Harmonizing Clinical Practice and Clinical Guidelines in the Management of Chronic Pain:
— From the Patient Perspective

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Introduction

- The moderate-to-severe pain market is in the midst of a transformation due to a number of factors, including: heightened concerns with overdoses from prescription medications, the recent release of the CDC recommendations, and the aftereffects of the rescheduling judgment affecting hydrocodone combination products.
  - In March of 2016, CDC published its “Guideline for Prescribing Opioids for Chronic Pain.” The Guideline was intended to provide recommendations directed toward primary care clinicians about the appropriate prescribing of opioids.

- As a result of the above factors, and others, the total number of dispensed opioid prescriptions declined by 2.2% in 2014 and 6.8% in 2015\(^1\). Based on findings from this survey, the downward trend is expected to continue.

- In response to the heightened concerns with opioid prescribing and the release of recent guidelines, this study was fielded by Pain Insights, Inc., surveying 1,000 patients suffering from moderate-to-severe chronic pain. Fielding of the study was completed at the end of 2016, approximately 8 months after the release of the CDC guidelines.

- Respondents were actively seeking care for their chronic pain by a medical practitioner, were either already taking an opioid (n=586), had previously taken an opioid (n=259), or were taking non-opioid therapies (n=155) for moderate-to-severe pain, and thus could be considered candidates for opioid therapy. The majority of patients in this survey were suffering from long-standing (65%: > 5 years) and debilitating pain (72%: significant interference/disabling).

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1. Secular trends in opioid prescribing in the USA; IMSHealth™ National Prescription Audit
The primary focus of the study was to characterize the recent dynamics in the treatment of chronic pain from the viewpoint of patients suffering from chronic pain.

- The research was designed to uncover the most significant impacts of pain on functioning (pain interference), discern the most desired patient-reported outcomes relating to function, identify steps that can be taken to improve therapy from the patient perspective, gauge awareness and impact of the CDC guidelines, and finally to analyze retrospective and future looks at the patient journey.

The above feedback from patients was used to create a needs/attitude/psychographic segmentation, grouping patients based on a series of statements that measured their behaviors and attitudes as they relate to products and services offered to patients with chronic pain.

- As a result of this needs based segmentation approach, patient segments with varying perspectives on opioids were identified, based on the accumulation of learnings about characteristics/demographics of each group.
- It is hoped that these learnings can inform better communications between patients and practitioners and lead to more patient-centered therapies and educational programs.
Methodology

- Internet-based surveys (average length: 40 minutes) were completed among one thousand patients suffering from moderate-to-severe chronic pain
  - Respondents were selected from a national panel which provided access to over 5 million American consumers profiled for 30 different medical conditions, including chronic pain; patients had already been members of the panel but did have to doubly-opt-in to participate in this market research study

Key Screening Criteria:

- Patient demographics:
  - Representative sample according to age, gender, and ethnicity
    (weighted according to the National Health Interview Survey for patients with pain “most days/every day”)
  - Minimum age: 18 years old

- Patients had to have chronic pain due to an illness or medical condition for at least 3 months

- Patients had to experience pain at least monthly

- Patients had to take an OTC or Rx medication for pain under a doctor’s supervision

- Patients taking non-opioid therapies had to be suffering from at least moderate pain (≥4 on an 11-point numeric pain scale)

- Patients had to visit a healthcare provider for pain at least one time per year

- Excluded patients suffering only from migraine/headache or only taking migraine-specific medications

Past opioid users and patients who have never used opioids had to have a minimum average pain rating of ≥4 (moderate pain) to qualify for the study; a criteria that is common in clinical trials involving opioid therapy for chronic pain.
**Methodology**

