

# **THE VERACT INTRACTABLE PAIN AND PALLIATIVE CARE CLINIC (Since 1975)**

## **MISSION, GOALS, AND OPERATIONS**

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**and**

**FAMILIES FOR INTRACTABLE PAIN RELIEF**

**FAMILY**

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## THE CLINIC

The VIPC is a highly structured medical clinic dedicated to the education, study, and treatment of severe, intractable pain patients who have failed to find relief with conventional or standard pain therapy. The clinic maintains a small patient base that provides an education and research base to develop treatment regimens, protocols, and diagnostic tests that can be adopted by practitioners in every community.

MISSIONS: (1) To provide intractable pain, palliative, and end-of-life care to patients who have attempted and failed the usual means of standard or conventional care; (2) Develop effective, low-cost opioid sparing protocols that can be used by primary care practitioners in every USA community. The newest mission in the clinic is to treat the underlying disease which causes the pain rather than simply prescribing symptomatic drugs.

## BRIEF HISTORY

The clinic was established in 1975 as a few severe, intractable pain patients began to emerge who were initially considered “narcotic addicts”. Withdrawal with detox procedures and methadone maintenance proved to be fruitless unless the source of pain could be removed. After a series of studies, it was determined that some of the early patients could maintain and function well on opioids while some only required opioids for a relatively short time period and could transfer to a non-opioid pain control program. The precise causes of severe, intractable pain in these early years couldn’t be accurately identified in most cases, and patients were given such nondescript diagnoses as chronic low back sprain, peripheral neuropathy, and arthritis. Over a several year period we have been able to identify and diagnose the underlying medical conditions which cause intractable pain. We have been able to measure the biochemical and hormonal changes caused by intractable pain, and develop clinical protocols to not just provide symptomatic pain relief but treat the underlying, causative diseases. The extremely high cost of medications in recent years has caused the clinic to incorporate cost reduction into the research effort.

## CLINIC ENROLLMENT

The clinic enrollment is limited to 150 patients. Some are in each of the various stages of treatment: (1) intractable, (2) palliative, (3) end-of-life, or (4) disease-specific. Any additional patients are consultation cases in which we only provide advice and recommendations to the patients' local physicians.

## DISEASE SPECIFIC

The clinic has been receiving referrals for patients with earlier stage, underlying disease than a few years ago. This is especially true for adhesive arachnoiditis, post-viral encephalopathy, and Ehlers-Danlos Syndrome. We have developed non-opioid or minimal opioid protocols for these problems. While we retain our long-term palliative and intractable pain patients, our fastest growing clinic population consists of these patients.

## CLINIC APPLICATIONS FOR ADMISSION

The clinic receives far more applications than it can possibly accept. Patients submit a standard application form in addition to an MRI, physician referral, lab tests, and family requests.

## FEES AND FINANCING

The clinic operates on a subsidized basis. Patients pay modest fees (\$125 monthly visit for California residents) and about \$200 for admission. The only pay is for Dr. Scott Guess (Pham D). The Tennant Foundation pays for research and its presentation at scientific meetings. Neither Miriam nor Forest Tennant are paid. All patients fees and other funds are retained for clinic research, treatment, and educational efforts (e.g. writing, speaking, consulting).

## CRITERIA FOR ADMISSION

1. The patient's pain meets the definition of severe intractable pain as provided below; it is incurable by any known means, and is severe enough to produce biologic and biochemical changes which can be detected by laboratory testing.
2. Patient has sought and obtained treatment from multiple physicians over the course of their illness, has been prescribed treatments in accordance with the WHO 3-step analgesic ladder (attached), and has failed attempted efforts at standard or conventional care.
3. After clinical evaluation, the patient is found to have a greater than 50% chance of dying within one year without treatment.
4. Must be referred by a personal physician and accompanied by a family member.
5. Must demonstrate, by laboratory testing and physical examination, centralization of pain, autonomic nervous system alterations, and biochemical changes.

## DEFINITIONS FOR OPERATION

### INTRACTABLE PAIN

A pain condition that is not curable by any known means. As with other medical conditions it may be mild, moderate, or severe.

