OBSERVATIONAL STUDY PROTOCOL

Version 02 of 9.10.2022

TITLE OF THE STUDY

Italian Registry of Patients Suffering from Chronic Pain

ACRONYM OF THE STUDY:

REALIZER (*Italian Registry of Chronic Pain Patients)*

PROMOTER: SIAARTI

Coordinating Centre: IRCCS Maugeri Pavia

Introduction

This protocol defines the role and type of database that is intended to be established by SIAARTI.

This registry involves the prospective collection of data from subjects suffering from Chronic Pain of any origin.

Participation in the study requires each subject to sign an informed consent form.

In this protocol the terms Registry and Database will be considered synonymous.

In this project there will be 3 phases:

PHASE 1

Pilot project (3 months): Participation of 7 centers proposing the project. Objective: structuring of the dataset and data entry methods. Dissemination of the project.

PHASE 2

Project extended to centers that wish to collaborate (24 months): Centers participate on a voluntary basis and are distributed evenly across Italy. Objective: full operation of the register to meet the objectives of the project.

FASE 3

SIAARTI promotes the register at the institutions for the establishment of a national register compliant with the DECREE OF THE PRESIDENT OF THE COUNCIL OF MINISTERS March 3rd, 2017 “Identificazione dei sistemi di sorveglianza e dei registri di mortalita', di tumori e di altre patologie. (17A03142) (GU Serie Generale n.109 del 12-05-2017)”

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1. RATIONALE TO SUPPORT THE ESTABLISHMENT OF THE DATABASE

The IASP (International Association for the Study of Pain) defines pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage[1]. The physiological function of pain is to serve as a warning sign of a medical condition or injury. In these cases, treatment of the underlying medical condition is critical and can resolve the pain. However, pain may persist despite adequate management of the underlying condition, or the underlying medical condition may not be successfully treated. If the pain persists or recurs for more than three months, the pain is defined as chronic[2,3]. Long considered a non-life-threatening condition and often overlooked, persistent pain over time can actually become the sole or predominant clinical problem in some patients, generating a chronic condition that significantly impacts patients' quality of life through a wide range of negative physical, psychological and functional effects that limit social participation [4,5,6]. For this reason, chronic pain is a condition that deserves a specific diagnostic evaluation and appropriate therapeutic efforts, integrated in a multidisciplinary context of physical and psychological rehabilitation. According to many authors, access to adequate pain care should be considered a human right[7,8]. Recent observations have highlighted a worrying prevalence of pain throughout the world, with significant variations between countries (ranging from 9, 9% to 50.3%)[9]. For this reason, and due to the impact that chronic pain has on healthcare spending, adequate pain control is considered a global health priority. In fact, chronic pain causes the greatest loss of productivity compared to any other health condition[10] and constitutes a significant share of healthcare spending with costs reaching 3-10% of the gross domestic product of European countries[11,12].

An important milestone in the European health regulatory framework is represented by Law 38/2010, which established the citizen's right to not suffer[13]. The law paved the way for recommendations to develop structures dedicated to palliative care and pain therapies and to organize hospital and outpatient facilities to guarantee diagnostic-therapeutic continuity for patients with chronic pain. Nonetheless, the provision of adequate care appears difficult to apply

in our country. Recent data puts Italy in third place in Europe in terms of prevalence of chronic pain (around 24%),[14] and at least a third of patients suffering from it remain without a diagnosis or suffer a significant delay in referral to pain management clinics[15,16,17]. One of the reasons this happens could be found in the poor implementation of pain therapy networks in the various Italian regions caused by the lack of knowledge of the influx and need for pain therapy centers. For these essential resources to streamline clinical care pathways in the effort to manage chronic pain, it is necessary to understand the needs of the population. The epidemiological data available are mostly retrospective, collected on a regional basis and not across the entire territory, and are often incomplete or collected with methodological biases that do not make them usable for public health purposes. Furthermore, there is no clear clinical characterization of the patients who are referred to pain therapy centers to estimate the actual needs and effectiveness of the proposed treatments. In addition, there are no epidemiological data on the distribution of chronic pain and the association with potential risk factors in Italy, as there is no epidemiological register on the regional or national level.

