Opioid Patient Decision Support with ATHENA

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and Stanford University Medical School

Financial Disclosure

- No potential conflicts of interest

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- CRAVE was supported by grant RRP 07-316: “Validation of computerized risk assessment for prescription opioid abuse” from VA QUERI and VA Rehabilitation Research and Development

A Service Delivery Problem

- Primary care providers uncomfortable with opioid prescribing and pain management
  - Lack of training
  - Lack of time
  - Difficult patients
- But prescribe a lot of opioid medication
  - 10% of all US prescriptions are for opioids
  - In VA ~15% of patients in primary care are on opioids at any given time
    - 50% of patients report chronic pain and about 30% of these are prescribed opioid therapy for their pain

Concerns

- Increasing problems
  - Rates of overdose
  - Rates of prescription medication abuse
    - For example: According to the NSDUH, in 2002, 2.5 million Americans reported using prescription opioids for non-medical purposes for the first time. In 1990, this number was 537,000. Notably, 55% were female and 56% were over 18.
- Lack of evidence of efficacy
  - No randomized trials with outcome data past 4 months (Martell, 2006)
- Patient demand
  - In a household survey, substance use problems (OR 3.57) or depression/anxiety (OR 4.43) in 1998 were predictors of last month opioid therapy in 2001 (Sullivan, 2006)

Clinical Practice Guidelines

- Exist
  - Are primarily consensus based
  - Delineate good care practices
- Are underused
  - Practices not consistently followed

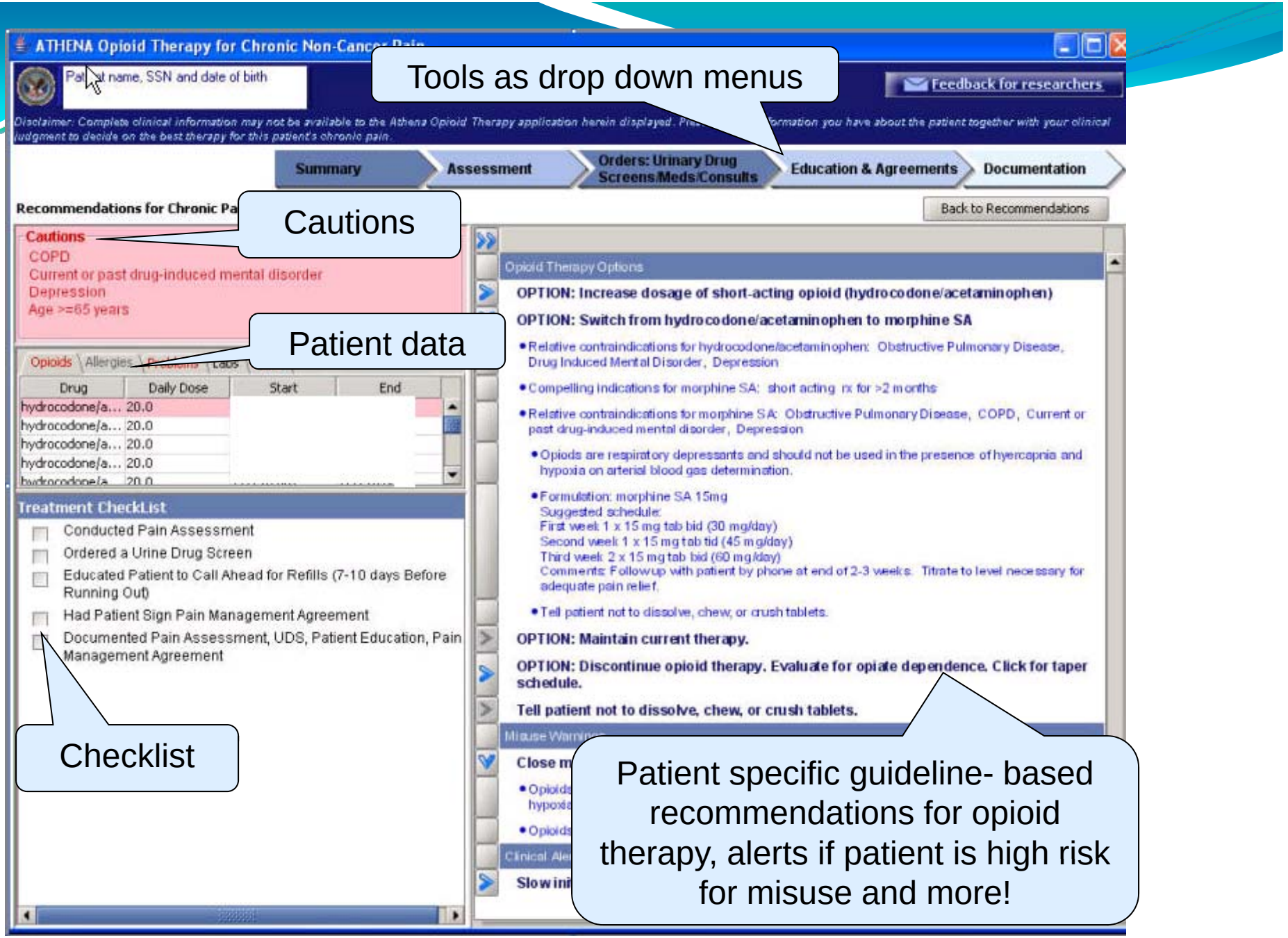
- What system-level changes can we make to encourage opioid prescribing practices that maximize safety and effectiveness?

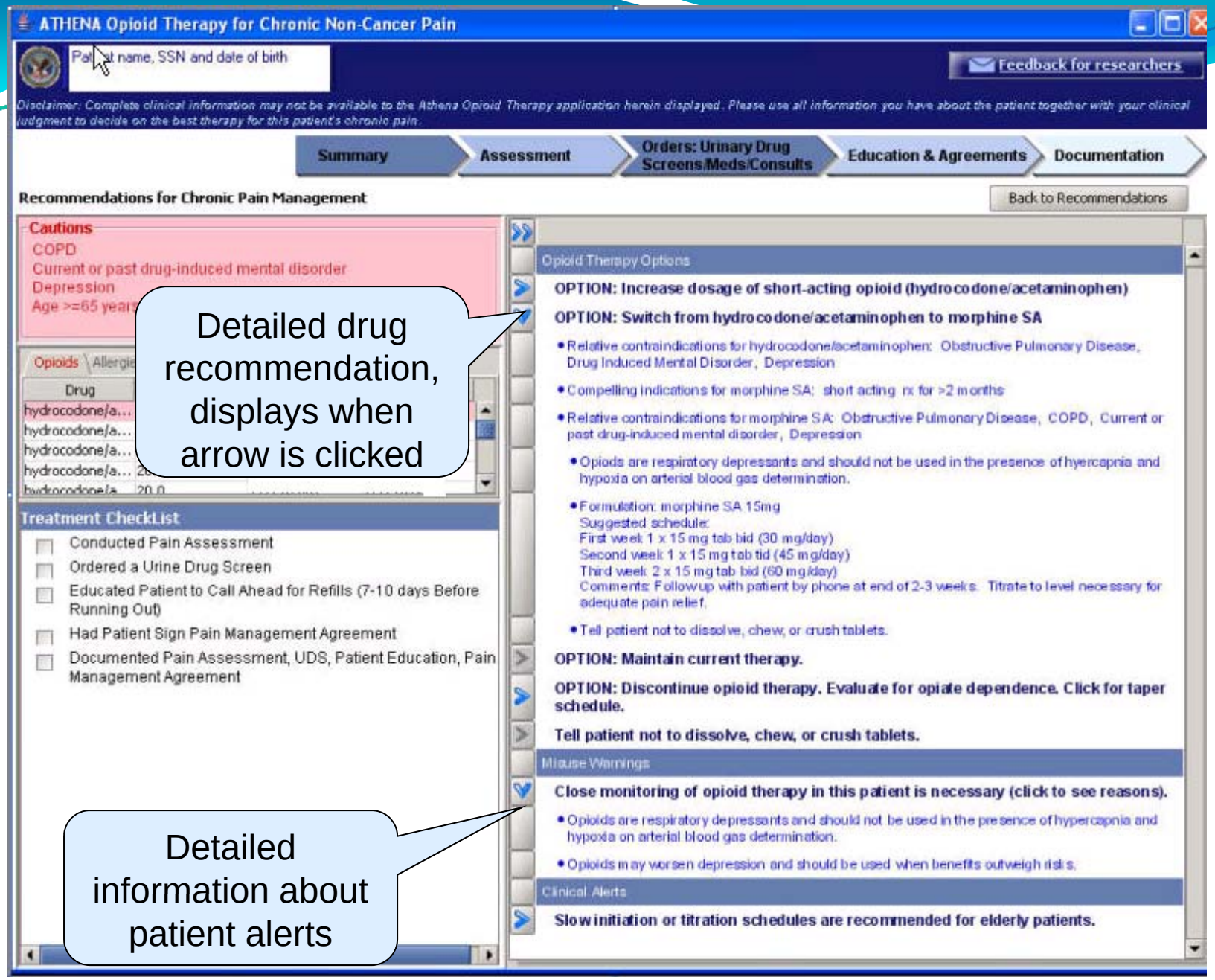
ATHENA-Opioid DSS

- Objective: Provide primary care providers patient specific guideline-based information relevant to opioid prescribing at the time of clinical decision making (outpatient visit).
- Based on 2003 VA/DOD clinical practice guideline for opioid therapy for chronic non-cancer pain

