International Adhesions Society

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www.adhesions.org
www.iscapps.org

International Adhesions Society

- Advocacy, support and research for patients suffering from adhesions.
- Abnormal tissue connections commonly caused by surgery, endometriosis or infection.
- Annual admissions for abdomino-pelvic adhesions rival those for heart, hip and appendix operations and cost over $5 billion.

CAPPS
Complex Abdomino-Pelvic & Pain Syndrome

- Adhesions patients often develop a constellation of pelvic, bladder, bowel, genital and back symptoms.
- Become largely indistinguishable from those with interstitial cystitis and IBS.
- We have termed this CAPPS.
- Liberates diagnosis and treatment from the constraints of compartmentalized medical practice.
- 15-30 million Americans with CAPPS, predominanatly women.

Wiseman DM. Disorders of Adhesions or Adhesion-Related Disorder: Monolithic Entities or Part of Something Bigger-CAPPS? Semin Reprod Med. 2008; 26:356

Reduced Access of Chronic Pain Patients to Analgesia: Proposed FDA Label Changes

- Collaboration of nine other patient groups
  - Arachnoiditis Society for Awareness and Prevention
  - Endometriosis Association, Endometriosis Research Center
  - Interstitial Cystitis Association, Interstitial Cystitis Network
  - EaseNervePain.com, HysterSisters.com, livinginpain.org, drugwatch.com
- 2840 patients with chronic pain:
  - Pelvic, abdominal & spinal adhesions, endometriosis, interstitial cystitis
  - 92% women, ~90% conditions CAPPS-related

10 most common types of pain

Interstitial Cystitis	71%	Other pain related to urination	35%
Intercourse pain	57%	Migraine	33%
Back pain	53%	Arthritis/ other joint pain	32%
Vulvodynia/vaginal pain	40%	Hip pain	31%
IBS	38%	Pain due to adhesions	29%

www.synechion.com/IAS2013-FDA-OpioidSurvey.pdf

Proposed FDA Label Changes for Opioids

- Opioid use “off-label” in 92% of our patients.
- Compromised access to, or reimbursement for, opioids in > 80% of patients?
  - Exceeds 90 days (86%), > 2 years (55%).
  - Exceeds 100mg morphine equiv./day (24%).
  - Treats pain that is less than severe (46%).
  - Needed with non-severe pain - failure of other approaches.

Recommendation #1:
With CAPPS as a predominantly female issue, use data to support efforts addressing gender disparity in access to analgesia.

Ownership of Problem of Abuse & Misuse?

- Combatting abuse through questionably-founded labeling changes conflicts with FDA's own mission.
- Programs like Project Lazarus - effective without compromising legitimate opioid access.
- At least five agencies (FDA, ONDCP, CDC, NIDA, DEA) are involved in tackling abuse – any coordination?
- IPRCC is poised to propose that one lead agency be designated or created.

Recommendation #2:
Establish coordinated national strategy for opioid abuse & misuse

Flawed Strategic Approach to Abuse & Misuse

- FDA and other policymakers are:
  - *"striving to find a balance between minimizing opioid drug abuse and misuse, while simultaneously enabling appropriate access to pain-relieving drugs."* **(aka "the balance statement")**
- Accepts that:
  - opioids are the analgesic drugs of choice
  - drugs are the treatment of choice for pain
- We are societally addicted to opioids!

Opioid Abuse & Misuse - Part of National Pain Strategy

- Defeating abuse and misuse - part of the pain strategy:
  - Must aim to wean us from opioids by funding, developing and facilitating access to pharmaceutical and non-pharmaceutical alternatives to opioids.

- Amend "**balance statement**" - We must strive to:

  "to find a balance between minimizing opioid drug abuse and misuse, while simultaneously enabling appropriate access to pain-relieving drugs, devices and other modalities."

Recommendation #3:
Integrate opioid abuse & misuse strategy into national pain strategy.