Clinical registries play an important role in monitoring diseases and healthcare delivery patterns. They represent the starting point for generating "real-world" evidence and for evaluating the impact of treatment and service delivery models on health outcomes. Registries are useful tools for directing projects to improve the quality of care to improve healthcare processes, adherence to guidelines and standards of care, and, ultimately, to optimize the costs of providing care. It has also been demonstrated that the establishment of clinical registries has a significant positive impact on outcome [18].

This project aims to create an Italian registry of patients suffering from chronic pain with the aim of collecting clinical, epidemiological and outcome information on subjects belonging to pain therapy centers on a regional basis as part of the pain management assistance.

Description of the purposes of the database

The purposes for establishing this database are the following:

• continuously and systematically collect, evaluate, and archive relevant demographic and clinical information on patients belonging to chronic pain treatment centers, making it available for studies and research.

• promote the use of uniform and comparable classification systems, definitions, and records

in the structures participating in the database.

• Define the flow of patients referring to pain therapy centers to allow adequate

health planning and the priority areas of intervention of the national health plan.

The data collected will facilitate the planning of future studies aimed to:
• define the impact of chronic pain at a local and national level, and its territorial and temporal variations over time, through prevalence and incidence measures;
• identify clinical subtypes, risk factors, predisposing and triggering factors;
• increase knowledge in the field of chronic pain to standardize diagnostic/therapeutic pathways and promote adequate management strategies.

2. Objectives

Primary Outcomes

Identify the profiles of patients belonging to oain therapy centers in terms of:

1. Location and type of pain
2. Prescribed therapies
3. Effectiveness of therapies
4. Time needed to reach the efficacy outcome

Secondary Outcome

1. Evaluate the proportion of patients who reach the outcome of 30 or 50% improvement
2. Evaluate the healthcare resources used in terms of number of visits and time needed to achieve the best outcome (30 or 50% improvement)
3. Identify patient profiles that are related to clinically significant outcomes and the specific treatments performed, plus their intermediate surrogate outcomes in relation to specific patterns

4. Describe the relevant clinical variables in the study population. In particular, the absolute and relative frequencies of those clinical variables relevant to the effectiveness of the treatment will be described, categorized by type of treatment, and the timing of the start of treatment with respect to the onset of pain. The data collected may be used for predictive analyses.

3. Study Design

This is a prospective, multicenter, non-profit observational cohort study. No intervention on patients outside of common clinical practice is envisaged.
The study is divided into three phases.
Phase 1, expected to last three months, involves the participation of 7 centers proposing the project and aims to structure the dataset and data entry methods. Actions will also be implemented for dissemination of the project by trying to recruit centers distributed across the national territory. Estimated start date 01/03/2023.

In phase 2, the project expands to the centers that wish to join, and this protocol will be fully operational.

The duration of phase 2 is two years and six months, presumably starting from 01/06/2023. Patient enrollment at each center will begin at different times depending on the rollout of the registry and local ethics committee approval. It is likely that the first patient will be prospectively enrolled in 01/06/2023. The last patient will be enrolled by 01/03/2025 and it will be possible to enter data and follow-up until 01/09/2025. The results of this study will be available by 01/12/2025.

Once the patient has been enrolled, it will be possible to trace the patient's personal file and update it at each follow-up until the end of enrollment.

In phase 3, SIAARTI will promote the register at the institutions for the establishment of a national register compliant with the DECREE OF THE PRESIDENT OF THE COUNCIL OF MINISTERS 3 March 2017 "Identification of surveillance systems and registers of mortality, tumors and other pathologies. (17A03142) (GU General Series n.109 of 12-05-2017)"

Setting

The study aims to collect demographic and clinical data from patients belonging to pain therapy centers recognized at the regional level and belonging to the pain therapy networks established incompliance with law 38/2010 and according to the Agreement between the Government and the Regions of 25 July 2012.