ATHENA-Opioid Therapy DSS

- Features include:
  - Patient specific recommendations
    - Warnings about patients at high risk for misuse
    - Specific drug dosing recommendations
  - Highlighted opioid therapy-relevant patient information
  - Checklist of good clinical practices
  - Standardized pain assessment with write-back to medical record
  - Tools
    - Patient education materials
    - Drug conversion calculator
    - Referrals for mental health & behavioral treatments, exercise programs and self-help
    - Guidelines for use of non-opioid pain medications
    - Suggested responses to aberrant medication use behaviors


ATHENA Opioid Therapy for Chronic Non-Cancer Pain
Patient name, SSN and date of birth
Feedback for researchers
Disclaimer: Complete clinical information may not be available to the Athena Opioid Therapy application herein displayed. Please consider information you have about the patient together with your clinical judgment to decide on the best therapy for this patient's chronic pain.
Summary
Assessment
Orders: Urinary Drug Screens/Meds/Consults
Education & Agreements
Documentation
Recommendations for Chronic Pa
Back to Recommendations
Cautions
COPD
Current or past drug-induced mental disorder
Depression
Age >=65 years
Opioids
Allergies
Drug
Daily Dose
Start
End
hydrocodone/a... 20.0
hydrocodone/a... 20.0
hydrocodone/a... 20.0
hydrocodone/a... 20.0
Treatment CheckList
Conducted Pain Assessment
Ordered a Urine Drug Screen
Educated Patient to Call Ahead for Refills (7-10 days Before Running Out)
Had Patient Sign Pain Management Agreement
Documented Pain Assessment, UDS, Patient Education, Pain Management Agreement
Opioid Therapy Options
OPTION: Increase dosage of short-acting opioid (hydrocodone/acetaminophen)
OPTION: Switch from hydrocodone/acetaminophen to morphine SA
Relative contraindications for hydrocodone/acetaminophen: Obstructive Pulmonary Disease, Drug Induced Mental Disorder, Depression
Compelling indications for morphine SA: short acting rx for >2 months
Relative contraindications for morphine SA: Obstructive Pulmonary Disease, COPD, Current or past drug-induced mental disorder, Depression
Opiods are respiratory depressants and should not be used in the presence of hyercapnia and hypoxia on arterial blood gas determination.
Formulation: morphine SA 15mg
Suggested schedule:
First week: 1 x 15 mg tab bid (30 mg/day)
Second week: 1 x 15 mg tab tid (45 mg/day)
Third week: 2 x 15 mg tab bid (60 mg/day)
Comments: Followup with patient by phone at end of 2-3 weeks. Titrate to level necessary for adequate pain relief.
Tell patient not to dissolve, chew, or crush tablets.
OPTION: Maintain current therapy.
OPTION: Discontinue opioid therapy. Evaluate for opiate dependence. Click for taper schedule.
Tell patient not to dissolve, chew, or crush tablets.
Tools as drop down menus
Cautions
Patient data
Checklist
Patient specific guideline- based recommendations for opioid therapy, alerts if patient is high risk for misuse and more!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Detailed drug recommendation, displays when arrow is clicked
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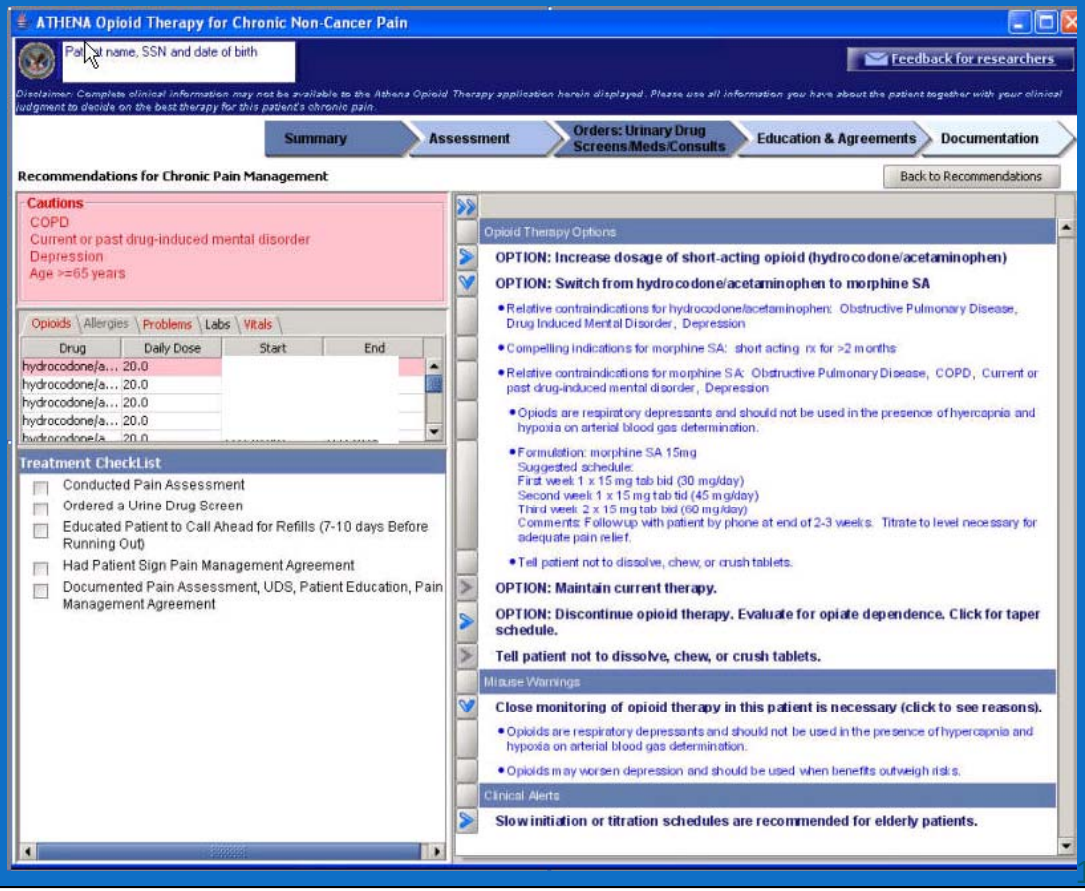
OPTION: Maintain current therapy.
OPTION: Discontinue opioid therapy. Evaluate for opiate dependence. Click for taper schedule.
Tell patient not to dissolve, chew, or crush tablets.
Misuse Warnings
Close monitoring of opioid therapy in this patient is necessary (click to see reasons).
Opioids are respiratory depressants and should not be used in the presence of hypercapnia and hypoxia on arterial blood gas determination.
Opioids may worsen depression and should be used when benefits outweigh risks.
Clinical Alerts
Slow initiation or titration schedules are recommended for elderly patients.

