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Educating Providers in Opioid Analgesia and Risk Management: What works?

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Over 30 years a major shift occurred in the use of opioids for chronic pain

1) Growing societal expectation of pain relief:

- **Terminal cancer pain (Hospice movement)**
- **Pain as 5th Vital Sign in the VA health system**
- **JCAHO standards**

2) Cancer pain specialists document that patients with cancer-related pain:

- **Are under-treated**
- **When in remission from cancer, tolerate opioids long-term without difficulty**

Over 30 years a major shift occurred in the use of opioids for chronic pain

3) Recognition that:

- **Chronic pain is common**
- **Poorly controlled pain damages the nervous system leading to neuroplastic changes, that are often difficult to reverse**
- **Pain becomes a chronic disease**
- **Uncontrolled pain is a public health problem**
  - **Costs to businesses**
  - **Costs to taxpayers**

Over 30 years a major shift occurred in the use of opioids for chronic pain

4) **Regular, daily opioids demonstrate efficacy / effectiveness, safety and tolerability in cross-sectional or short-term studies of patients *in structured clinical and experimental settings***
   - **Nursing homes (effectiveness)**
   - **Clinical trials (efficacy)**
   - **Laboratory (psychomotor safety)**

5) **Documented dangers of alternatives:**
   - **Under-treated pain: disability, depression, suicide**
   - **Analagesic options and organ system damage (e.g., NSAID, COX 2, TCA)**
   - **Back surgery failure rate**

6) **Opioid efficacy in neuropathic pain conditions (maldynias)**

7) **After severe limb trauma, early use of opioids associated with reduced chronicity**

Over 30 years a major shift occurred in the use of opioids for chronic pain

8) Emphasis on short-term cost-containment in managed systems to maximize profitability:

- Brief visits: Synergy with marketing of biomedical model and short-term clinical trials that promote:

**** pharmaceuticals***

**** procedures***

- Cost-shifting of treatment failures to public sector (ERs, workers compensation, SSDI)

- Drastic reduction of integrated, rehabilitation despite demonstrated cost-effectiveness (e.g., return-to-work)

Which patients with chronic pain , amongst the many millions being treated in primary care, should be considered for treatment with opioids ?

Patients

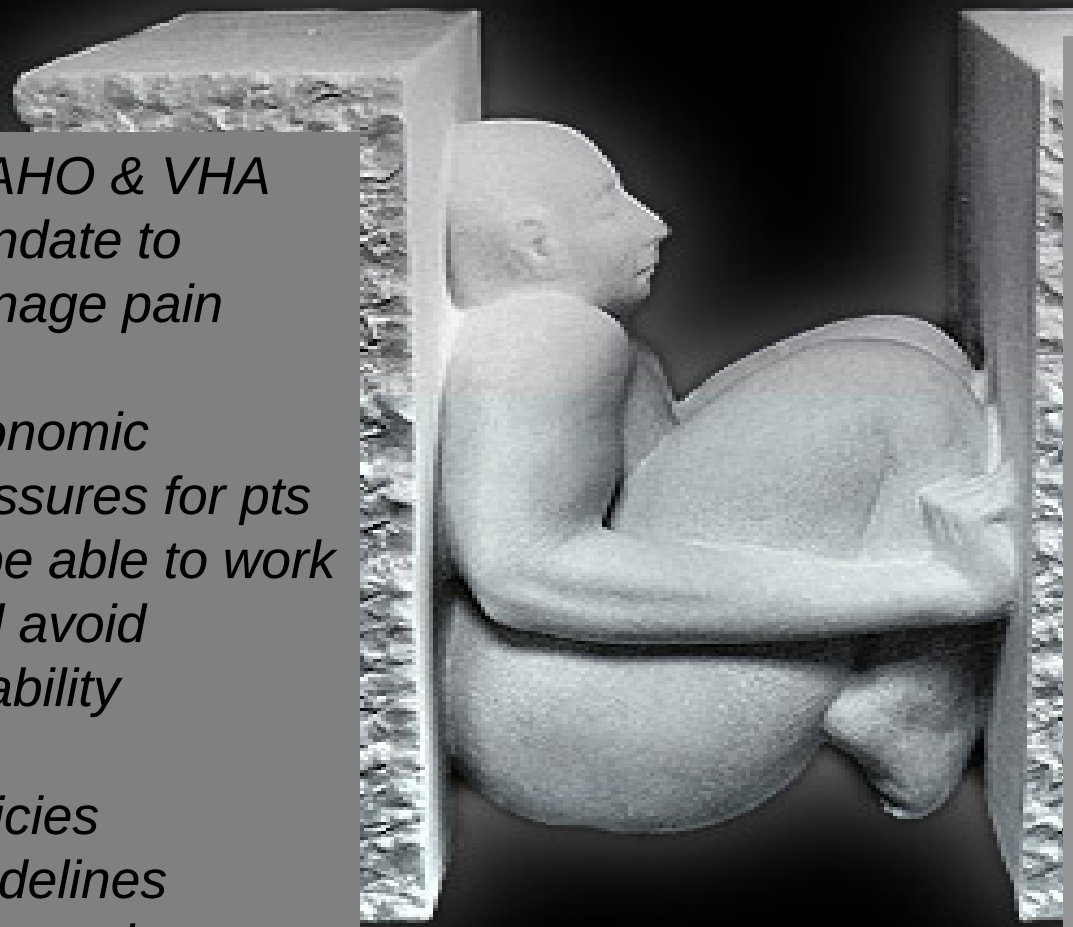
- Without addiction?
- With a remote history of addiction?
- With active/recent addiction?
  - Smokers?
- On opioid agonist therapy for addiction?

- Who misuses medications?
- Who are chemical copers?
- Are disorganized or impulsive?

- Have low self-esteem?
- Have major depression or PTSD?

How do we manage risk to create access to care?

Managing **PAIN** in Primary Care: Issues and Challenges



JCAHO & VHA Mandate to Manage pain

Economic pressures for pts to be able to work and avoid disability

Policies Guidelines Expectations

Brief visits

Complex patients

Little training in pain mgmt / addictions

Lack of reliable pain medicine / addictionology

Clinical Reminders

Minimal program resources (doc-in-box)

"The hole and the patch should be commensurate."