Patients will be registered regardless of the access modality (outpatient or hospitalization) and will be characterized by pathology and treatments performed. The participation of centers for the treatment of pediatric pain is expected. Data relating to patients under the age of 18 will be analyzed separately.

The database aims to follow the patients enrolled according to a code that makes them anonymous.

Participating Centers

The dissemination phase constitutes an integral part of the study and is not possible to predict the definitive number of centers involved. Key professionals have been contacted who will be responsible for the dissemination and implementation of this study based on each center's records. The ethics committee of the coordinating center will be regularly updated by the Principal Investigator as new centers join the study.

The complete list of centers involved initially is reported on the title page of the protocol.

Deviations from protocol

Any deviations from this protocol will be reported to the local Ethics Committee (EC) by the Principal Investigator by sending a request to modify the protocol. This request will be examined by the CE according to local/internal regulations.

Criteria for abandoning the ongoing study

The patient can renounce participation in the study at any moment by withdrawing informed consent. The data collected may be kept if made completely anonymous and if previously authorized by the patient.

Ending the study

In addition to reporting the start and end dates of the study for monitoring purposes, the Principal Investigator will inform the EC of an early termination of the study and the related reasons.

4. STUDY POPULATION

The Registry data will be collected by the structures involved in the management of patients suffering from chronic pain, regardless of the cause. It is necessary to keep the inclusion criteria as broad as possible to obtain a real picture of clinical practice at a national level.

Inclusion criteria

- Subjects > 4 years old
- NRS > 4
- Diagnosis of Chronic Pain according to the IASP19 criteria
- Adherence through written informed consent to participate in the study

Exclusion criteria

- Patients suffering from psychiatric pathology or severe cognitive impairment for which the enrolling doctor does not believe it is useful for the purposes of the study
- Patients unable to sign the informed consent

Description of the pathologies being studied

Adult patients will be enrolled, diagnosed with Chronic Pain (pain lasting > 12 weeks), regardless of the etiology, modality, and age of onset.

5. PROCEDURES EXPECTED AND INFORMATION COLLECTED

Enrollment procedure

Adult patients of both sexes who belong to pain therapy centers with a diagnosis of Chronic Pain (pain that lasts > 12 weeks), regardless of the etiology, modality and age of onset, will be considered eligible for enrollment.

It will be possible to enroll patients during their first visit (FIRST ANESTHESIOLOGICAL VISIT), or during a check-up visit (ANESTHESIOLOGICAL CHECK-UP VISIT) or during a scheduled hospitalization for pain procedures (ORDINARY OR DAY HOSPITAL ADMISSION)

Patients will be asked to join the study after having been informed in detail (also with the aid of a written information form) of the objectives of the project, as well as the methods with which these objectives will be pursued. Participants will be informed about the lack of informative feedback regarding the results of future clinical evaluations: the results of any research originating from the register, in fact, will not be delivered to the participants themselves. The subject who freely accepts will authorize the inclusion of their data in the project by signing the informed consent form of which they will receive a copy. It will also be clearly explained in the information sheet attached to the informed consent that each participant will have the possibility of withdrawing their participation from the study at any time, without providing any reason and without this jeopardizing the doctor-patient relationship with the specialists involved in the project.

Patients will be informed by the manager of the patient's pain center or the principal investigator for the center (assuming this is not the same individual).

The doctor will complete the electronic CRF after evaluating the patient and classifying him according to the criteria of the IASP (International Association for the Study of Pain) in terms of primary or secondary chronic pain. In the case of a patient enrolled during a check-up or during hospitalization, all data relating to the time in which the patient is in care at the center, the

invasive procedures previously undertaken, the drugs prescribed, will be collected. Retrospective data (only for patients already being treated at the center) will be collected according to a predefined group (e.g.: the patient has been in the care of the center for: > 5 years; from 1 to 5 years; from 1 year to 6 months; from 3 to 6 months; < 3 months).

