FDA U.S. FOOD & DRUG ADMINISTRATION

OPIOID SYSTEMS MODEL

Building informed policy options for the evolving crisis

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The opioid crisis is one the most complex public health problems of the 21st century. To improve understanding of and reaction to the crisis, FDA is developing a U.S. population-level system dynamics model. The model uses real data from various sources and parts of the health care system and allows for flexibility in simulating impacts of policy levers.

> " A fair comparison of the effectiveness of interventions… requires a **true systems model**, not just simple statistics. (NASEM, 2017) "

The model reflects lived experiences…

Every individual's journey with opioids is unique. The model represents these unique journeys as paths, or trajectories, through various states of opioid interaction. Using available data, the model examines different possible trajectories from good health, to therapeutic opioid use, to development of a use disorder. Given the limitations of available data, the model allows users to vary assumptions and test sensitivity. Feedback loops, time delays and behavioral variables help reflect the complexity of the opioid system. FDA has calibrated the model to current and historical data.

… and projects downstream effects of policies.

Using the model, FDA can explore how policy interventions may alter trajectories and affect public health outcomes, such as overdose and heroin use. Data inputs for these policy levers can be varied to allow for uncertainties in trajectories when simulating policy options. For example, the model can estimate changes in heroin use resulting from a specified decrease in the number of individuals with opioid prescriptions. Based on educated assumptions regarding the effects of an intervention, the model helps answer "what if" questions about possible scenarios; it does not provide guidance on how best to implement policies. FDA is partnering with other agencies and researchers to incorporate the model's insights with other efforts.

The model will help FDA:

- Identify high-impact interventions
- Assess unanticipated consequences
- Identify needs for further research

What's next?

FDA posted a white paper introducing the model. FDA is also preparing a publication including model documentation and initial policy insights. The model will be developed into an interactive policy tool with an associated analysis service. FDA has also initiated additional research to enhance and expand the model.

WHY SYSTEMS MODELING?

TRANSPARENT
Decision-makers can view model architecture and run specific simulations.

ADAPTABLE
The model can be adjusted to reflect new conditions and data.

CALIBRATED
Real data inputs produce quantified results calibrated to reality.