Thomas Jefferson

"Every reform, however necessary, will by weak minds be carried to an excess which will itself need reforming."

Samuel Taylor Coleridge

Pain management challenges in the VA population

- **Aging veteran population from Vietnam era**
  - **Chronic pain syndromes from war wounds and physical strain:**
    - *DJD spine and joints*
    - *causalgia after major nerve injury*
  - **Co-morbidities:** *PTSD, depression, substance abuse*
  - **Pain causing degenerative diseases associated with aging:**
    - *Arthritis, diabetic neuropathy, post-herpetic neuralgia*
    - *Cancer*
- **OEF-OIF "Tsunami" of:**
  - **Severely injured survivors with polytrauma pain and TBI**
  - **Common pain disorders (HA, LBP) with emotional trauma**
  - **"Pyschosocial" disorders:** *PTSD, depression, substance abuse, relationship and occupational mal-adjustment*

VHA Strategy

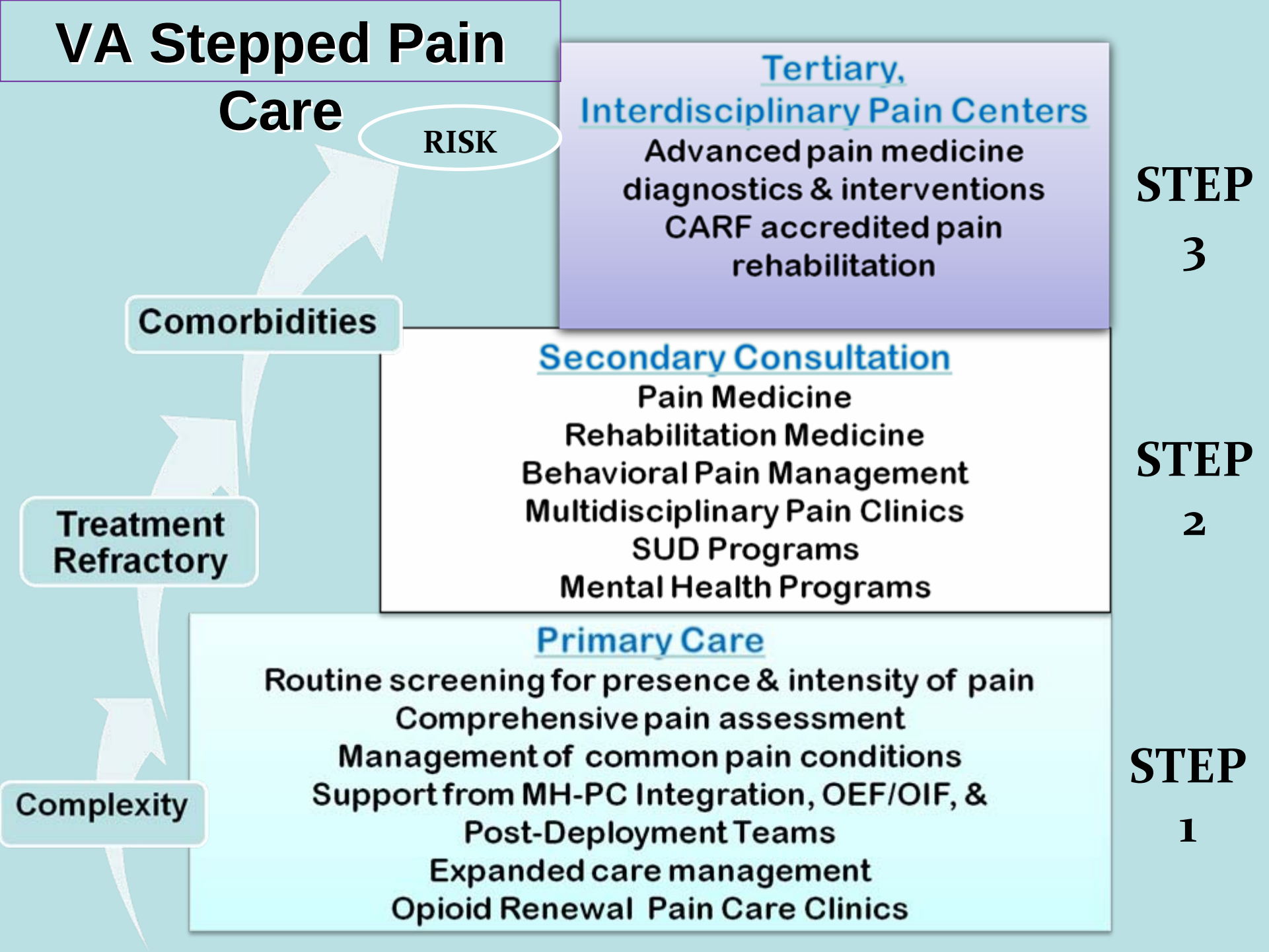
Standardize care:

1) National VA Pain Management Directive: Stepped Pain Care (Directive 058-2009)

2) DoD-VA Chronic Opioid Therapy Clinical Practice Guidelines.
   - Built on evidence since APS-AAPM CPGs
   - Adding specific teaching modules

3) National Opioid Pain Care Agreement

VA Stepped Pain Care



Educating Providers in Opioid Analgesia and Risk Management:

- How do we measure effectiveness?
  - Knowledge acquisition
    - Understanding pain pathophysiology, chronic pain conditions as disease state
    - Understanding that pain conditions are not “psychogenic” or “weakness leaving the body”
  - Attitude change
    - pain is important (impact on public health and patient/family outcomes)
    - Pain is medically treatable – I can do it
    - Risk is manageable

Educating Providers in Opioid Analgesia and Risk Management:

- **How do we measure effectiveness?**
  - **Clinical practice change**
    - **Appropriate use of opioids within a biopsychosocial paradigm focused on patient outcomes**
      - **Pain control in the service of:**
      - **Return to role function and quality of life: work, parenting, relationships, hobbies**
    - **Use of appropriate risk management procedures**
      - **Opioid Pain Care Agreements and Risk Management**
      - **Practice audits, like VA's opioid high alert program**