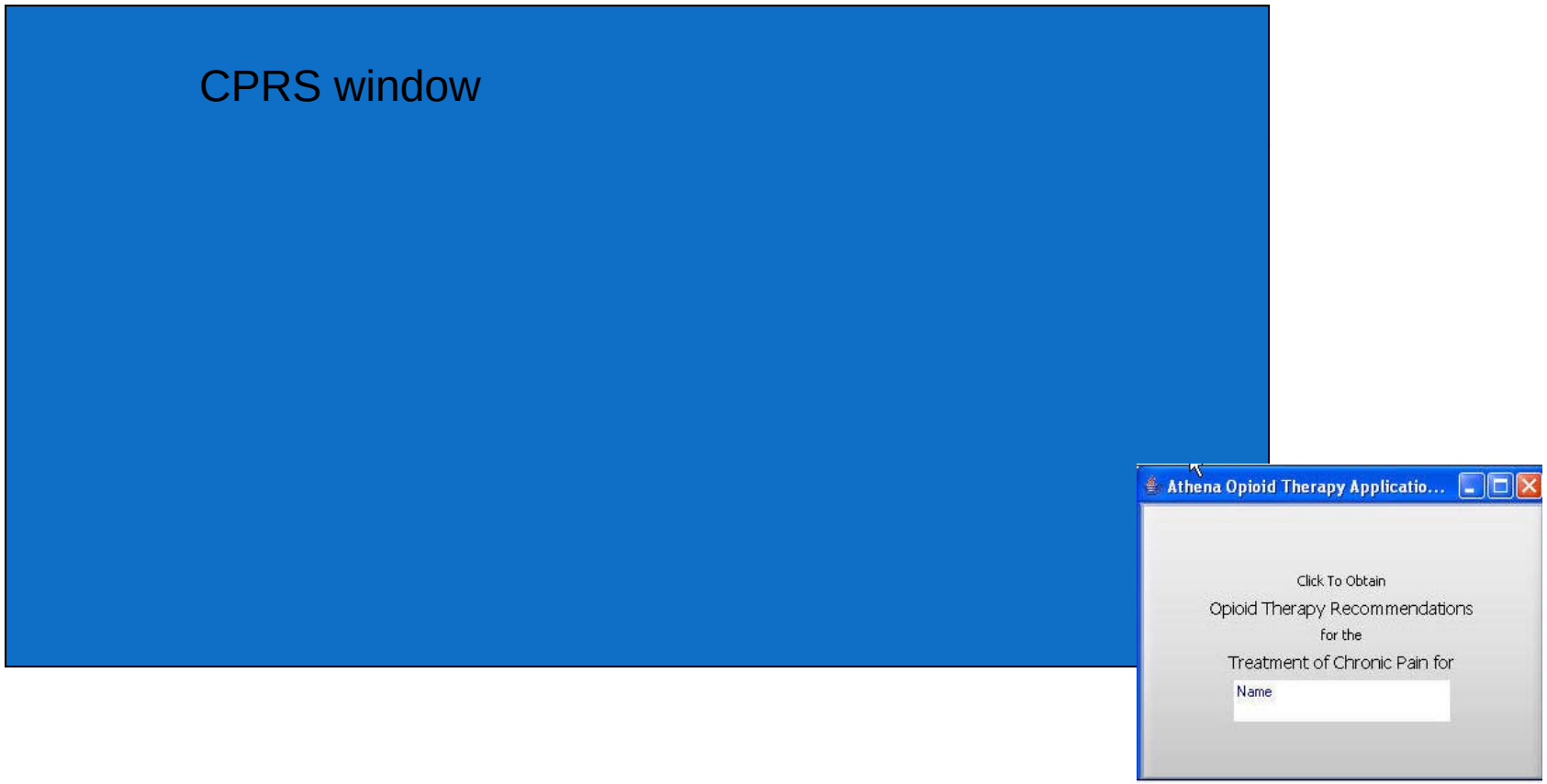
Automatic display when CPRS is opened for all patients with a visit scheduled within a 5 day window.

If patient is on opioids, the main page pops up in front of electronic medical record

