

Evaluation in Implementation

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Formative Evaluation

- **Formative evaluation** is a type of evaluation which has the purpose of improving programs or interventions as they are being designed or implemented.
- It is contrasted with **Summative evaluation** which evaluates the efficacy or outcomes of an intervention to judge the intervention after it is complete.
- Formative evaluation may use similar methods to summative evaluation (e.g. data collection, data analysis, comparison groups) but is used to provide feedback during the intervention to modify the intervention or implementation strategy.

Formative Evaluation is not designed to test efficacy

- Typically no randomized comparison group
- Power less relevant, consider precision instead
- Intervention changes over time
- Goal is to provide feedback on progress and remaining problems

Process Measures

- Intervention specific process measures
 - Is the intervention being done?
 - How often or consistently is it being conducted?
 - How well is it being conducted?
- Measure the quantity and quality of implementation

Example: Facility level guideline adherence metrics

- Developing administrative data based metrics to assess facility level adherence with the Chronic Opioid Therapy Clinical Practice Guideline VA/DOD guideline
 - Team includes guideline authors, Natl. Pain Management leads, and program evaluators
 - Focus on:
 - Providing feedback on organizational priorities and known practice gaps
 - Tracking processes thought to be key for safety and efficacy
 - Using broad definitions to capture all possible care, thus catching areas in which providers couldn't possibly be following specific guideline recommendations
 - E.g. count any contact with VA as potential follow-up

Example Guideline Adherence Metrics

- Monitoring and follow-up
 - % of new OT patients who have another clinical encounter within the recommended time frame for follow-up
- Side-effect Management
 - % of OT patients who receive a bowel regimen
- Safety
 - % of new OT patients who are started on an absolutely contraindicated formulation (e.g. high-dose long-acting)
 - % of OT patients with a concurrent Rx of a risky sedative
 - % of OT patients with concurrent Rx of > 4mg acetaminophen
- Misuse Risk
 - % of OT patients with a SUD diagnosis who receive SUD treatment and at least 1 UDS for every X days of opioid supply
- Use of other pain management options
 - % of patients who receive
 - Other pain pharmacotherapy
 - Mental or behavioral health treatments
 - Physical therapy or active rehabilitative activities (e.g. exercise, recreation therapy)
 - Complementary and Alternative medicine

Example 2: ATHENA-Opioid Therapy Decision Support System

- Single clinic formative pilot implementation of the computerized decision support system
 - System designed in collaboration with a primary care clinic to provide patient specific information and guideline-based recommendations for opioid prescribing

ATHENA Opioid Therapy for Chronic Non-Cancer Pain

Feedback for researchers

Disclaimer: Complete clinical information may not be available to the Athena Opioid Therapy application herein displayed. Please use 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 Pain Back to Recommendations

Cautions

- COPD
- Current or past drug-induced mental disorder
- Depression
- Age >=65 years

Patient data

Drug	Daily Dose	Start	End
hydrocodone/a...	20.0		
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

Tools as drop down menus

Checklist

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
- Opioids are respiratory depressants and should not be used in the presence of hypercapnia 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.**

Misuse Warning

- Opioids and hypoxia
- Opioids and respiratory depression

Clinical Alerts

- Slow in

Patient specific guideline- based recommendations for opioid therapy, alerts if patient is high risk for misuse and more!

System Testing

- Rules Development
 - Does the system to be implemented really match the intent of the clinical practice guidelines?
- Accuracy tests on sample patient cases
 - When used, does the intervention guide practice in the right direction?
- Lab-based usability testing
 - Is the intervention doable in regular clinical practice in the clinic? Is it easy to use?
- In-clinic pilot testing including Clinician feedback & Observation
 - How does the intervention actually work in clinical practice? How could it be improved? What practical problems or design issues limit its impact?
- All provided feedback for system redesign and were conducted repeatedly as system underwent major modifications

Measurement of system use

Table 2 Clinician exposure to the ATHENA Opioid Therapy system based on logged data

	Phase 1 (137 days)		Phase 2 (101 days)			Total
	Displays (N)	Unique Patients (N)	Displays (N)	Unique Patients (N)	Displays (N)	Unique Patients (N)
Stamp display*	2,274	720	3,188	1,035	5,462	1,482
Clicked on stamp for Full display	67	64	50	50	117	113
Full display†	430	155	516	180	946	285

* Stamp display appeared when patient did not have an active prescription for an opioid drug.