Educating Providers in Opioid Analgesia and Risk Management:

- **What Does Not Work to Change Practice?**
  - **CME Lectures**
  - **Seminars**
  - **Reading**
- **What Does Work to Change Practice?**
  - **Residency training, an apprentice model**
  - **Post-graduate training in apprentice model**
  - **ECHO program in South West**
  - **Academic Detailing**
  - **System supports for Case Management**

Impact of introducing anticoagulation-related prescribing guidelines in a hospital setting using academic detailing

Roberts GE, Adams R

Therapeutics and Clinical Risk Management 2006:2(3) 309–316

- **Principles of Academic Detailing:**
  - **Face-to-face sessions, preferably on an individual basis**
  - **Defining clear educational and behavioral objectives**
  - **Establishing credibility with respect to objectivity**
  - **Stimulating physician interaction**
  - **Use of concise graphic educational materials,**
  - **Highlighting key messages**
  - **Providing positive reinforcement of improved practices in follow-up visits**
- **Selected medical and surgical teams at 4 metropolitan teaching hospitals were detailed.**

Results of Intervention with Warfarin Initiation

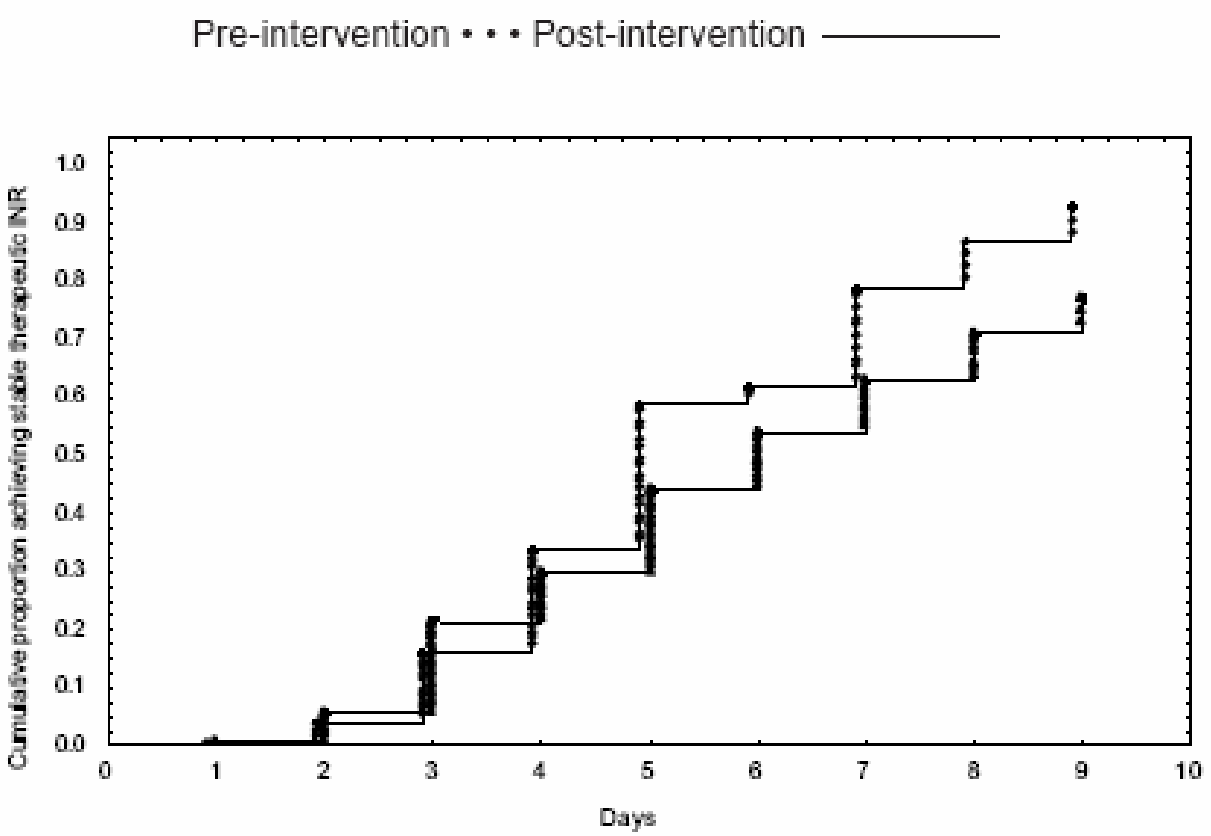


Figure 2 Time to a stable therapeutic INR during warfarin initiation (p=0.03).
Abbreviations: INR, international normalized ratio.

- Patients initiated on Warfarin post-intervention were quicker to get stable therapeutic INR (p=0.03)

Implications

- Academic detailing appears to be an effective approach welcomed by prescribers for encouraging uptake of clinical guidelines within hospital settings.
- Prescribers are more likely to follow guidelines if they are simple, clear and specific.
- Guidelines that produce obvious and/or immediate feedback for the prescriber may lead to better uptake.

  Academic detailing relies on timely interaction with prescribers, which necessitates ongoing commitment and resources to do this. Sustainability issues need to be considered.
- Academic detailing may have a more long-term effect with younger clinical prescribers.

Opioid Renewal Clinic: Development and Implementation

- **Phase I:** 1999-2001
  - ID of problem: OIG report on high use and costs of oxycodone sustained action at PVAMC
  - Support: from the top
    - 1 FTE primary care NP to manage
    - ½ FTE PharmD (coumadin clinic model)
    - Weekly pain team for support (ortho, rheum, psychology, addiction/psychiatry, neurology)
  - Learn:
    - Review literature, precept, interview thought leaders
    - PCP focus groups: what are your needs?
- **Phase II:** 2002-2003
  - Design and implement ORC
- **Phase III:** 2004 – present
  - Maintain, evaluate and replicate

Wiedemer NL, et al. *Pain Med*. 2007;8:573-584.

Opioid Renewal Clinic (ORC) Phase II

Goal: to support PCPs managing patients with chronic noncancer pain requiring opioids

- Provide appropriate treatment for patients
  - Opioid therapy when indicated
- Improve PCP confidence in prescribing opioid analgesics
- Improve monitoring and documentation
- Reduce overall costs of care by decreasing misuse or overuse of resources

Wiedemer NL, et al. *Pain Med*. 2007;8:573-584.