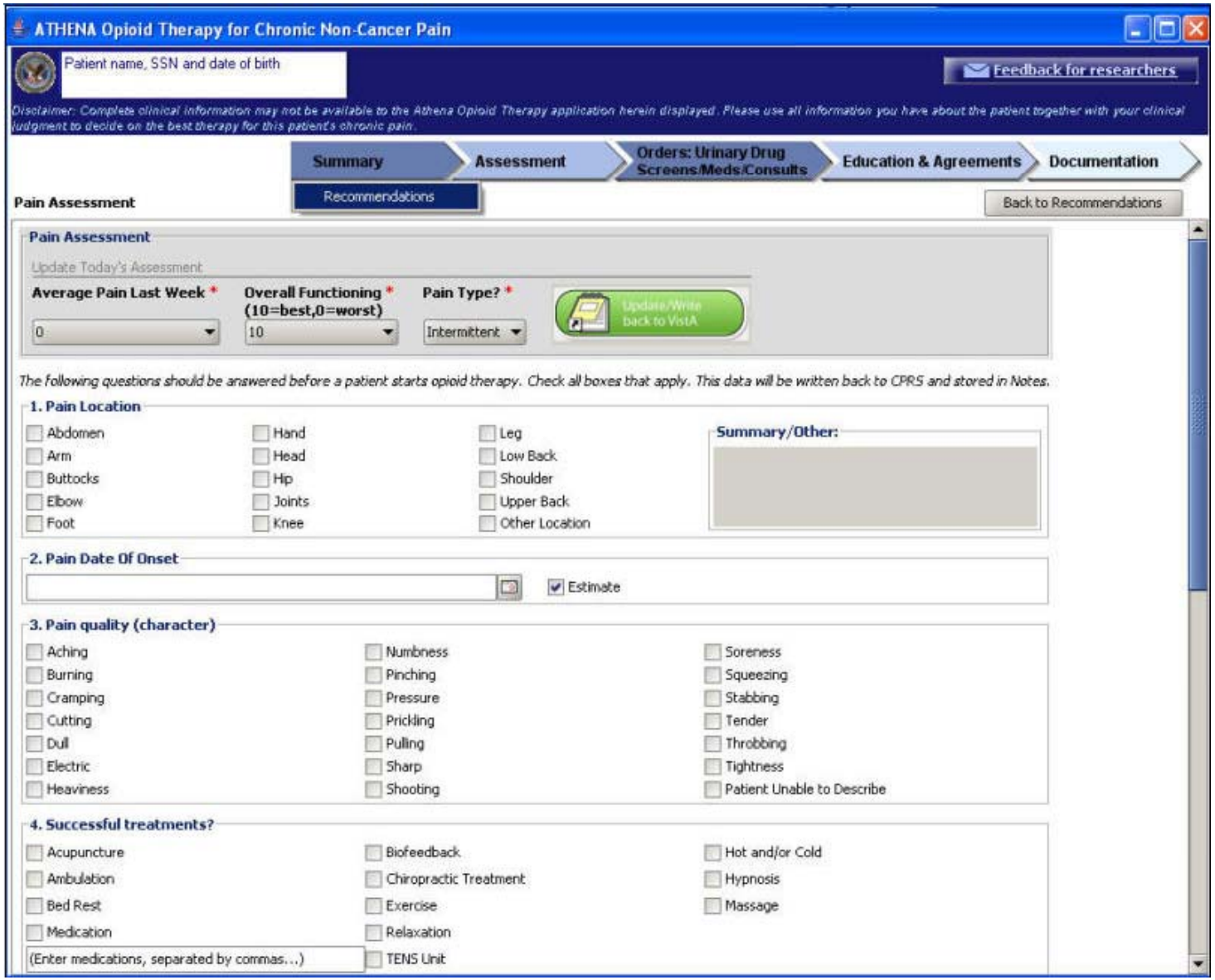
CPRS



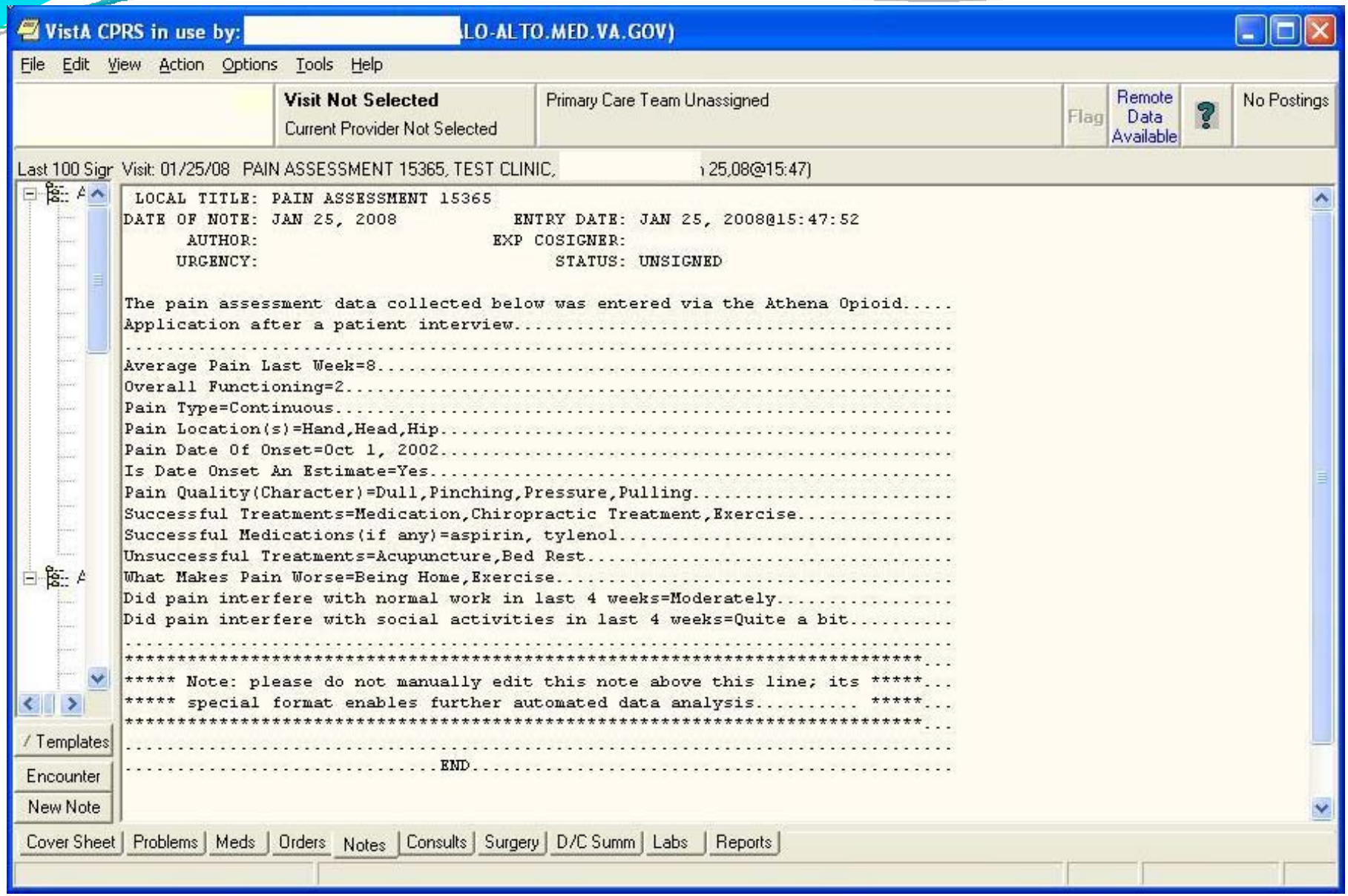
If patient is not on opioids, a stamp is automatically displayed. If you click on the stamp, the main page with all recommendations appears.



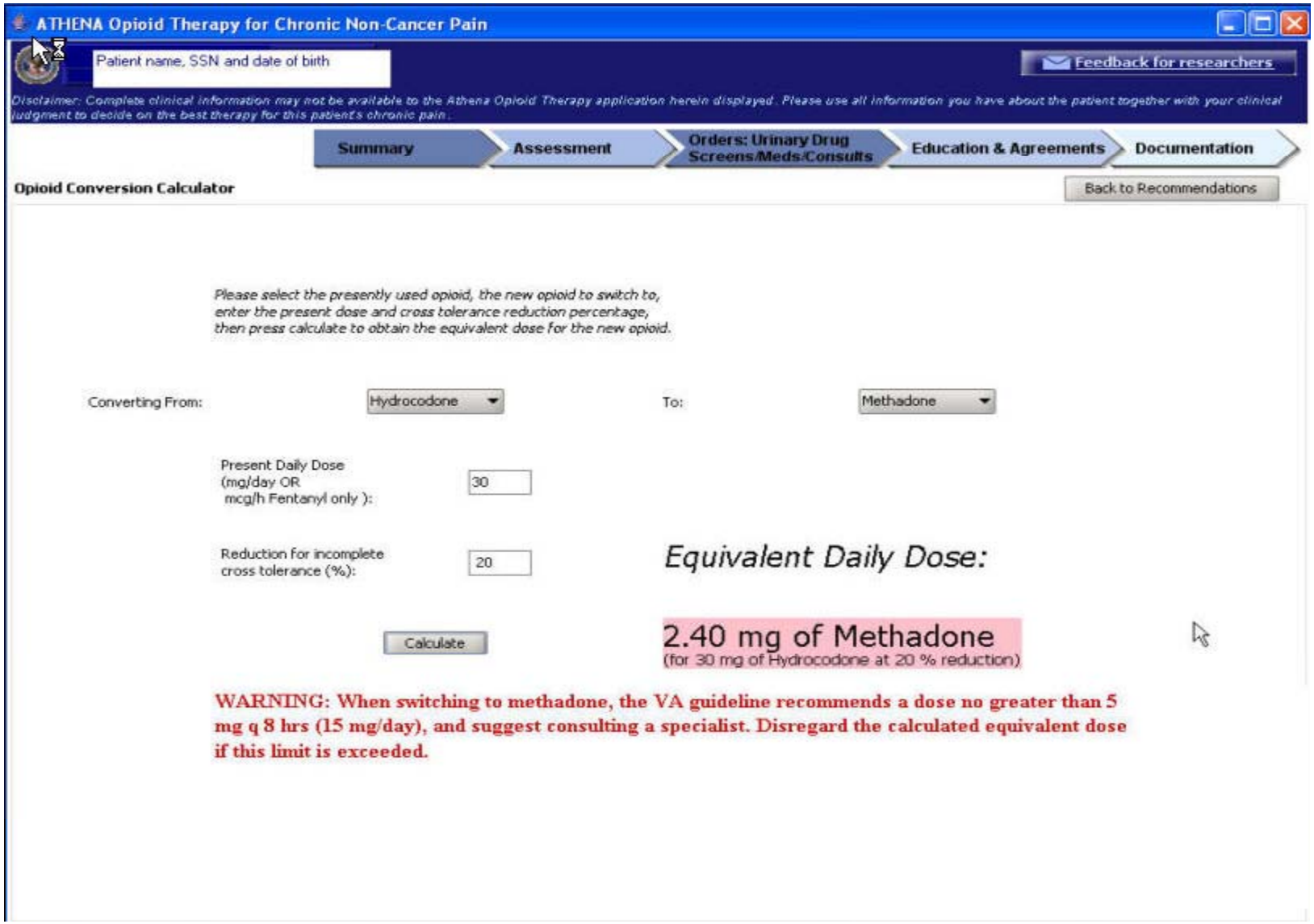
Pain assessment tool, is written back to electronic medical record as a note



