGE	PAI	NOPAI	PAI %	noPAI %	diff	p-value
W	3	155	0,159	1,063	-0,904	0.0001
G	67	2299	3,547	15,766	-12,219	< 0.0001
Y	48	1483	2,541	10,170	-7,629	< 0.0001
R	4	141	0,212	0,967	-0,755	0.0009

Similarly, table V shows the results of the analysis regarding hospitalizations. Despite the difference between the percentages of hospitalized patients not being significant, the one between re-hospitalizations in the two groups is favourable to PAIs (row 2). This result also drives the significant difference between the hospitalization days (row 4).

About the average hospital stay (row 5), it's reasonable to see similar values because patients in the two groups, matched by PAI pathology, are likely hospitalized for the same reasons.

TABLE V. HOSPITALIZATIONS ANALYSIS

Indicators	PAI	NOPAI	diff	p-value
Hospitalized patients (%)	13,87	15,27	-1,40	0.1099
Repeatedly (>1 time) hospitalized patients (%)	4,13	5,19	-1,06	0.0481
Repeated hospitalizations (%)	51,83	57,62	-5,78	0.0001
Days of hospitalization/ observation time (%)	0,4000	0,6098	-0,21	0.0001
AVG hospitalization days	7,16	9,28	-2,12	0.2609

Also, the number of yearly hospitalizations and ER accesses per patient has been evaluated. Wilcoxon tests were performed due to non-normality of data distribution, which revealed a significant difference between the datasets: for both accesses and hospitalizations, the resulting p-value was < 2.2e-16.

Finally, as seen in tables VI and VII, multivariate linear regression was performed on a dataset including, for each record (i.e. patient) his classification as PAI/noPAI, revealed that this parameter is an independent predictor for the number of hospitalizations and, even more significantly, for ER accesses.

Other predictors signaled by clinical experts as possibly significant for the analysis are also shown in the tables: the multimorbidity level, the age and the sex- the latter only for hospitalizations, indicating that male and female patients access the ER at the same rate, but males are more likely to be hospitalized.

TABLE VI. REGRESSION MODEL FOR HOSPITALIZATIONS

Variable	Coefficient	p-value
Intercept	0.049	0.3807
PAI/noPAI class	0.035	0.0302
Level (2)	-0.208	5.37e-08
Level (3)	-0.298	4.56e-15
Sex (m)	0.053	3.84e-07
Age	0.005	< 2e-16

TABLE VII. REGRESSION MODEL FOR ER ACCESSES

Variable	Coefficient	p-value
Intercept	-0.188	0.00295
PAI/noPAI class	0.279	< 2e-16
Level (2)	-0.254	3.31e-09
Level (3)	-0.303	1.24e-12
Sex (m)	0.010	0.37694
Age	0.004	< 2e-16

V. DISCUSSION AND CONCLUSIONS

The results obtained with this preliminary analysis seem to confirm the effectiveness of the *Presa in carico* service and the consequent PAI. This supports the hypothesis that the introduction of this new personalized model helps optimizing the process of individual care and reducing the costs for the providers (less interventions means less waste of resources).

Our study suffers from some limitations that can be overcome in future iterations. First, considering that the current window of data availability ends in Jul 31, 2019 and the patient enrolment started in Apr 2018, a part of the evaluated subjects did not get a full year of observation. Thus, robustness of results should be verified with a longer observation period.

Second, there are additional aspects that can be taken into consideration and included in the study to make it more complete and precise. For example, data about prescription of drugs, control visits, diagnostic tests, etc., can be used to evaluate physicians' adherence to clinical

practice guidelines during the creation of the PAI as well as patients' adherence to the PAI, in terms of both execution and timeliness (in relation to the "advised" time-range, specified in the detail plan).

Third, reports of interventions undergone prior to the beginning of the PAI can be used to build a "frailty" index, that can be used as a further correction factor in the regression model.

Finally, data related to the patients' Quality of Life and costs can also be analyzed, in order to gauge the perceived efficacy of the model and provide health policy decision makers with a comprehensive economic evaluation of the PAI introduction.

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