ORC Services

- Assist with management of ***challenging*** patients requiring structured prescribing and monitoring of long-term opioid therapy
  - Patients with aberrant drug related behaviors to r/o substance misuse vs. pseudoaddiction vs. addiction
  - Patients with h/o addiction, recent addiction, active addiction
  - Patients with complexity (e.g., psych co-morbidity)

ORC: Services

- Assist with opioid titration and rotation
- Assist with routine opioid renewals
  - Patients who have stabilized
  - Part-time providers

Phase III: Outcome Measures

PCPs variables:

- Increase in use of the Opioid Treatment Agreement
- Increase in Urine Drug Testing by PCPs
- Satisfaction with the program

Patient variables:

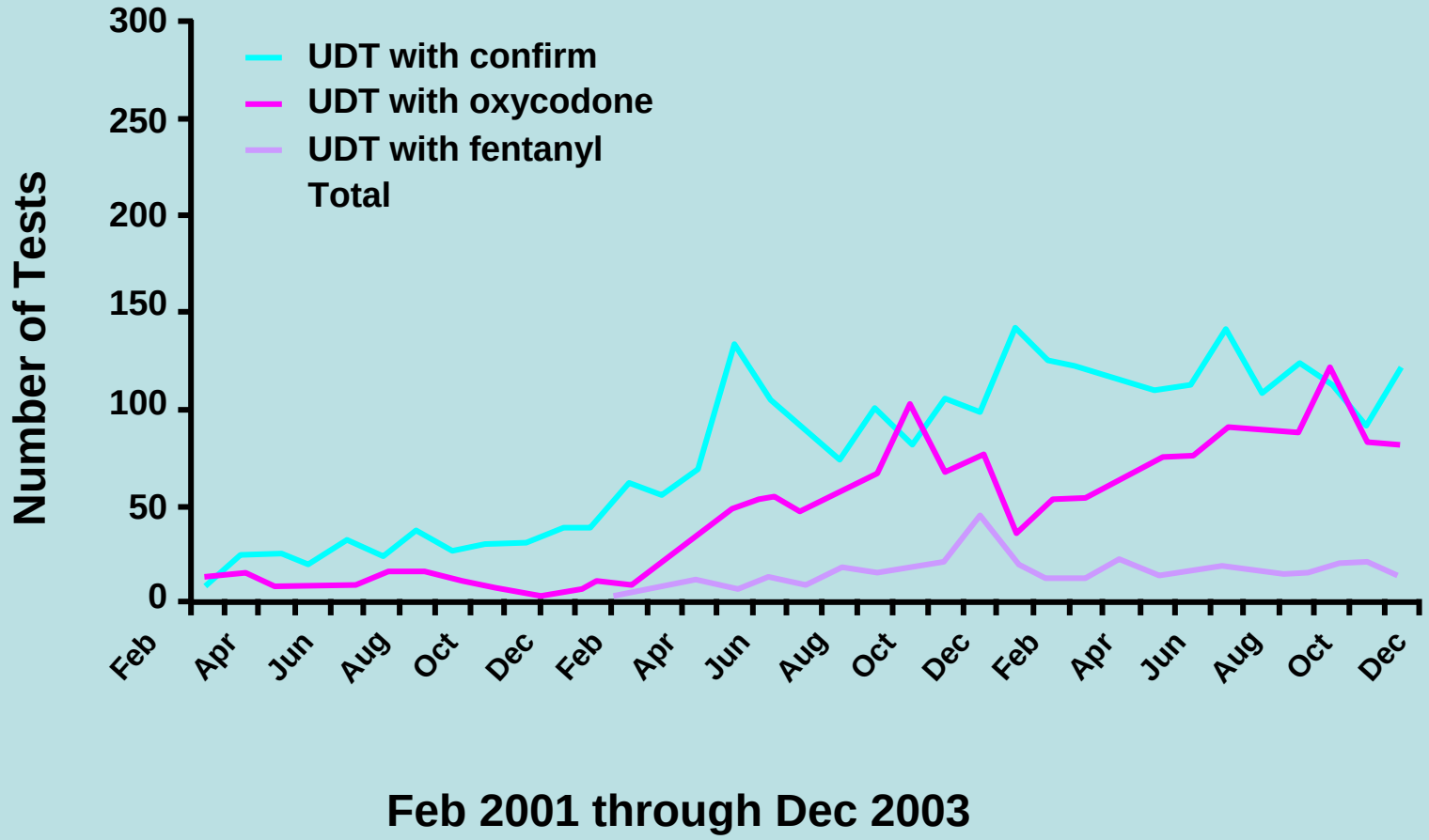
- Adherence to the Opioid Treatment Agreement
- Reduction of inappropriate clinical visits and contacts

Pharmacy variables:

- Oxycodone sustained action use

Opioid Renewal Clinic

Increased Use of UDT

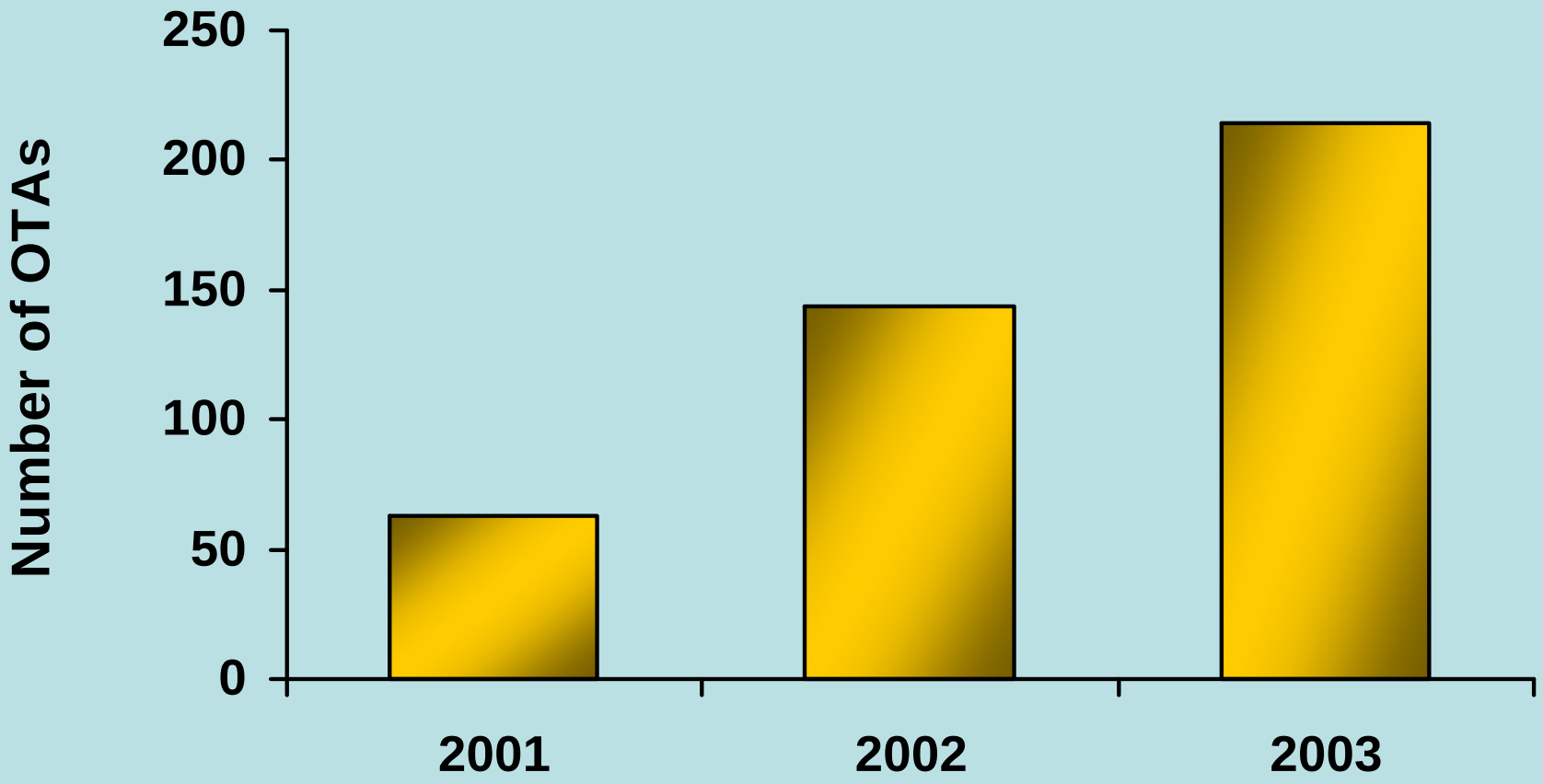


Feb 2001 through Dec 2003

Wiedemer NL, et al. *Pain Med*. 2007;8(2):573-584.

Opioid Renewal Clinic

Increases in Opioid Treatment Agreements



Wiedemer NL, et al. *Pain Med*. 2007;8:573-584.

ORC Results:
One year follow-up data on patients consecutively referred from **1/2/02 – 12/6/06**

N = 784 referrals

Aberrant Behavior
366 (47%)

- UDT:
  - + for illegal drugs or unprescribed drugs,
  - negative for prescribed drugs
- overusing prescribed opioids

No Aberrant Behavior
418 (53 %)

- Opioid rotation or titration
- Hx. of recent abuse
- Conflicts with providers
- Part-time clinicians- referred for assistance with monthly monitoring

100% adherence

Results

366 (47%) with documented aberrant behavior

Resolution of aberrant behavior	**147 (40.2%)**
Discharge from ORC **n=101 (28 %) self-discharged** **n= 86 (23 %) ORC discharged**	**187 (51 %)**
Referred to addiction tx.	**24 (6.6 %)**
Consistently negative UDT **weaned from opioids**	**7 (1.9 %)**
Undeclared – still monitoring	**1 (0.3%)**

Predictors of Resolution of Aberrant Drug Behavior in Patients Referred to ORC:

Meghani et al, *Pain Med 2009*

- **Logistic Regression analysis (resolved/not resolved) found two variables most important in predicting aberrant drug behavior outcomes.**
  - **History of Cocaine Addiction:**
    - **History of Cocaine addiction increased the odds of failure (not resolved) by *5 times* (OR = 4.970, p = .001).**
  - **Number of Pain Diagnoses:**
    - **Each additional pain diagnosis reduced odds of failure by about 14% (OR = 0.837, p = 0.008).**

Opioid Renewal Clinic
Provider satisfaction**

- 63.0% use opioid treatment agreements more often
- 89.5% routinely order drug screens
- 89.0% more comfortable managing chronic pain after ORC
- 77.0% receive fewer complaints regarding pain medications

** Strongly agree or agree

Wiedemer et al. *Pain Med*. 2007;8:573-584.