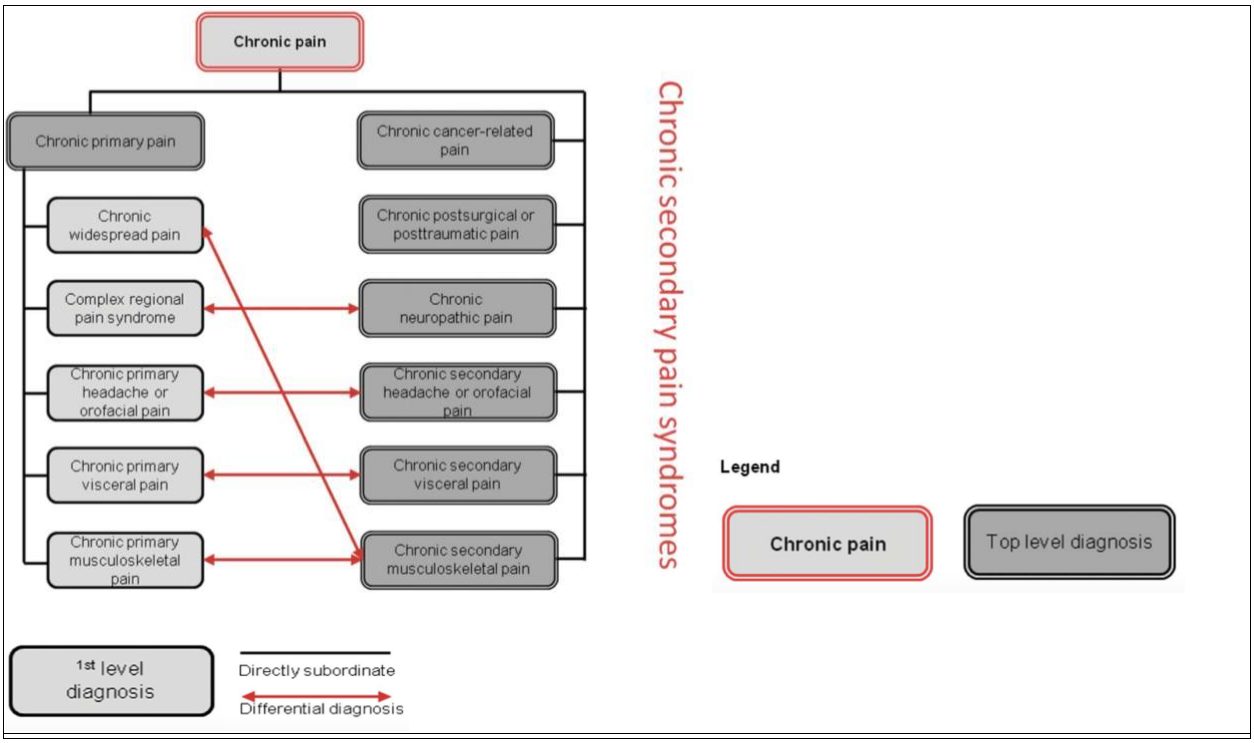
Follow-up procedure

Once enrolled, the patient will be followed prospectively until the end of enrollment. At each visit it will be possible to retrieve the patient's chart and fill in the data relating to the intensity of pain and the treatments undertaken. It will also be possible to modify or add an etiological diagnosis in forms of secondary chronic pain. There is no limit to the number of follow-ups for each patient as long as the database is active (3 months from the date of enrollment of the last patient, considering a 12-month active enrollment expected for this study).