Understand Cost Centers in Chronic Pain

- Opioid Price Tags
  - Side-effects, do not address the chronic nature of the pain
  - Increased pain sensitivity and possible prolongation of the chronic pain state
  - Abuse and misuse costs over $56billion/ year
  - Opioid induced constipation in a VA population - $39,068/ patient

- Procedures used to treat pain – example: hysterectomy
  - ~ 100,000 hysterectomies / year for pelvic pain: ~ $3 billion
  - Evidence of effective pain relief: *"insufficient to comment"*
  - Premenopausal hysterectomy in these patients:
    - heralds the broadening of symptoms
    - may accelerate cognitive decline or even Alzheimer's.

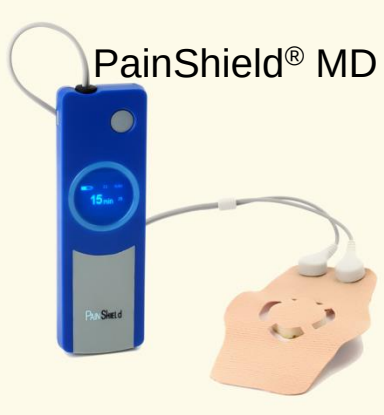
Recommendation #4:
Review cost centers, and allocate funds to develop and deploy effective alternatives.

Andrews J. et al. AHRQ Comp Effect. Rev 41. 2012 11:EHC088-EF
Bove R et al. Am Acad Neurol; San Diego. 2013: S24.

Iyer S et al. Manag Care. 2010 19:44
Tishler TA et al. Neurobiol Aging. 2012 33:1950
Wiseman DM. Semin Reprod Med. 2008; 26:356

Developing Alternatives to Treat Chronic Pain: Opportunities & Challenges

- IAS studied novel, wearable therapeutic ultrasound device.
- In refractory CAPPS patients reduced:
  - Painful bowel, bladder, genital & musculoskeletal
  - Use of opioids and other drugs
- KevMed, LLC. founded to market device.
- Other promising & easily deployable technologies face barriers.



Recommendation #5:

A pain strategy must provide for:

- Expedited FDA approval for alternatives
- Streamlined reimbursement approval for alternatives.
- Reimbursement that allows modalities such as physical and psycho-therapy to be used adequately for pain relief.

Wiseman, DM, Petree, T. Reduction of chronic abdominal and pelvic pain, urological and GI symptoms using a wearable device delivering low frequency ultrasound. Int. Pelvic Pain Soc; Chicago, IL. 2012, Abs 42. www.kevmed.com/ClinicalData.html

How are we going to pay for this?

- US opioid sales ~ $9 b
- Societal costs of opioid abuse & misuse > $56b (2007)
  = 2 x NIH appropriation ($32b - 2012)
  = 140 x NIH spending on chronic pain research ($399m - 2013)
  = 30% less than the Federal budget sequester ($85b - 2013)
- How can we not pay for this?

Recommendation #6:
Make the case for expanded funding of programs that will bring the dream of a pain-free America closer to reality

Birnbaum H et al. Pain Med. 2011; 12:657
www.nih.gov/about/director/budgetrequest/NIH_BIB_020911.pdf
http://report.nih.gov/categorical_spending.aspx

Recommendations

1. With CAPPS as a predominantly female issue, use data to support efforts addressing gender disparity in access to analgesia.

2. Establish coordinated national strategy for opioid abuse & misuse.

3. Integrate Opioid Abuse & Misuse Strategy into National Pain Strategy.

4. Review cost centers, and allocate funds to develop and deploy effective alternatives.

5. A pain strategy must provide for:
- Expedited FDA approval for alternatives
- Streamlined reimbursement approval for alternatives.
- Reimbursement that allows modalities such as physical and psycho-therapy to be used adequately for pain relief.

6. Make the case for expanded funding of programs that will bring the dream of a pain-free America closer to reality.

Disclosures

- President of Synechion, Inc. - consulting income from entities with a financial interest in medical products, particularly related to adhesions and CAPPS.
- Synechion owns adhesions.org and iscapps.org web sites.
- President and owner of KevMed, LLC
  - Markets a medical device for pain, PainShield® MD.
- I or my immediate family members may have shares in companies that sell medical products.
- No consulting clients have sought to influence our participation in this meeting.