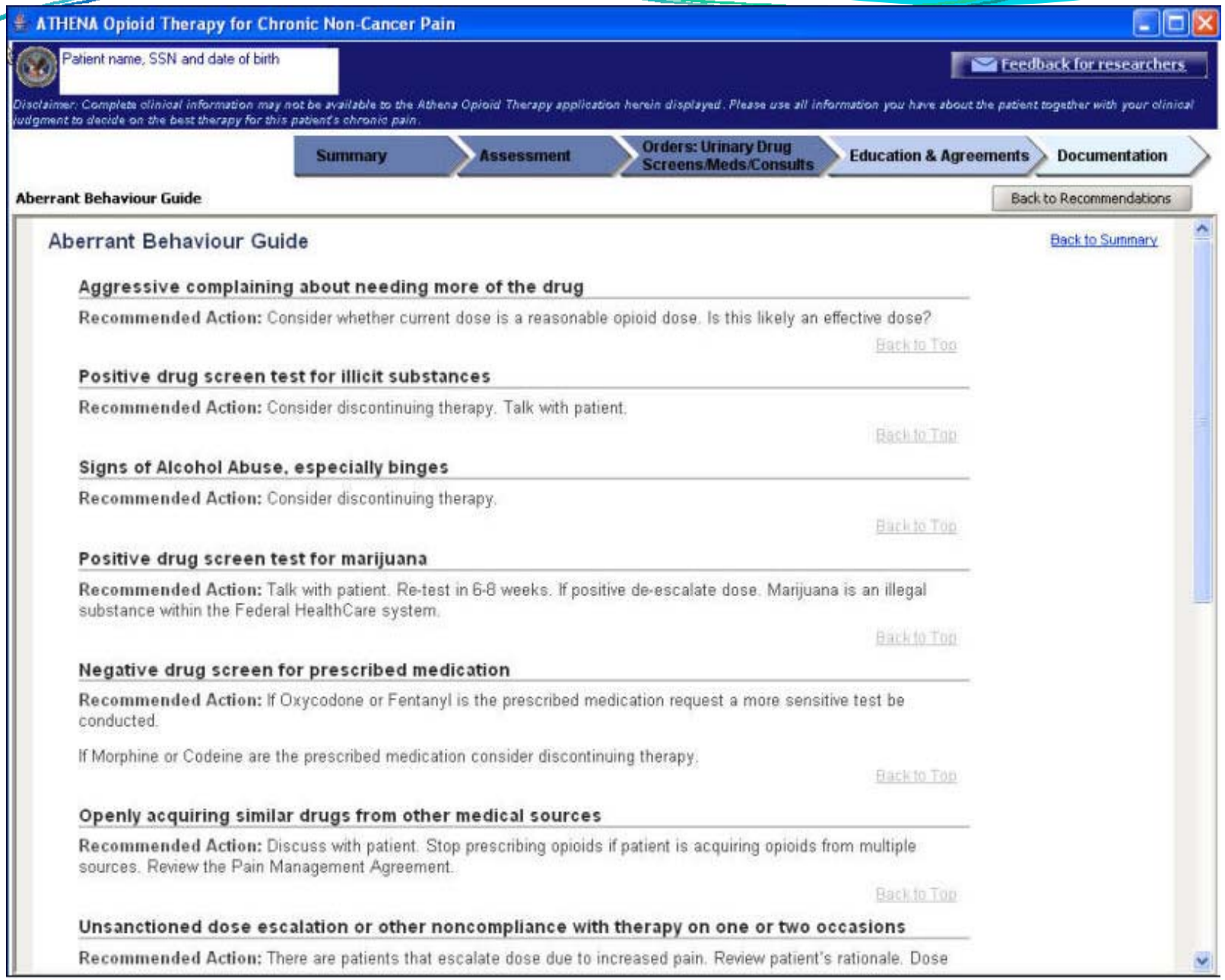
Pain assessment note in CPRS



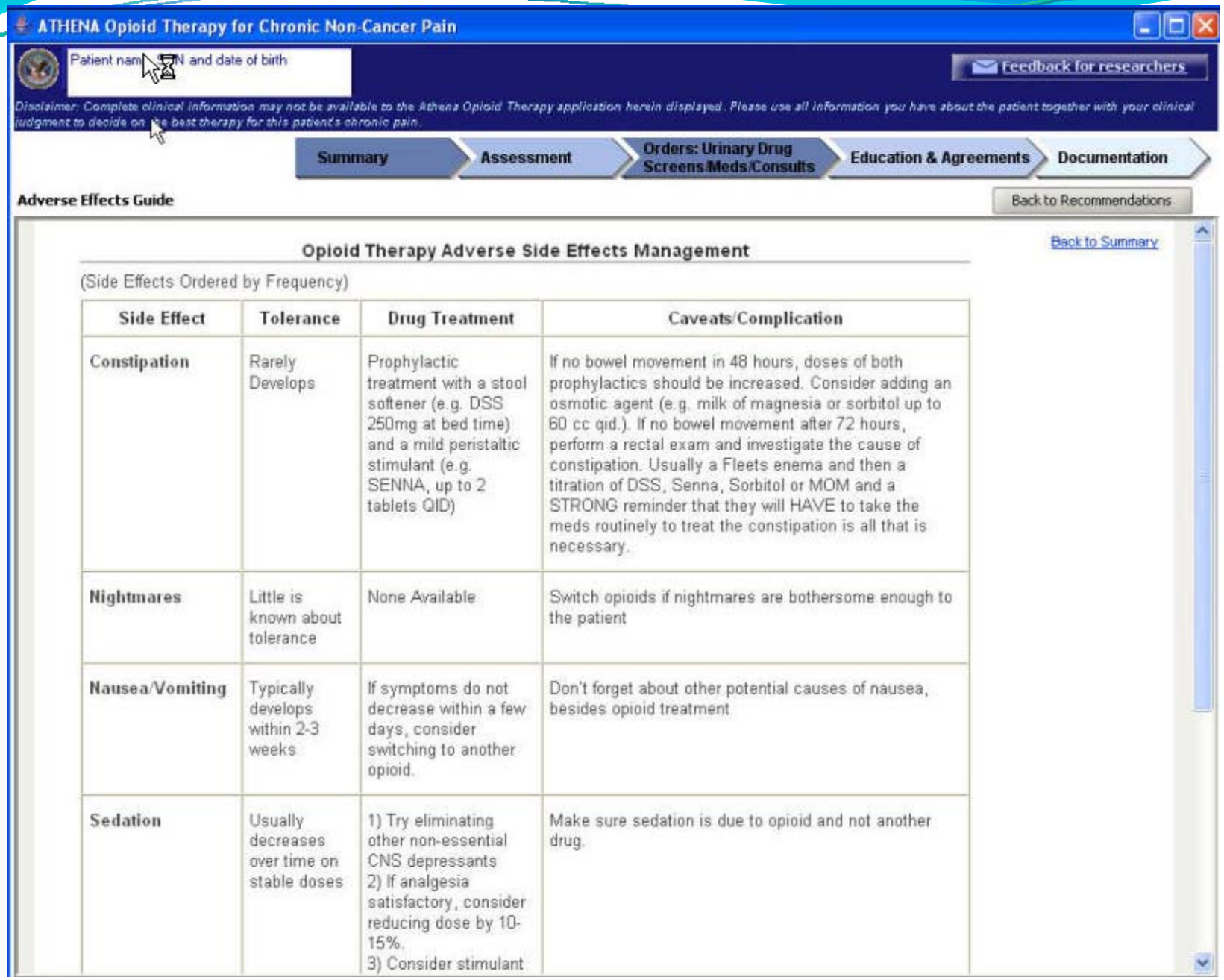
Conversion calculator tool



Aberrant Behavior Guide tool



Side effects management tool

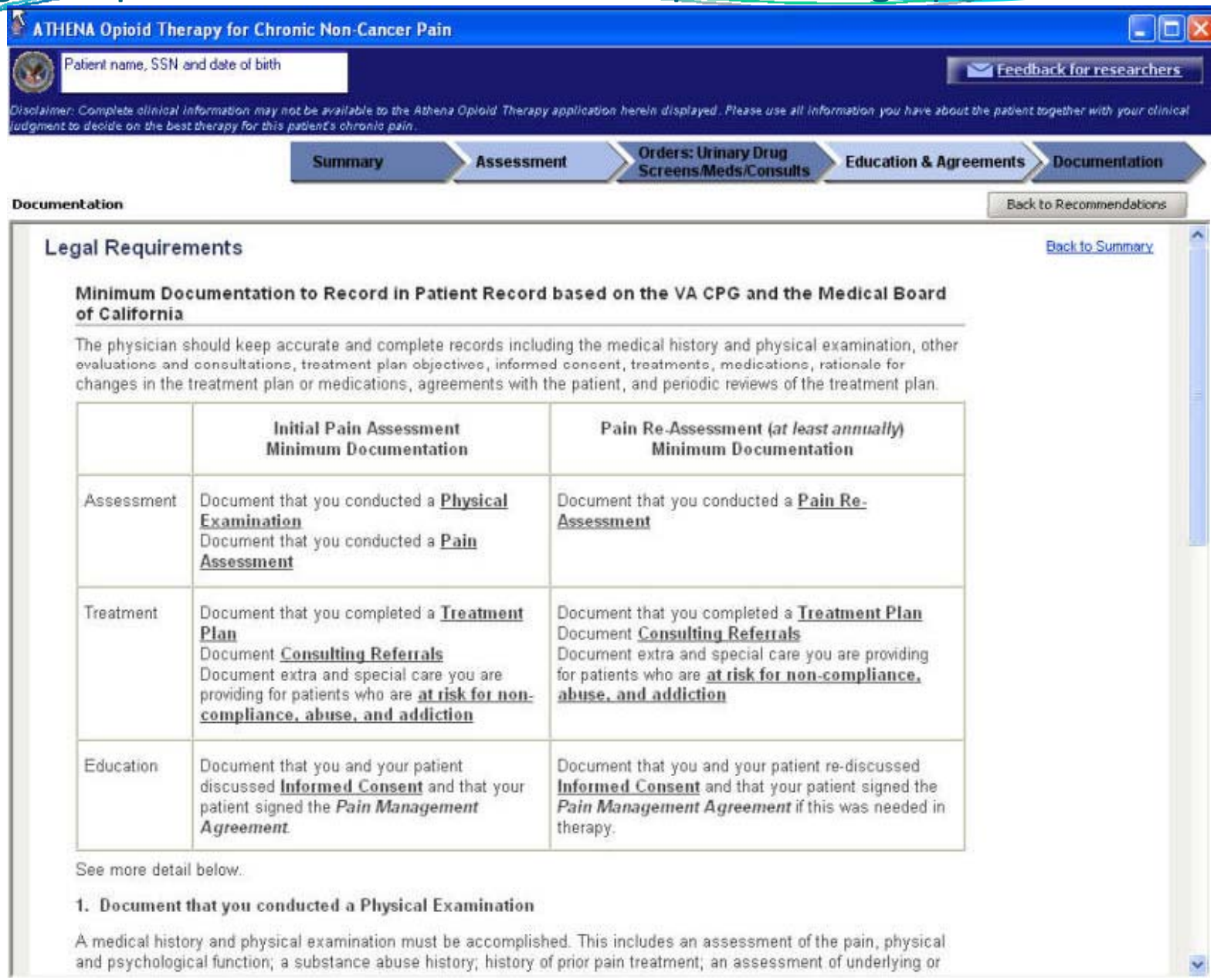


Opioid Therapy Adverse Side Effects Management

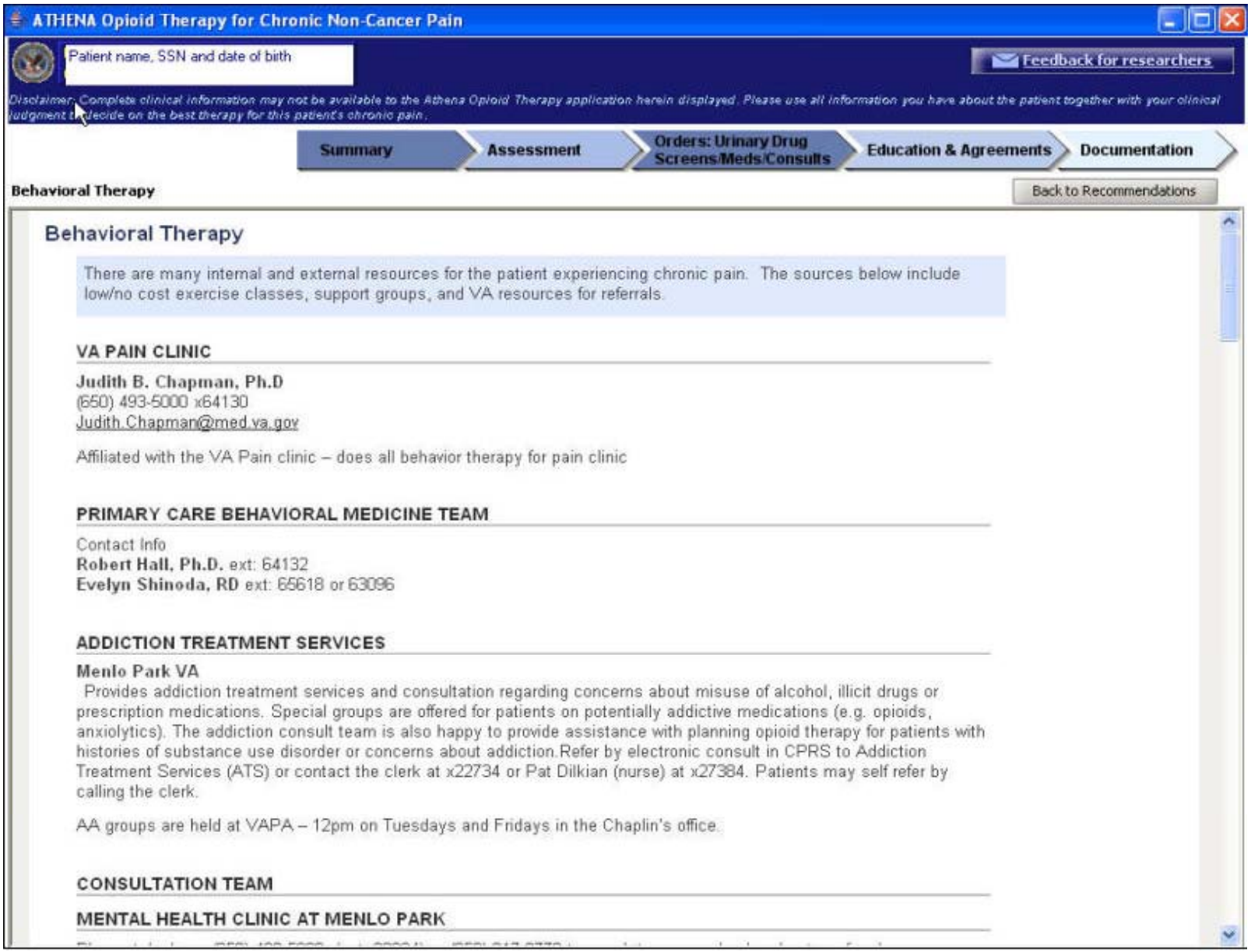
(Side Effects Ordered by Frequency)

Side Effect	Tolerance	Drug Treatment	Caveats/Complication
Constipation	Rarely Develops	Prophylactic treatment with a stool softener (e.g. DSS 250mg at bed time) and a mild peristaltic stimulant (e.g. SENNA, up to 2 tablets QID)	If no bowel movement in 48 hours, doses of both prophylactics should be increased. Consider adding an osmotic agent (e.g. milk of magnesia or sorbitol up to 60 cc qid.). If no bowel movement after 72 hours, perform a rectal exam and investigate the cause of constipation. Usually a Fleets enema and then a titration of DSS, Senna, Sorbitol or MOM and a STRONG reminder that they will HAVE to take the meds routinely to treat the constipation is all that is necessary.
Nightmares	Little is known about tolerance	None Available	Switch opioids if nightmares are bothersome enough to the patient
Nausea/Vomiting	Typically develops within 2-3 weeks	If symptoms do not decrease within a few days, consider switching to another opioid.	Don't forget about other potential causes of nausea, besides opioid treatment
Sedation	Usually decreases over time on stable doses	1) Try eliminating other non-essential CNS depressants 2) If analgesia satisfactory, consider reducing dose by 10-15%. 3) Consider stimulant	Make sure sedation is due to opioid and not another drug.