Data gathered

The activities of the registry do not replace routine diagnostic tests or visits to your doctor. The data collected by the registry will include relevant demographic data of the patient, comorbidities, the duration of the pain (> 5 years; from 1 to 5 years; from 1 year to 6 months; from 3 to 6 months), the type of pain, the location of the pain, the intensity of the pain (Brief Pain Inventory- Severity (BPI-S) and pain interference in daily activities (Brief Pain Inventory-Interference (BPI-I), treatments received (categorized according to pharmacological therapy, infiltrative therapy, ablative or neuromodulatory therapy, implants), the tests conducted, the number of other medical specialists contacted for the pathology being studied, the professional who sent it to the center. Specifically, the data collected is shown in Attachment 1
In particular, patients will be characterized by:

Type of pain (chronic primary or chronic secondary according to the scheme proposed by IASP)



Location of pain according to the following scheme (multiple options are possible)

Lower back pain
Thoracic
Upper arts
Lower limbs
Head/Neck
Pelvis

Pain Intensity
Brief Pain Inventory-Severity (BPI-S)

Interference with daily activities
Brief Pain Inventory-Interference (BPI-I)

Clinical information related to the pathology

Therapy

Pharmacological
Infiltrative
Implantable

Data collection methods and anonymization

The data collected will be used for scientific and epidemiological purposes. Each data will be created by a participating center and recorded on the SIAARTI Servers via a web application using the RedCap® data management software.

The study data will be collected and managed using the REDCap[20,21] electronic data acquisition tools made available by SIAARTI. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies. It provides:
1) an intuitive interface for acquiring validated data;
2) Controlled channels with customized access privileges for monitoring data manipulation and export procedures;
3) automated export procedures for continuous data download to common packages of statistical software;
4) procedures for data integration and interoperability with external sources.

Data will be recorded in the e-CRF only after being anonymized using coding procedures described in a separate document, in accordance with applicable data protection laws, including the EU GDPR. The encryption key of the anonymous data which contains the patient's name, surname and date of birth will be archived only in the files of the local site in a register that allows registration and research of the subject.
For each center participating in the project, an account will be created on the REDCap platform. The data will be recorded using an encrypted data connection (HTTPS) of anonymized input via a web browser or mobile app.
To enable data analysis, each patient will be assigned a unique Subject ID (Patient Identification Number).
REDCap is a secure web application for creating and managing online databases. Unauthorized access to data is impossible since access is permitted according to a hierarchical and role-based criterion. Access to REDCap will be allowed only to data collection personnel of the participating centers, according to the methods established by this protocol. These people will keep the information private.

Data management and storage

RedCap management software will be used for data management. The identification of individual patients by name will not be necessary or required at any time. During the collection and processing of data, therefore, all necessary measures will be adopted to effectively establish anonymization. SIAARTI will also take care of data storage. Each participating center can only access the patient data it has generated and registered on the REDCap platform. Each participating center is required to provide periodic ad hoc reports on the data collected.

Data ownership

Individual data provided by a participating center are primarily the property of the center that generated the data. All investigators have the right to access their data at any time. SIAARTI will be co-owner of the data, in agreement with each participating center.

Subsequent use of the data

SIAARTI and the executive committee, on behalf of the investigators, have the right to use all data collected in the database for scientific purposes. The executive committee and the SIAARTI study groups have the right to access the data in the registry, for research purposes after the conclusion of the research project, and with the approval of the SIAARTI Scientific Committee. In any case, the researchers who contributed to the project will be regularly informed about the ongoing study activities and will be given the opportunity to be included among the authors of any publications.

Storage

A copy of the electronic database will be kept at the SIAARTI headquarters and kept for 5 years for subsequent use by SIAARTI and the executive committee.

6. ENDPOINT

Primary Endpoint

The number of patients referring to the centers, the type of pain, the proportion of patients who reach the clinically significant outcome, the type of therapies prescribed (pharmacological, neuromodulatory or implanted) necessary to achieve the outcome and the number of accesses and the Time in which a clinically significant improvement will be achieved (Change in BPI-s or BPI-I; a reduction of > 30% is considered clinically significant and a reduction of > 50% is considered optimal, the data will be evaluated for each Item).

