| | Populations | | Knowledge/Skills/Process |
|---|---|---|---|
| | **Folks with Pain** | **Non-patients (abuse, addiction, etc., kids)** | **Healthcare Providers** |
| • Reducing fatal prescription opioid overdose | **"Do high-dose/potent ER opioids get prescribed to opioid naïve patients?"**<br>- (Medicaid, claims data, PMP)+case review, EMR<br>**"How many decedents had a prescription?"**<br>- PMP +(vital statistics, ME). | **"How many decedents had a prescription?"**<br>- PMP +(vital statistics, ME)<br>**"Changes in distribution of pediatric overdoses?"**<br>- vital stats, ME, poison centers, etc. | **"Changes in knowledge about titration, prescribing methods, etc.?"** |
| • Reducing non-fatal prescription opioid overdose | | ED Visits, poison centers, survey of active users, naloxone programs | See above |
| • Ensure adequate access to quality pain treatment | **"Do shifts in ER to IR act as surrogate to pain relief?"**<br>- Sales data<br>- Lawsuits for docs not treating pain<br>- Cohort<br>- Use of online pain resources<br>- Online pain communities<br>- Surveys of pain patients<br>**"Are patients properly consented/informed of the benefits *and* risks of these medications?"**<br>**"Are treatment agreements being used? How are they received?"** | - Online discussion boards | **"How many Rx'ers get training?"**<br>- Traffic to professional pain skills websites<br>**"How many prescribers get certified, and rate?"**<br>- Changes in trajectory of individual prescribing from PMPs and commercial vendors<br>**"Do physicians use screening tools?"** |
| • Reducing addiction to prescription opioids | | **"What are the number of treatment admissions?"**<br>- Detox in hospitals, bup clinics, ASI-MV, ED admissions, qualitative sources, out-of-treatment drug user surveys<br>**"What other drugs are used instead of ER opioids?"**<br>- longitudinal follow-up of | |

| | | | |
|---|---|---|---|
| | | individuals entering treatment, NESARC, total drug seizures<br>**"What are the changes in access to and satisfaction with ER opioids?"**<br>- internet discussions, focus groups | |
| • Reducing unintended, unanticipated consequences | **"Does diversion of ER opioids increase among pain patients to compensate for decreased availability/psuedoaddiction?"**<br>**"Does the proportion of pain+addiction admissions to drug treatment centers change? Source of drugs in this population?"**<br>- Treatment admissions to substance use tx<br>**"Are adherent, well-managed patients switched to IR (when they should be continued on ER)?"**<br>- claims data, physician surveys<br>**"Do GI/hepat. consequences increase, secondary to IR combo opioid exposure?"**<br>**- poison centers, AERS**<br>**"Increase in crime for ER opioids?"**<br>- DEA form 106, UCR<br>**"Are patients refusing to take opioids, even when prescribed?"**<br>- registration completion failures | **"Does heroin use increase?"**<br>**"Are more bioavailable routes of administration evident?"**<br>- SEPs, internet<br>**"Do polysubstance ODs increase (heroin+Rx opioid)?"**<br>- vital statistics | **"Number of referrals and waiting times to specialty pain practices?"**<br>- claims/financial, prescriber surveys |

Early on, we will be looking at process measures. Later we will have more data on time trends.

Baseline data can be first year of program.

Many, many, many other contributing factors…

Formulation-specific considerations

Hard outcomes: mortality

- Patients
    - Opioid-naïve
- Non-patient pain
    -
- Accidental – pediatrics
- At-risk populations (occasional users, college students)
- Substance use disorders/addiction
- Reduction in negative effects
- Unintended consequences
    - Mortality
- Cost-Benefit effects
    - Are the costs passed along to the patients?
    - Are there societal cost changes outside the healthcare setting?
    - What are the costs to the substance use treatment system?
        - Is there a decrease in quality with increase in volume?
    - What are the costs of more pain treatment?

Impact of REMS on psych and mental health
Impact on substance use disorder treatment
Impact on pipeline products
Cost of medications to patients
Burdens at the clinical interface
Erosion of trust between patients and doctors (pain, addiction)
Stigmatization of a class of medicines
Short-acting vs. long-acting/extended-release, reversing advances in pain control
Tamper resistant formulations
Generic vs. branded
Program commensurate with the risks of the drug
Outcomes for REMS vs. other interventions
Bureaucracy vs. benefits
Knowledge of clinicians about opioid prescribing