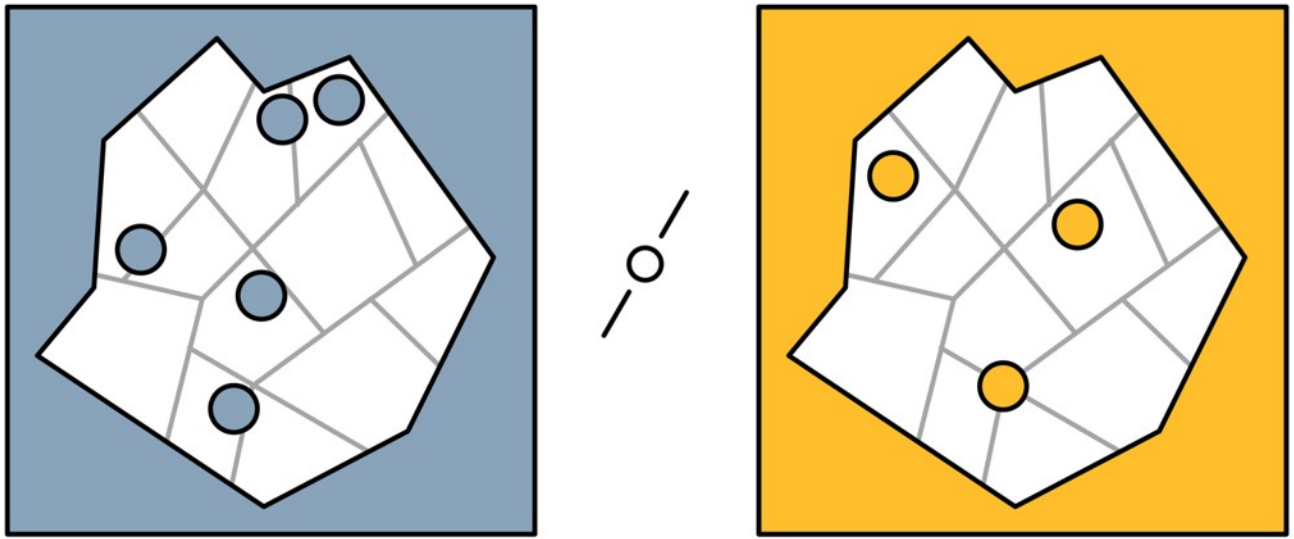
Overview of Evaluating ADFs in the Community



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Opioid Data Lab
University of North Carolina at Chapel Hill