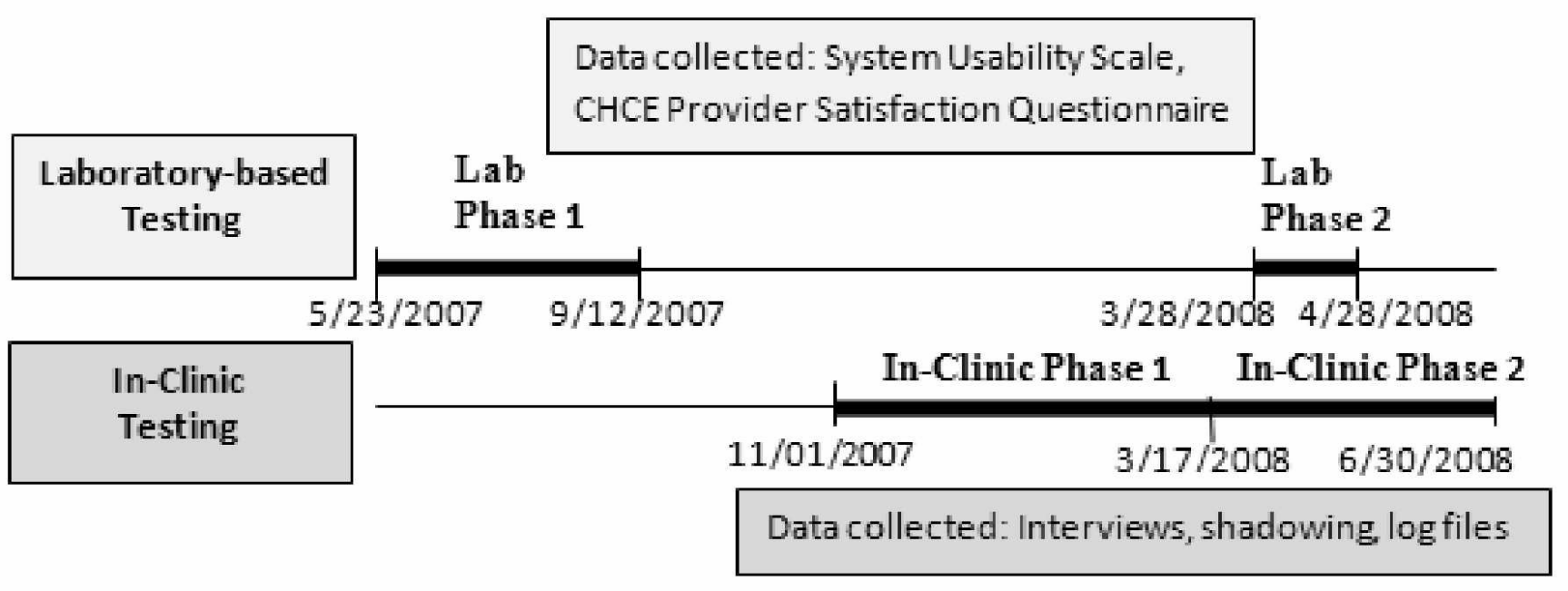
Opioid Renewal Clinic
Conclusions

A structured program for opioid management for chronic noncancer pain patients can successfully be employed in a primary care setting:

- to manage risk in patients with demonstrated aberrant drug related behaviors or other psychiatric risk factors
- to facilitate the use of opioid analgesics in pain treatment for all patients, regardless of risk.
  - Standardized documentation
  - OTAs
  - UDTs
  - Frequent visits
  - Patient education
- To improve PCPs satisfaction with pain management and the doctor-patient relationship
- To potentially reduce health system costs and public health effects of addiction / diversion

Wiedemer NL, et al. *Pain Med*. 2007;8:573-584.

Trafton J. et al.
Evaluation of the acceptability and usability of a decision support system to encourage safe and effective use of opioid therapy for chronic pain by primary care providers. *Pain Med* 2010;11(4).



Trafton J. et al. *Pain Med* 2010;11(4).