Secondary Endpoint

1. The effectiveness of the treatments will be described in terms of
    a. Change in pain intensity according to the Brief Pain Inventory-Severity questionnaire (BPI-S) A reduction of > 30% is considered clinically significant and optimal a reduction > of 50% the data will be evaluated for each Item)
    b. b. Change in pain interference on daily activities according to the Brief Pain Inventory-Interference questionnaire (BPI-I). A reduction of > 30% is considered clinically significant and a reduction of > 50% is considered optimal; the data will be evaluated for each item)
2. Proportion of patients achieving clinically significant outcomes in relation to baseline characteristics and specific treatments performed and their intermediate surrogate outcomes in relation to specific patterns.
3. Resources used: Number of visits to the center for each patient in a year; Number of ordinary or day hospitalizations for each patient in a year.
4. The clinical variables relevant to the outcome will be described (e.g. type of pain, comorbidities, the time between treatment and clinically significant improvement, type of therapy undertaken - pharmacological, invasive, implant-based)

7. INFORMED CONSENT

Patients enrolled in the study will be given a complete and exhaustive explanation about the nature, purposes, possible risks, and benefits of the study. The patient will be informed that he/she will be free to stop the study at any time. The patient will be given the opportunity to ask questions and will be given as much time as desired to evaluate the information provided. For the pediatric population, consent will be requested from parents in the same way.

The investigating doctor will keep the original of the signed written informed consent.

In the written informed consent form it will be specified that the study data will be stored in computerized form and that the confidentiality of the data itself will be maintained in accordance with the provisions of current legislation.

8. STATISTICAL ANALYSIS

All enrolled patients registered in the registry will be included in the analyses. A descriptive analysis will be performed on the collected data. In general, qualitative variables will be described using frequency distributions; the quantitative variables will be described by mean and standard deviation if normally distributed, and by median and interquartile range if asymmetrically distributed. As appropriate, statistical tests will be used for exploratory purposes. Treatment effects (Change in BPI-S and BPI-I scores) will be calculated as the ratio of the difference between baseline and follow-up scores to the baseline score. If the data allow it, inferential analysis will be applied on quantitative data (such as: comparison of Student's t means, Fisher's F, etc.), or on qualitative data (such as: chi square, odds ratio, Mann Whitney U, etc.). The prevalence of the different pathologies and the related confidence intervals will be estimated. Detailed statistical analysis plans will be set up in future research protocols that will use this database as a source of data.

Sample Size

Since this is an observational registry, no prior sample size calculation is required. Considering an expected participation of 12 centers, an estimate of 2500 patients included appears reasonable.

9. DATA MANAGEMENT AND PROCEDURE TO GUARANTEE PATIENT DATA CONFIDENTIALITY

The individual pain centers, which are the sources of the data, are responsible for detecting, enrolling, coding and recording cases and are functionally linked to the primary center from which they draw methodological indications of an operational nature. Sensitive data will be noted, anonymized through an encryption procedure, and stored in a secure place.

10. SECURITY AND ADVERSE EVENTS

This observational study will be conducted according to the current protocol. This is a non-interventional observational study. Any study based on this registry will not receive any guidance on the treatment of patients. Complications and adverse events that occur during follow-ups will be recorded in the registry.

11. ADMINISTRATIVE/REGULATORY CONSIDERATIONS

Economic considerations

No additional costs will be charged to the Healthcare System.

Insurance considerations

Given the observational nature of the study and which involves recording what happens in common clinical practice without deviations from the standard of care in each participating center, an additional insurance policy to that already provided for normal clinical practice is not necessary.

12. ETHICAL CONSIDERATIONS

This observational study is designed and will be conducted according to the current protocol, in accordance with EU Directive 2001/20/EC relating to the implementation of the principles of good clinical practice in the conduct of clinical trials on medicinal products for human use, in accordance with the principles published in Good Clinical Practice (GCP) guidelines and in accordance with the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, adopted by the General Assembly of the World Medical Association (1996),

The investigator guarantees that personal patient data will be protected and processed in accordance with the General Data Protection Regulation (EU) 2016/679 (GDPR) on data protection and privacy.