FDA Advisory Committee Meeting

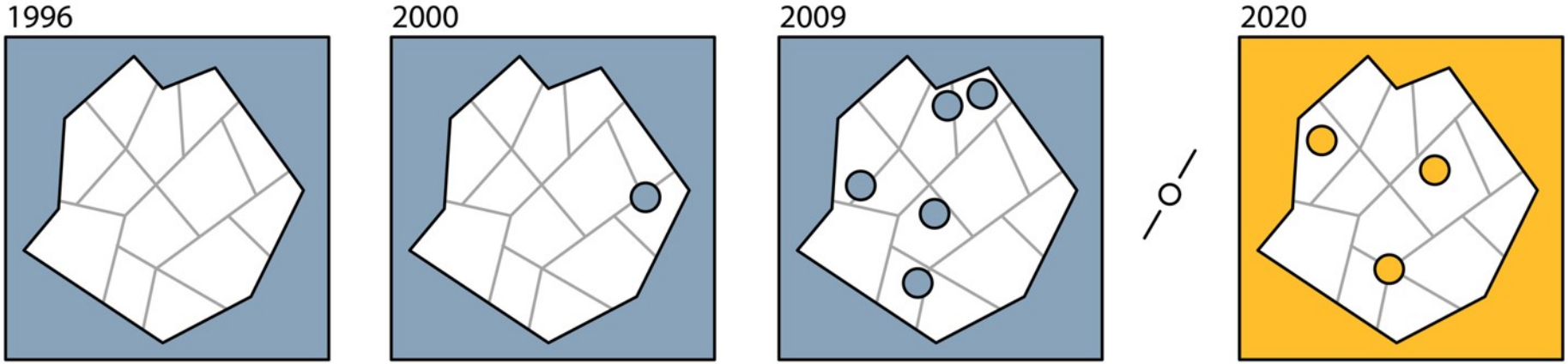
September 10, 2020

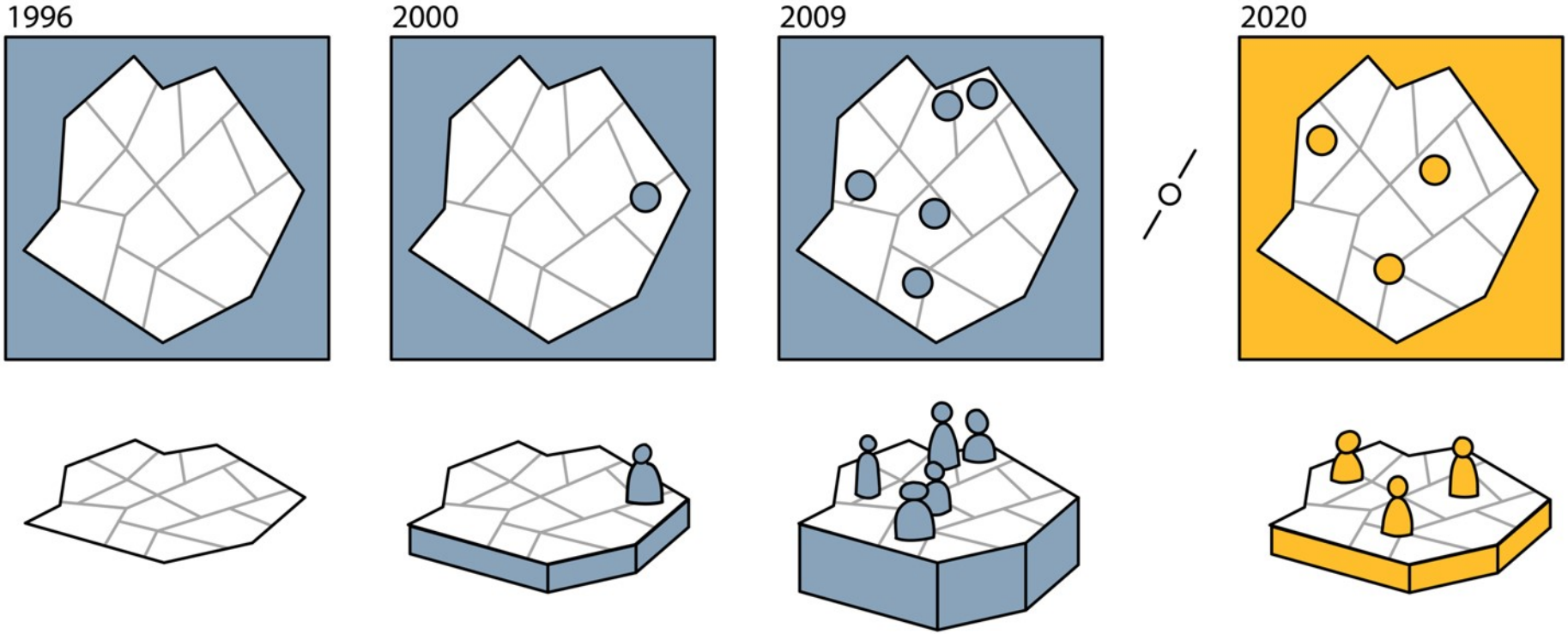
Disclosures

Dr. Dasgupta is contracted by the US Food and Drug Administration for epidemiologic methods research on abuse deterrent opioids.

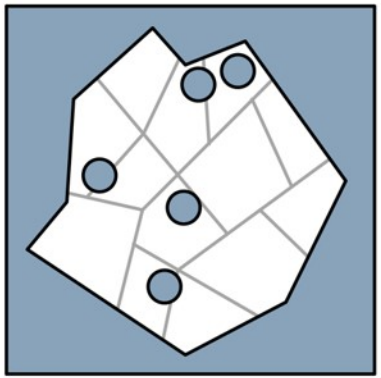
Dr. Dasgupta is funded by the US Centers for Disease Control and Prevention for overdose prevention evaluation research.