Legal requirements to be met when prescribing opioids



Behavioral therapy referrals within and outside VA

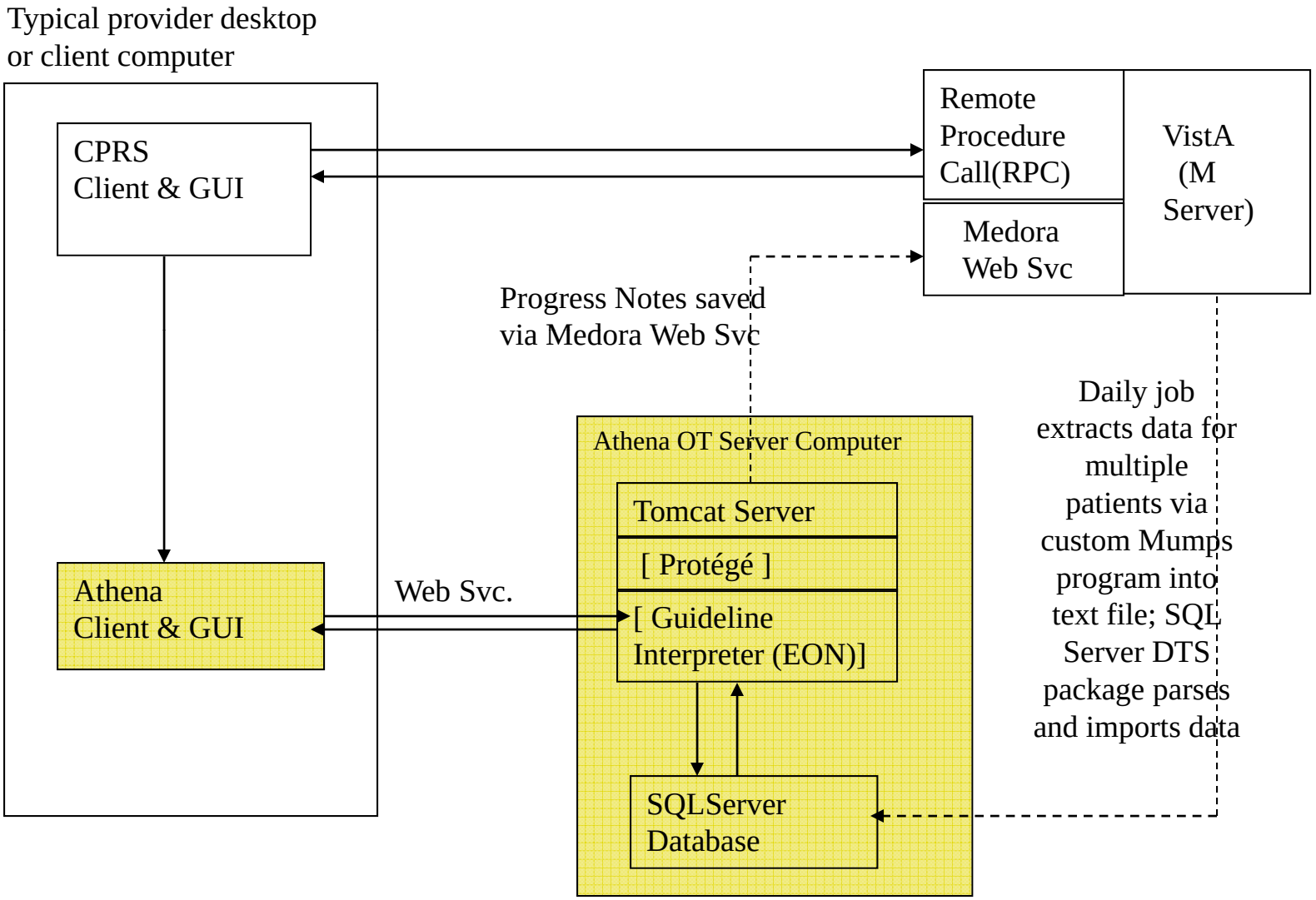


System Testing

- Rules Development
- Accuracy tests on sample patient cases
- Lab-based usability testing
- In-clinic pilot testing
  - Clinician feedback
  - Observation

- All provided feedback for system redesign and were conducted repeatedly as system underwent major modifications

Athena Opioid Therapy (OT) Architecture



ATHENA Opioid-Therapy (OT): Operations

Patient Data Extraction

- Patients in selected clinics with appointments in a 5-day window
- Every night a M(MUMPS) program extracts data into a text file which is then FTP'ed to the Athena OT server.
- SQL Server package imports this data into the predefined tables.

Convertor Program

- Transforms data into format ready for use by guideline interpreter (EON).

Precompute Program

- Invokes EON to calculate therapy recommendations from patient data, which are then stored as individual "precompute" files.

ATHENA-OT: Operations

OT Client (process/program running on provider desktop)
- **Listener:** starts in background when provider logs in to Windows Network
- **GUI**: displays recommendations to providers. This is hidden unless the listener decides to display it on the desktop screen.

CPRS: provider Log-in
- Listener captures Windows message and obtains provider ID.

CPRS: patient selection by provider
- Listener captures Windows message and obtains patient ID. Listener checks if patient and provider are in the database and if so,....

GUI
- Displays recommendations, relevant clinical data and checklist for opioid therapy, also enabling access to various tools, such as opioid conversion calculator, pain assessments (can be saved to VistA as an unsigned note), etc.

System Rated Highly Usable

Table 1: System Usability Scale:

	Round 1		Round 2	
	mean	**sd**	**Mean**	**sd**
1. I think that I would like to use this system frequently	2.75	0.50	3.25	0.96
2. I found the system unnecessarily complex	2.50	1.11	3.00	0.00
3. I thought the system was easy to use	3.00	0.76	3.25	0.50
4. I think that I would need the support of a technical person to be able to use this system	3.50	1.51	4.00	0.00
5. I found the various functions in this system were well integrated	2.50	0.82	3.00	0.82
6. I thought there was too much inconsistency in this system	3.25	0.98	3.75	0.50
7. I would imagine that most people would learn to use this system very quickly	3.25	0.69	3.00	0.00
8. I found the system very cumbersome to use	2.75	1.11	3.75	0.50
9. I felt very confident using the system.	3.00	0.53	3.25	0.50
10. I needed to learn a lot of things before I could get going with this system	3.25	1.27	3.75	0.50
Overall Score:	74.38		84	p=0.0167

Items scored 0-4. Total scores in the upper seventies to high eighties are defined as better products. This product would be in the top quartile of software products tested with the SUS. Mapping of scores to adjective descriptions: 73 = good, 85 = excellent.

Potential but not fully realized utility

- Main page viewed for approximately 30% of patients
  - Automatic pop-up for those on opioids plus
  - Click from stamp for patients not on opioids
- Additional screens rarely viewed
- Detailed recommendations rarely viewed
- Observations indicate that system fit well into most clinicians standard practice but was typically only glanced at briefly.

Issues

- Many guideline recommendations are vague and difficult to operationalize
  - Opioid prescribing is still an art, not a science
  - Meant we had to:
    - Leave out some guideline criteria that could not be reliably defined from records
    - Provide vague recommendations to providers
- Most guideline recommendations lay out elements of good clinical practice, but do not indicate the appropriate course of action
  - Tell you to get a good history, document, develop clear treatment plans, educate patient etc.
    - We addressed by providing checklist and tools
  - Do not tell you specifically when to initiate, titrate up or down, switch medications or discontinue
    - We addressed by providing detailed OPTIONS

Issues

- Predictors of prescription opioid misuse are neither sensitive nor specific
  - Try to encourage dialogue and monitoring
  - Underuse may be just as common as overuse in at risk populations
- Good practice and use of our DSS may increase rather than decrease the amount of time required for pain management by the PCP
  - Brings up other problems that PCPs are also not comfortable treating (e.g. substance use disorders, mental health problems)
- Opioid prescribing decisions may require communication among the patient, primary care providers, mental health professionals, rehabilitation specialists, other specialists, nurses, and family members
  - How do you insure or facilitate this communication?

Current Status

- OI&T recently banned installation of any new Class III software.
- We received a Greenfield Innovation Award to help bring existing ATHENA systems (Opioid Therapy and Hypertension) through the Class I software approval process. We are creating contracts to get this work completed.
- Study team is analyzing medical record data from providers participating in the in-clinic trial before versus during system implementation
  - develop outcome measures and determine effect sizes for change in clinician behavior for a future clinical trial

Questions?

Identifying High Risk Patients

- Existing screeners include:
- SOAPP, ORT, assess for risk of opioid misuse
- COMM and PDUQ assess for current opioid misuse behaviors
- These screeners emphasize personal and family substance use history, addiction behavior, trauma history, age, and psychological disorders (i.e. OCD, ADHD, schizophrenia, bipolar and depression)
- Screeners are only moderately predictive, may bring up uncomfortable content or stigmatize patients, and do not assess for information with additional clinical utility

New Studies on Predictors of Opioid Misuse
Study 1: POPS

- Led by Ian Carroll and Sean Mackey at Stanford
- Assessed patients before entering surgery
  - Followed patients daily until they reported no opioid use and no pain
- Looked at predictors of delayed opioid discontinuation

Results

- On-going pain predicted only a bit more than 50% of variability in time to opioid cessation
- Personal or family history of substance or alcohol use disorders did not predict time to opioid cessation.
- After controlling for pain, Self-Assessed Vulnerability to Opioid Addiction (1 item) was a significant and better predictor of time to opioid cessation than the SOAPP

- Even mild depression significantly increased time to opioid cessation after controlling for pain.