**Survey Flow**

- Underlying causes of chronic pain
- Medical practitioners or other allied healthcare professionals visited
- Average and worst pain levels during the past week
- Activities most impacted by pain/Desired PROs
- Pain medications (opioid/non-opioid) currently being taken
- Non-drug therapies employed/Rating of response
- Most common side effects encountered with therapy/Reasons for discontinuation
- Trends in the opinions of the appropriateness of opioid therapy for chronic pain (patient/family/physician/pharmacist)
- Patient journey (decision to use, degree of pain relief, satisfaction, future intent)
- Patient suggestions to improve their current pain management regimen and satisfaction level with therapy
- Communication between patients and healthcare professionals
- Current issues with chronic pain management: Awareness/attitudes
- Awareness/impact of the CDC guidelines
- Reaction to new risk management policies suggested or implemented by various organizations (CDC, state medical boards, insurers, REMS, etc.)
- Value/willingness to pay for abuse-deterrent opioid formulations
- Patient co-morbid conditions/demographics
Degenerative back conditions, arthritis, neck/shoulder issues, conditions causing neuropathic pain, and trauma/surgery were cited most frequently.

- Neck pain/Shoulder pain: 48%
- Migraine/Headache: 19%
- Spinal stenosis / Spinal degeneration: 27%
- Female chronic pelvic pain: 9%
- Neuropathic Pain: 31%
- Back Pain: 57%
- Fibromyalgia: 21%
- Rheumatoid arthritis: 13%
- Other joint conditions or soft tissue conditions: 21%
- Arthritis / Osteoarthritis: 56%

Base: All respondents.
Level of Pain Interference

Daily functioning & quality of life are significantly impacted, with 18% indicating that their pain is disabling most of the time.

- 54% Interfered significantly with daily activities - requiring lifestyle changes
- 28% Nagging, annoying, interfered little with daily activities
- 18% Disabling most of the time; unable to perform daily activities

Base: All respondents.
<table>
<thead>
<tr>
<th>Drugs/Drug Categories</th>
<th>Non-drug Therapies</th>
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<tbody>
<tr>
<td>Over-the-Counter analgesics</td>
<td>Chiropractic manipulation</td>
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<tr>
<td>Nonsteroidal anti-inflammatory drugs</td>
<td>Acupuncture</td>
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<tr>
<td>Celebrex</td>
<td>Transcutaneous electrical nerve stimulation (TENS)</td>
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<td>Prescription Topical NSAIDs</td>
<td>Physical therapy</td>
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<tr>
<td>Prescription Topical Lidocaine</td>
<td>Exercise</td>
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<tr>
<td>Antidepressants</td>
<td>Rest or sleep</td>
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<tr>
<td>Neuromodulators</td>
<td>Biofeedback</td>
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<td>Benzodiazepines</td>
<td>Cognitive behavioral therapy (CBT)</td>
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<tr>
<td>Muscle Relaxants</td>
<td>Nutritional/Herbal supplements</td>
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<td>Corticosteroid injections</td>
<td>Ultrasound</td>
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<td>Hyaluronic acid injections</td>
<td>Spinal-cord stimulation (SCS)</td>
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<td>Medicinal marijuana</td>
<td>Radio-frequency ablation (RFA)</td>
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<td>Immediate-release Opioids</td>
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<td>Extended-release Opioids</td>
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About Pain Insights, Inc.

- Pain Insights, Inc. is a full service marketing research and strategic planning firm established in 2001. We are the only firm to provide qualitative and quantitative market research, forecasting support, and strategic/marketing consultation exclusively in the area of pain management.

- We have conducted hundreds of studies focused on pain for clients ranging from large pharma to developmental companies to private investment firms. Studies have included market landscapes, opportunity assessments, new product evaluations, positioning development, promotion/educational program testing, and patient research, among others.

- The principals each have more than 25 years of experience in the pain management area.

- A differentiating feature of Pain Insights is that the principals are intricately involved in all phases of every project, from initial study design, through information collection, data analysis and authoring of all reports, with actionable recommendations.

- This level of total involvement is enhanced by the breadth of experience and pain market acumen that we bring and apply to each and every study assigned to us.

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