Treatment Goal: Provide life-long pain relief sufficient to enable total independent living and normal mental, social, and physical function.

### SEVERE INTRACTABLE PAIN:

A severe, constant pain that is not curable by any known means, causes adverse biologic and biochemical changes in the body's cardiovascular, hormone, and neurological systems, and leads to a bed- or house-bound state and early death if not adequately treated.

Treatment Goal: Provide life-long pain relief sufficient to normalize physiologic and mental functions and enable the patient to carry out activities of daily living to the maximum extent possible.

### PALLIATIVE CARE:

Daily medical treatment of a severe intractable pain patient who has a shortened life expectancy due to the patient's underlying, painful disease and who requires daily caregiver support to carry out activities of daily living. Palliative care may include treatment that might cure a serious illness or slow its progress. Patients for whom palliative care is indicated are likely to die within one year if untreated.

Treatment Goal: Provide life-long comfort and relief of suffering in the late stage of life, seek to normalize physiologic and mental function as much as possible if appropriate, and enable the patient to independently carry out activities of daily living to whatever extent is possible.

#### END-OF-LIFE CARE:

Patient whose underlying painful disease is causing rapid biologic progression to terminus which is estimated to be a maximum of 6 months.

Treatment Goal: Provide life-long comfort and relief of suffering in the final stage of life.

#### DISCHARGES FROM CLINIC

##### VOLUNTARY

Referred to the patient's local physician. A major goal of treatment is to stabilize patients so they may be managed by their local physicians. This may include opioid elimination or minimization.

##### INVOLUNTARY

If a patient exhibits aberrant behavior such as recurrent missed appointments, failure to obtain laboratory tests, participates without family, or drug misuse, they are discharged.

#### FAMILIES FOR INTRACTABLE PAIN RELIEF

This is the clinic support and advocacy group. A major goal of treatment is to introduce our rare and relatively rare patients to others in a similar situation. Self-help and group support is deemed a critical element of our treatment efforts. The vast majority of our patients require family support, and the families need to support each other. The functions of our support and advocacy group include the following: (1) assist others with administrative and clinical issues; (2) give advice and guidance to the clinic; (3) assist a patient in crises; (4) set patient rules for the clinic; and (5) advocate and educate to outside agencies and organizations.

#### RESEARCH EFFORTS

The clinic has recently made great strides in intractable pain understanding and research. Some of our advances, which are being widely adopted are:

1. Identifying the 6 major causes of severe, intractable pain: (1) Adhesive Arachnoiditis; (2) Ehlers-Danlos Syndrome; (3) Reflex Sympathetic Dystrophy (RSD)/Complex Regional Pain Syndrome (CRPS); (4) Traumatic Brain Injury; and (5) Post-Viral Encephalopathy/Neuropathy, Systemic Lyme Disease.
2. Identifying potent, non-opioid alternatives for outpatient control of pain flares: (1) ketamine; (2) oxytocin.
3. Development of a clinical protocol for neuroinflammation and neuroinflammation diseases including adhesive arachnoiditis and RSDs.
4. Specific treatment of the underlying painful condition with neurohormones and neuroinflammatory agents in addition to symptomatic pain care.
5. Lowering the cost by avoiding expensive drugs and procedures.

## RESEARCH RESULTS

Our research results have allowed the clinic to reduce overall opioid dosage by about 40-50% over the past 2 years. We daily receive requests from physicians, patients, and families for our treatment protocols. Our oxytocin-ketamine combination is being widely adopted at this time in order to reduce opioid dosages. Potent opioids such as TIRF-REMS products, OxyContin®, and methadone are essentially no longer needed in new patients.