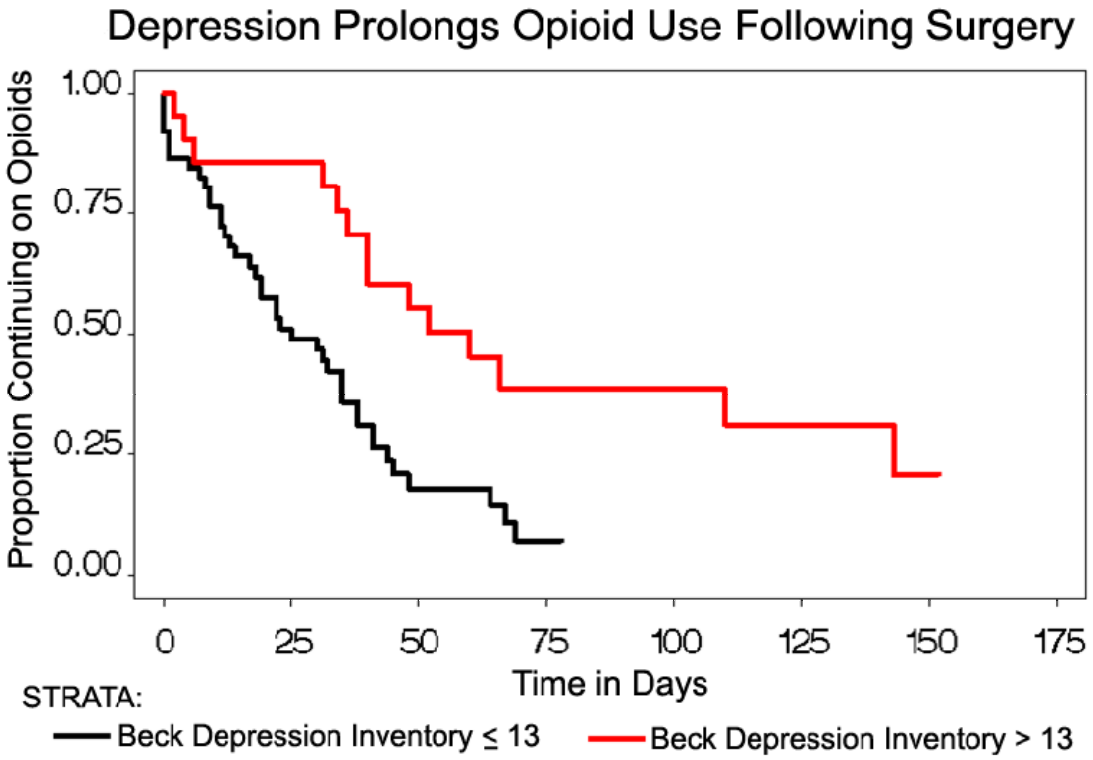


Figure C2: Elevated levels of depression measured preoperatively by the Beck Depression Inventory (BDI) predict markedly more persistent prescription opioid use following surgery. 21% of patients with depression (BDI>13) continue taking opioids 150 days following surgery compared to 7% of patients without depression (BDI≤13). (Log Rank p<.003)

Study 2: CRAVE

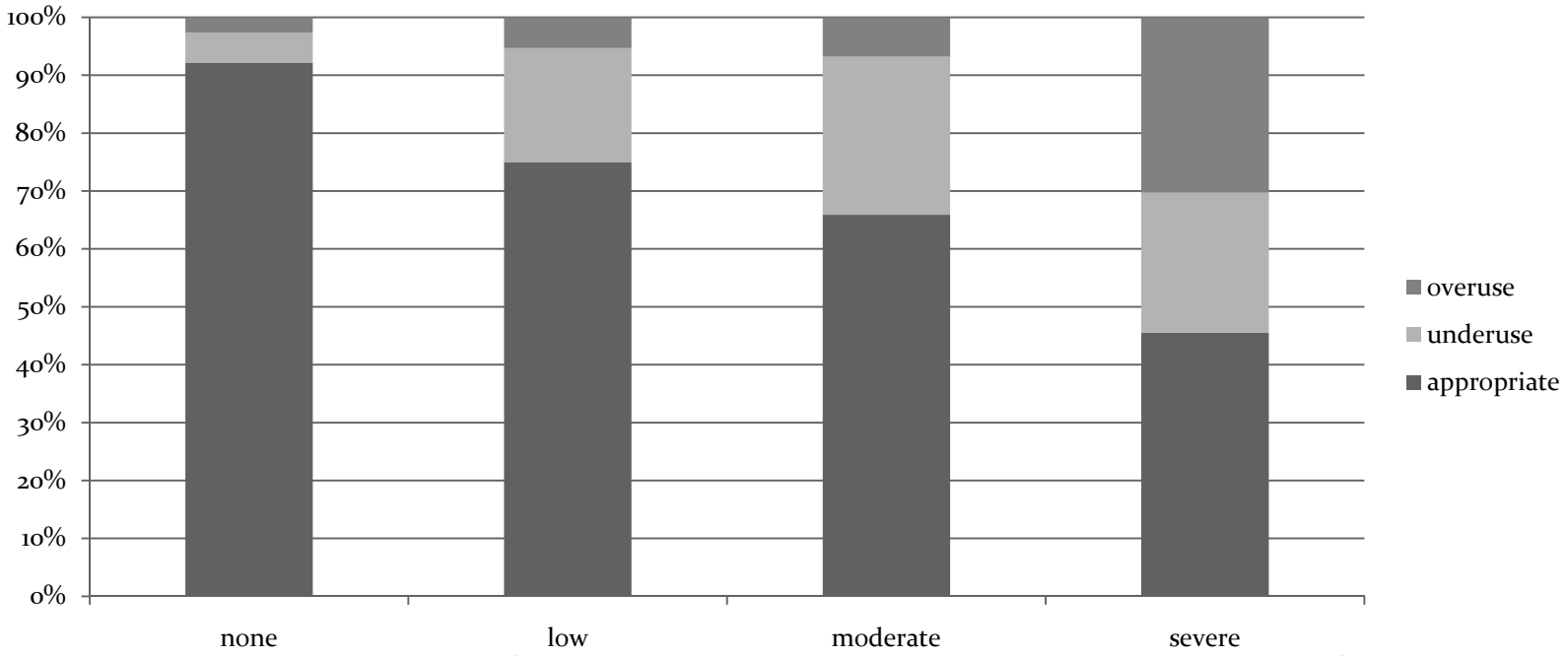
- Led by Jodie Trafton and Eleanor Lewis
- Interviewed a convenience sample of 200 VA patients who had received opioid prescriptions in the last year about their experiences with the medication, including risks, behaviors and signs of misuse.
- Sample was enriched for persons with medication misuse risk.

Medication Non-adherence

- Under-use (i.e. non-use of Rxed opioids despite on-going pain) was common.
- Under-using patients often did not discontinue prescriptions for opioids, even though they did not take the medications.
- Patients who spontaneously reported disliking taking medications during the interview were highly likely to under use their opioids.

Somatization and Misuse

- Somatization, conversion of anxiety into physical symptoms, was measured using the PHQ-15. Somatization was associated with over and under use of opioid medications



(Cuccaire, Oser, Lewis, Trafton, in prep)

- Examined similar concepts (i.e. Depression and opioid side-effects) that were also associated with opioid non-adherence
- Somatization mediated the relationship between:
  - depression and opioid prescription non-adherence
  - side-effects and opioid prescription non-adherence
- Suggests that:
  - Depression leads to non-adherence primarily by increasing physical symptoms
  - Side-effects lead to non-adherence when coupled with health anxiety

Conclusions

- Asking simple questions and conducting pain-relevant mental health assessments may help us identify patients at higher risk of opioid misuse for closer follow-up.
  - Ask patients if they want medication-based pain management before prescribing. Ask them if they are taking their medication before continuing Rx.
  - Ask patients if they think they are at high risk of developing opioid addiction problems before Rx.
  - Screen for somatization and depression problems
- Provides more clinically relevant information. Avoids potentially stigmatizing or uncomfortable questions included in current opioid misuse screens.

Acknowledgements

- ATHENA-Opioid Therapy was designed and tested by Susana Martins, Dan Wang, Martha Michel, Naquell Johnson, Denise Daniels, Mary Goldstein, and Samson Tu
- POPS was designed and conducted by Ian Carroll, Sean Mackey, Keith Humphreys, Jarred Younger, Peter Barelka, Walter Cannon, Charlie Wang et al.
- CRAVE was conducted and analyzed by Eleanor Lewis, Ann Combs, Susana Martins, Mike Cuccaire, and Megan Oser

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