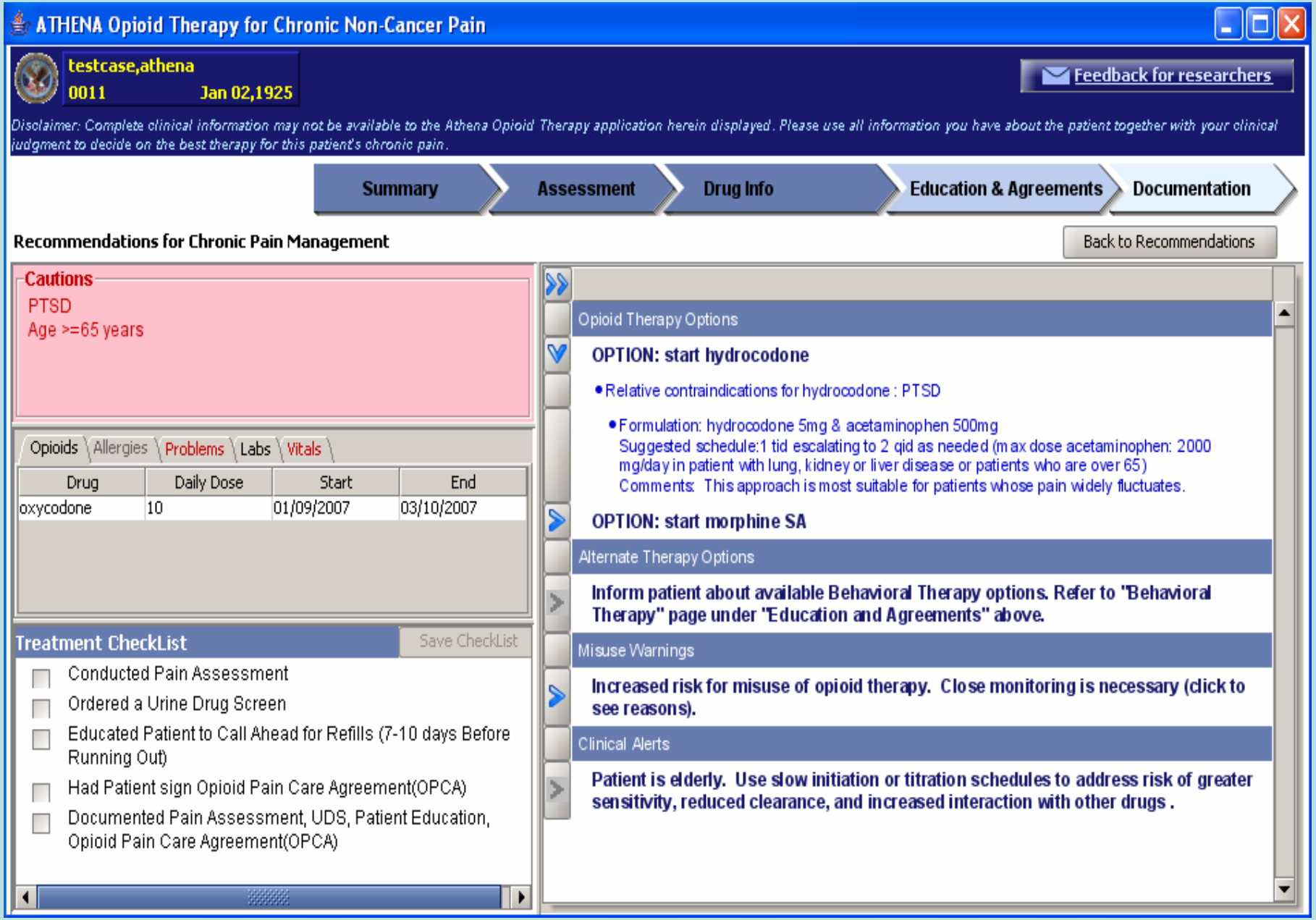


Table 1: Results, CHCE Provider Satisfaction and SUS

CHCE Provider Satisfaction Questionnaire (SD)	Mean (SD) Round 1	Mean (SD) Round 2	Overall Mean
1. Usefulness of the information	4.00 (0.50)	4.60 (0.58)	4.33 (0.71)
2. Ease of understanding the information presented	4.50 (0.48)	4.00 (0.82)	4.22 (0.67)
3. Use of graphics	3.00 (0.00)	3.60 (0.58)	3.43 (0.53)
4. Improvement in provider-patient encounters	3.67 (0.19)	3.80 (1.41)	3.75 (1.04)
5. Does the DSS save time	3.25 (1.42)	3.00 (0.82)	3.11 (1.05)
6. A regular part of daily practice	4.00 (0.00)	3.60 (1.73)	3.75 (1.16)
7. Improvement in attitude toward treating patients	3.33 (0.69)	3.60 (1.41)	3.50 (1.60)
8. General satisfaction with the system	3.67 (0.51)	4.00 (0.82)	3.88 (0.64)

Opioid Pain Care Agreements: Where We Are Nationally

- Variable usage of Opioid Agreements
  - 80% of facilities use OAs; 20% don't
  - Multiple versions
    - Content
    - Tone
    - Reading levels
- Different locations
- Disparity in enforcement

"My way or the highway"

National OPCA Work Group

<u>Chair</u>: Francine Goodman, PharmD, BCPS, Clinical Pharmacy Specialist, VACO Pharmacy Benefits Management Services

- IT / iMED / CPRS: Robert Silverman, Raymond Frazier, Loren Stevenson
- General Counsel: Eric Raun
- Ethics: Kenneth Berkowitz
- Hospice Palliative Care: Scott Shreve
- Hematology / Oncology: Paulette Mehta
- Primary Care / Pain: Robert Kerns, Mac Gallagher, Nancy Wiedemer, Stephen Eraker, Lisa Knoff, Matt Bair, Michael Clark, Jack Rosenberg, Beverly Rashad, Anthony Mariano, Mitchell Nazario, Diana Higgins, Sue Millar, Karl Frohm, Michael Mangione, Tim Lee
- Patient Education Panel: Pam Hebert, Charlene Stokamer, Janette Elliott
- Provider Education: Anne Turner, Robert Sproul

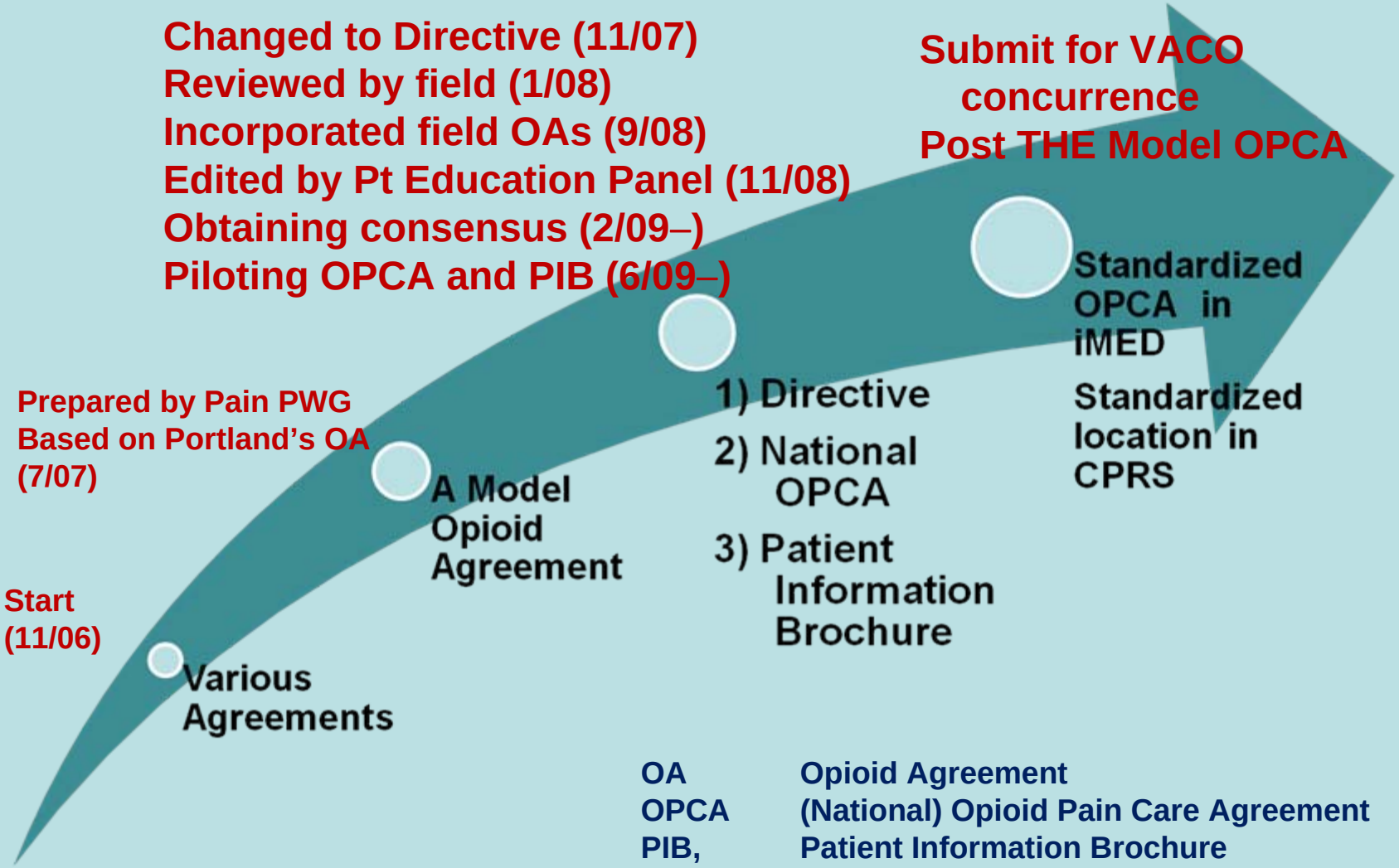
What is the evidence ?