ATTACHMENT 1
DATA GATHERED FOR EACH PATIENT

- ◊ CENTER CODE
- ◊ UNIQUE PATIENT CODE
- ◊ ACCESS METHOD (TO BE COMPLETED ONLY THE FIRST TIME FOR EACH PATIENT
- ◊ DATE (the CRF must be filled in each time the patient has a visit/admission)
- ◊ SENT BY:
    - FAMILY DOCTOR
    - OTHER SPECIALIST
    - ADVICE FROM A RELATIVE/ACQUAINTANCE
    - WEB SEARCH
- ◊ REFFERAL METHOD (TO BE COMPLETED ONLY THE FIRST TIME FOR EACH PATIENT)
    - ◊ FIRST ANESTHESIOLOGICAL VISIT
    - ◊ ANESTHESIOLOGICAL CHECK-UP EXAMINATION
        - o UNDER CARE AT THE CENTER FOR:
            - > 5 years;
            - from 1 to 5 years;
            - from 1 year to 6 months; or 3 to 6 months;
            - < 3 months
    - ◊ ORDINARY HOSPITALIZATION
        - o IN EMPLOYMENT AT THE CENTER FOR: o > 5 years;
            - from 1 to 5 years;
            - from 1 year to 6 months; or 3 to 6 months;
            - < 3 months
    - ◊ DAY HOSPITALITY (DAY SURGERY OR DAY HOSPITAL)
        - o IN EMPLOYMENT AT THE CENTER FOR:
            - > 5 years;
            - da 1 a 5 anni;
            - da 1 anno a 6 mesi; o da 3 a 6 mesi;
            - < 3 mesi

LEVEL 1: DEMOGRAPHICS

- ◊ AGE .....
- ◊ SEX
  - o M
  - o F

STATE/COUNTY OF RESIDENCE

SCHOOL LEVEL

- ◊ Not Known
- ◊ Grade School
- ◊ High School
- ◊ University

WORK

- ◊ WORKER
- ◊ UNEMPLOYED

COMORBIDITIES

- ◊ CARDIOVASCULAR
- ◊ DIABETES
- ◊ RESPIRATORY
- ◊ AUTOIMMUNITY
- ◊ CHRONIC INFLAMMATION
- ◊ OTHER

LEVEL 2: DIAGNOSIS

TYPE OF PAIN

- ◊ PRIMARY CHRONIC
  - o CHRONIC WIDESPREAD PAIN
    - ▪ FIBROMYALGIA
    - ▪ OTHER
  - o CRPS

- HEADACHE OR OROFACIAL PAIN
- MUSCULOSKELATAL
  - LOW-BACK PAIN
  - ALTRO

◊ SECONDARY CHRONIC

- ONCOLOGICAL
- POSTSURGICAL
  - LUMBAR
  - CERVICAL
  - BREAST
  - INGUINAL HERNIA
  - THORACOTOMY
  - OTHER
- POST TRAUMATIC
  - CRPS
  - OTHER
- NEUROPATHIC
  - PERIFERAL
  - POST-TRAUMATIC
  - DIABETIC
  - TRIGEMINAL
  - POST-HERPETIC
  - OTHER
- CENTRAL
  - POST-ISCHEMIC
  - SM
  - TRIGEMINAL
  - NEURODEGENERATIVE DISEASES
- HEADACHE OR OROFACIAL PAIN
- VISCERAL
- SKELETAL MUSCLE
  - LOW-BACK-PAIN
  - OTHER

AREA OF PAIN

◊ LOWER BACK PAIN

- ◊ THORACIC
- ◊ UPPER LIMBS
- ◊ LOWER LIMBS
- ◊ HEAD/NECK
- ◊ PELVIS

PAIN INTENSITY AND INTERFERENCE

- ◊ BPI-S

WORST PAIN IN THE LAST 24 HOURS
• 1 • 2 • 3 • 4 • 5 • 6 • 7 • 8 • 9 • 10
LEAST PAIN IN THE LAST 24 HOURS
• 1 • 2 • 3 • 4 • 5 • 6 • 7 • 8 • 9 • 10
AVERAGE PAIN IN THE LAST 24 HOURS
• 1 • 2 • 3 • 4 • 5 • 6 • 7 • 8 • 9 • 10
CURRENT PAIN
• 1 • 2 • 3 • 4 • 5 • 6 • 7 • 8 • 9 • 10
HOW MUCH RELIEF HAVE YOU HAD FROM THE THERAPY (%)
• 10• 20• 30• 40• 50• 60• 70• 80• 90• 100