## PROFILE OF PATIENTS ADMITTED

1. In the past the majority of patients were already taking high doses of opioids (>100 mg MED) at the time of admission to the program; opioid regimens upon application were 200 mg – 500 mg MED or more.
2. Most patients, upon evaluation, are diagnosed with one of several serious/rare disease conditions known to cause severe intractable pain. These include:
  - a. Adhesive Arachnoiditis
  - b. Reflex Sympathetic Dystrophy (RSD)/Complex Regional Pain Syndrome (CRPS)
  - c. Post-Viral Neuropathy/Encephalopathy
  - d. Traumatic Brain Injury
  - e. Genetic diseases such as Ehlers-Danlos Syndrome and Marfans Syndrome
3. Prior Treatment Efforts: Patients admitted to the intractable pain and palliative care program have to show that they have failed the World Health Organization 3-Step Analgesic Ladder. Attached are tables which show characteristics and past treatment efforts. A study of 40 consecutive patients admitted between 2012 and 2015 showed that these patients had previously consulted 461 physicians, 172 pain specialists, 104 psychologists or psychiatrists, and 23 universities.

## GENERAL CATEGORIES OF PATIENTS

The below are general estimates of current patients:

Intractable	45%
Disease Specific	30%
Palliative Care	20%
End-of-Life	5%

## DISTINGUISHING CHARACTERISTICS OF THE VERACT INTRACTABLE PAIN AND PALLIATIVE CARE CLINIC

1. More time is spent by an internist pain specialist in direct patient care – as much time as required.
2. The Intractable Pain Program is highly structured and can be duplicated.
3. Patient involvement in self-care and commitment to treatment protocols is necessary to continue Intractable Pain Program participation.
4. Family member attendance and participation is mandatory.
5. Consent to non-standard treatments and waiver of confidentiality are required.

6. Families for Intractable Pain Relief, a dedicated support and advocacy group, provides assistance and encouragement to patients and families.
7. Only patients diagnosed with severe intractable pain or other pain patients suitable for ongoing research studies are treated.
8. Special formulated low-cost pharmaceuticals are usually required for most patients.

#### LEGAL AUTHORITY FOR CLINIC

California Law provides for treating severe chronic pain patients who have failed standard and conventional therapies:

(1) California Business and Professions Code Section 725 c & d

(c) A practitioner who has a medical basis for prescribing, furnishing, dispensing, or administering dangerous drugs or prescription-controlled substances shall not be subject to disciplinary action or prosecution under this section.

(d) No physician and surgeon shall be subject to disciplinary action pursuant to this section for treating intractable pain in compliance with Section 2241.5.

(2) California has a "Pain Patient's Bill of Rights" (Health and Safety codes 124960-124961 which states in part "A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities to relieve his or her pain".

#### OUTREACH AND SHARING

A major mission of the clinic is to share information with practitioners and patients to enhance treatment of intractable pain patients. We provide the following:

1. Four websites for education;
2. Two bulletins (Hormones and Pain Care and Arachnoiditis);
3. Review (Free) MRI's;
4. Share all protocols and procedures.

<b><u>CONSECUTIVE TREATMENT FAILURES OF 101 SEVERE INTRACTABLE PAIN PATIENTS</u></b>	
<b><u>CHARACTERISTIC</u></b>	<b><u>NUMBER (%)</u></b>
FEMALES	62 (61.4%)
MALES	39 (38.6%)
CENTRALIZED CONSTANT PAIN with insomnia, fatigue, and excess sympathetic discharge	100 (100%)
NO. WITH CYP450 DEFECTS	91 (90.1%)
NO. WITH INEFFECTIVE RESPONSE TO ORAL OPIOIDS - MALABSORPTION	20 (19.8%)

<b><u>40 CONSECUTIVE INTRACTABLE PAIN PATIENTS ADMITTED BETWEEN 2012 AND 2015</u></b>	
<b><u>CHARACTERISTIC</u></b>	<b><u>NUMBER (%)</u></b>
<u>TOTAL PHYSICIANS CONSULTED</u>	<u>461</u>
<u>TOTAL PAIN SPECIALISTS CONSULTED</u>	<u>172</u>
<u>TOTAL PSYCHOLOGISTS/PSYCHIATRISTS CONSULTED</u>	<u>104</u>
<u>TOTAL UNIVERSITIES CONSULTED</u>	<u>23</u>

**WORLD HEALTH ORGANIZATION**

**THREE STEP ANALGESIC LADDER**

**1982 - 1986**