- High quality evidence (multiple Level 2 studies) for **safety** concerns:
  - Risk of abuse of and addiction when associated with aberrant behavior, psychiatric co-morbidity, history of substance use
  - Risk of diversion of opioids
  - Risk of overdose
- Poor quality evidence for clinical effectiveness of OPCA used alone (Starrels et al Ann Int Med 2010)
  - No controlled trials or quality systematic reviews

What is the evidence ?

- Moderate quality evidence (one Level II study) for clinical impact when combined with urine drug screens and monitoring
  - Opioid Renewal Clinic associated with:
    - Control of aberrant behavior for 50% of patients referred for aberrant behavior and 100% of patients with risk factors (e.g., presence of psychiatric co-morbidity, history of substance abuse)
    - Positive identification of addiction
- Strongly recommended by various experts and groups, most notably:
  - APS/AAPM Guidelines (Chou et al, 2009)
  - VA/DOD Chronic Opioid Guidelines (2009 revision is in process)

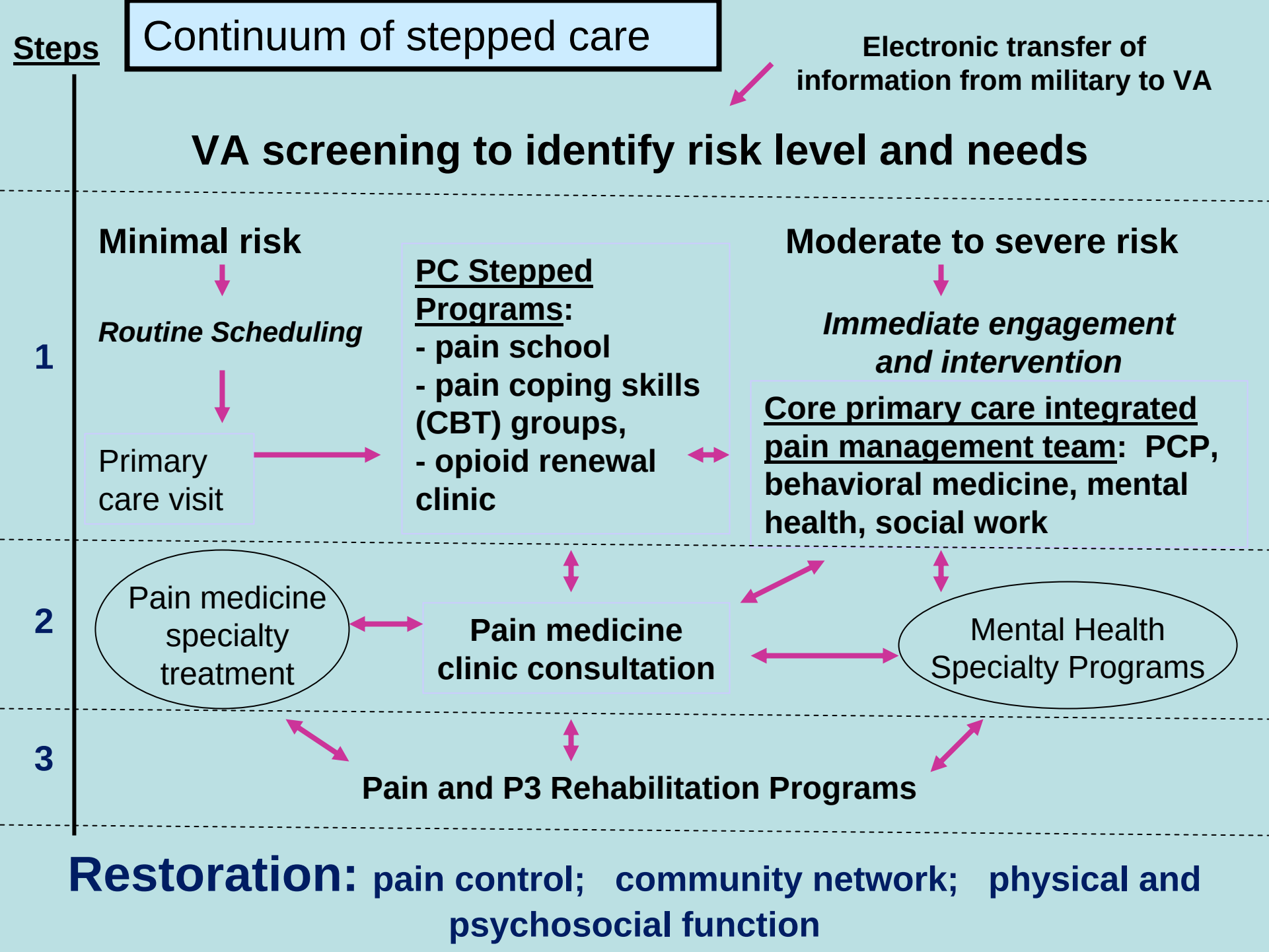
Evolution of the National OPCA



OA	Opioid Agreement
OPCA	(National) Opioid Pain Care Agreement
PIB,	Patient Information Brochure
PWG	Pharmacy Work Group

TENSION  BALANCE

- Patient Rights and Patient Safety
- Public Safety
- Clinician judgment and responsibilities


Steps
Continuum of stepped care
Electronic transfer of information from military to VA
VA screening to identify risk level and needs
Minimal risk
Routine Scheduling
Primary care visit
PC Stepped Programs:
- pain school
- pain coping skills (CBT) groups,
- opioid renewal clinic
Moderate to severe risk
Immediate engagement and intervention
Core primary care integrated pain management team: PCP, behavioral medicine, mental health, social work
1
2
3
Pain medicine specialty treatment
Pain medicine clinic consultation
Mental Health Specialty Programs
Pain and P3 Rehabilitation Programs
Restoration: pain control; community network; physical and psychosocial function

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