BPI-I (PAIN INTERFERENCE ON)

ACTIVITY IN GENERAL
• 0•1•2•3•4•5•6•7•8•9•10
MOOD
• 1 • 2 • 3 • 4 • 5 • 6 • 7 • 8 • 9 • 10
ABILITY TO WALK
• 1 • 2 • 3 • 4 • 5 • 6 • 7 • 8 • 9 • 10
NORMAL WORKING ABILITY (both at home and outside)
• 1 • 2 • 3 • 4 • 5 • 6 • 7 • 8 • 9 • 10
RELATIONSHIPS WITH OTHER PEOPLE
• 1 • 2 • 3 • 4 • 5 • 6 • 7 • 8 • 9 • 10
SLEEP
• 1 • 2 • 3 • 4 • 5 • 6 • 7 • 8 • 9 • 10

PLEASURE OF LIVING

• 1 • 2 • 3 • 4 • 5 • 6 • 7 • 8 • 9 • 10 • **1 • 2 • 3 • 4 • 5 • 6 • 7 • 8 • 9 • 10**

REQUESTED EXAMS

- ◊ INSTRUMENTAL EXAMS
  - o XRAY
  - o MRI
  - o SCINTIGRAPHY
  - o EMG/ENG
  - o OTHER
- ◊ LABORATORY EXAMS

COMPLETED EXAMS

- CLINICAL EXAMINATION OF SENSITIVITY
- QST-TEST
- DIAGNOSTIC BLOCK

LEVEL 3: THERAPY

PHARMACOLOGICAL THERAPY

- ◊ SNRI
- ◊ GABAPENTINOIDS
- ◊ TRICICLICS
- ◊ OPIOIDS
  - o TRAMADOL
  - o CODEINE/PARACETAMOL
  - o OXYCODONE/PARACETAMOL
  - o MORPHINE SR
  - o MORPHINE IR
  - o OXYCODONE
  - o OXYCODONE/NALOXONE
  - o HYDROMORPHONE
  - o TAPENTADOL
  - o TRANSDERMAL FENTANYL
  - o TRANSMUCOSAL FENTANYL
  - o BUPRENORPHINE
  - o METHADONE

- ◊ NSAIDs
  - AS NEEDED
  - INTERVALS/REGULARLY (indicate how many days)
- ◊ COXIB
  - AS NEEDED
  - INTERVALS/REGULARLY (indicate how many days)
- ◊ PARACETAMOL
- ◊ OTHER

INFILTRATIVE THERAPY

- ◊ EPIDURAL
- ◊ INTRA-ARTICOLAR (SHOULDER, KNEE, ANKLE, HIP, ECC)
- ◊ SPINAL FACET JOINTS
- ◊ SACRO-ILIAC
- ◊ PERIPHERAL NERVE

NEUROMODULATORY/NEUROABLATIVE THERAPY

- ◊ GANGLIAR RADIOFREQUENCY
- ◊ RADIOFREQUENZY OF PERIPHERAL NERVES
- ◊ CRIOAMODULATION
- ◊ EPIDUROLYSIS
- ◊ EPIDUROSCOPY

IMPLANTS

- ◊ SCS NON-RECHARGABLE
  - CERVICAL
  - DORSAL
- ◊ SCS RECHARGABLE
  - CERVICAL
  - DORSAL
- ◊ STIMULATION OF PERIPHERAL NERVE
- ◊ GANGLIAR STIMULATION
- ◊ INTRATHECAL PUMP

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