† Full display appeared when patient had an active prescription for an opioid drug.

Is the system useable?

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

Patient Outcome Measures

Goals:

- Clinical Use – Assessment-based care
 - Assess current patient status and needs to design and adjust treatment planning
 - Monitor change to assess success of treatments
 - Key recommended opioid prescribing practice
- Assessment of clinical changes in retained patients
 - Monitor effects of treatment among those that stay in care
 - Assess impact of interventions on patients in care
- Assessment of program or practice effectiveness
 - Requires intent to treat assessment/follow-up of patients who discontinue treatment or leave care setting

Pain Outcome Measures

- Effectiveness
 - 4 A's:
 - Analgesia,
 - Activities of daily living,
 - Adverse effects,
 - Aberrant drug taking
- Safety
 - Rates of overdose, accidents, emergency department visits, inpatient admissions, side-effects

Example: Prescription Opioid Documentation System (PODS)

- Computer assisted assessment and documentation system
 - Brief Pain Inventory
 - Functional Impairment
 - Analgesic side effects
 - Current Opioid Misuse Measure
 - Substance use disorder, depression, PTSD, panic disorder, GAD
 - Randomized UDS requests
 - Prescription History
- Used clinically to organize information to guide treatment planning and risk stratification
- Saved in an Access database which allows for analysis of program level trends in patient characteristics, treatment use, and outcomes over time
- Meets goals 1 and 2: clinical use and assessment of outcomes in retained patients
- Wilsey BL, Fishman SM, Casamalhuapa BS, and Singh N. (2010) Computerized progress notes for chronic pain patients receiving opioids; the Prescription Opioid Documentation System (PODS). *Pain Medicine* 11(11): 1707-1717.

Examples: TIDES collaborative care for depression

- To assess the impact of the TIDES intervention on patient care:
 - Established registries of patients referred for collaborative care in the 7 demonstration clinics
 - Recorded all patient contacts with the clinic
 - Assessed and recorded depression symptoms with the PHQ-9
 - Created quarterly summary reports on referrals, contacts, and patient symptoms at the local, regional and national level which were distributed to regional clinical managers to guide on-going QI

Risk of unintended consequences

- People naturally work to the test
 - If it is easier to improve your score by making a useless or detrimental practice change than by making the desired practice change, the measure may drive unintended consequences
- Example: If you measure mean outcomes of patients at the clinic as an assessment of clinic performance, the easiest way to show improvement is to drive your sickest patients away
- Example: If you have trouble meeting a claims based process measure, you could change your coding practices
- Example: If a process measure assesses whether you treated diagnosed patients, you could stop diagnosing patients

Ways to address

- Improving data collection
 - Providing guidance and training in assessment or coding
- Testing validity of measures
 - Chart review
 - Independent patient assessment
- On-going redesign of evaluation
 - Revise assessments and measures to refocus intervention, improve measures or avoid consequences
- Mixed methods
 - Include discussion, site visits, and facilitator/barrier assessment with intervention sites regarding practices and face-validity of measures
- Multiple measures
 - Measure the same thing in multiple ways, compare findings and address inconsistencies
- Composite measures
 - Merge multiple measures into composites to make measure more robust and more difficult to “cheat”

Fostering a collaborative evaluation and quality improvement culture

- Eliminate threat of punishment
 - Reward identification of problems and suggestions for solutions
- Focus on rewarding improvement
- Leadership support is key
 - Provide time and resources for QI and evaluation
- Include the evaluated in the design, redesign, and interpretation of the evaluation
 - Provide feedback in a clear and constructive manner
- Consider methods to maintain gains