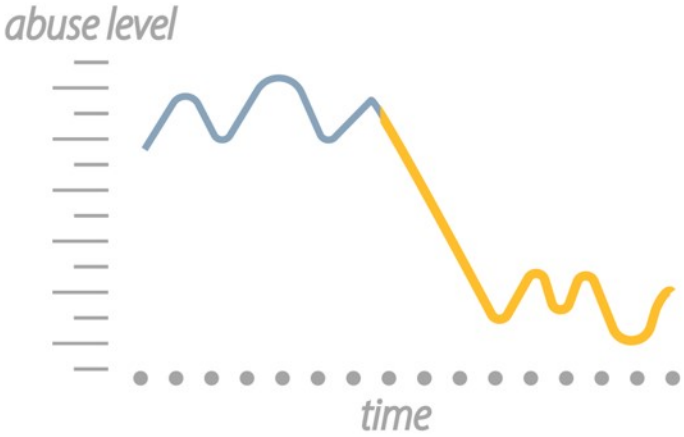
Dr. Dasgupta is an epidemiologic methods consultant to the RADARS System.


1996
2000
2009
2020

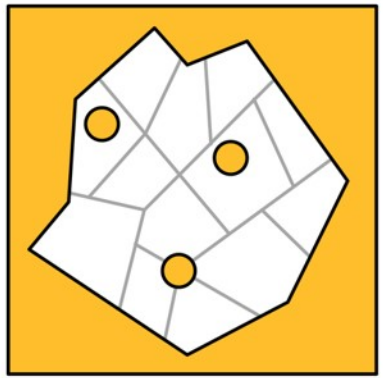

1996
2000
2009
2020

Original



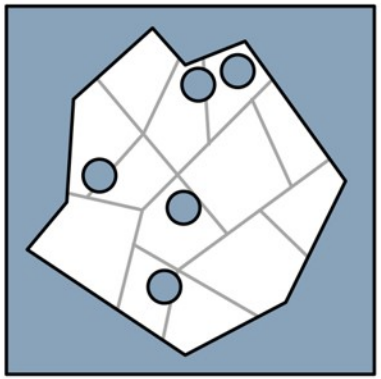


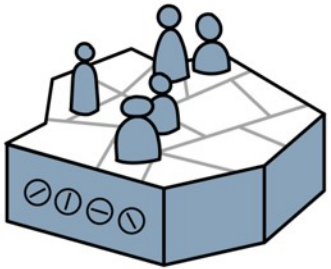
Reformulation

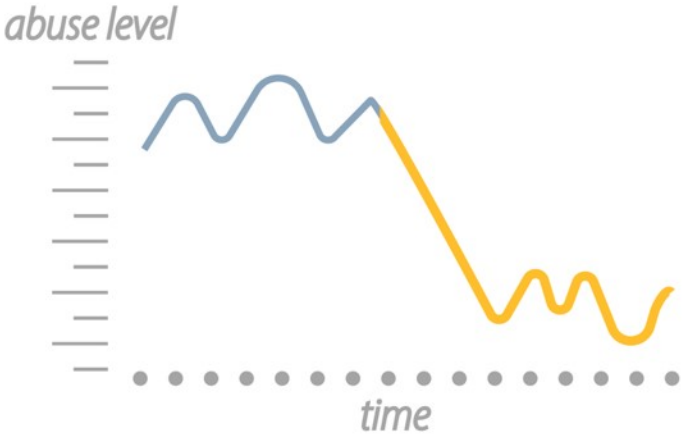


population rate

Original

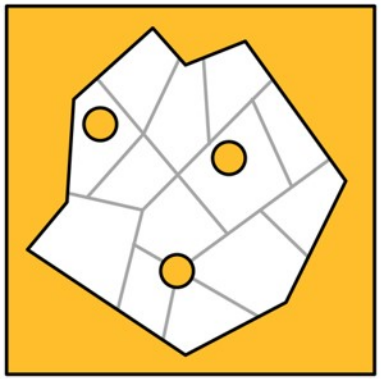




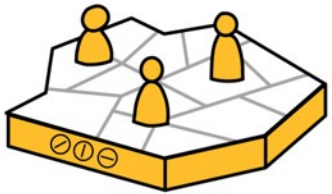


statistical model

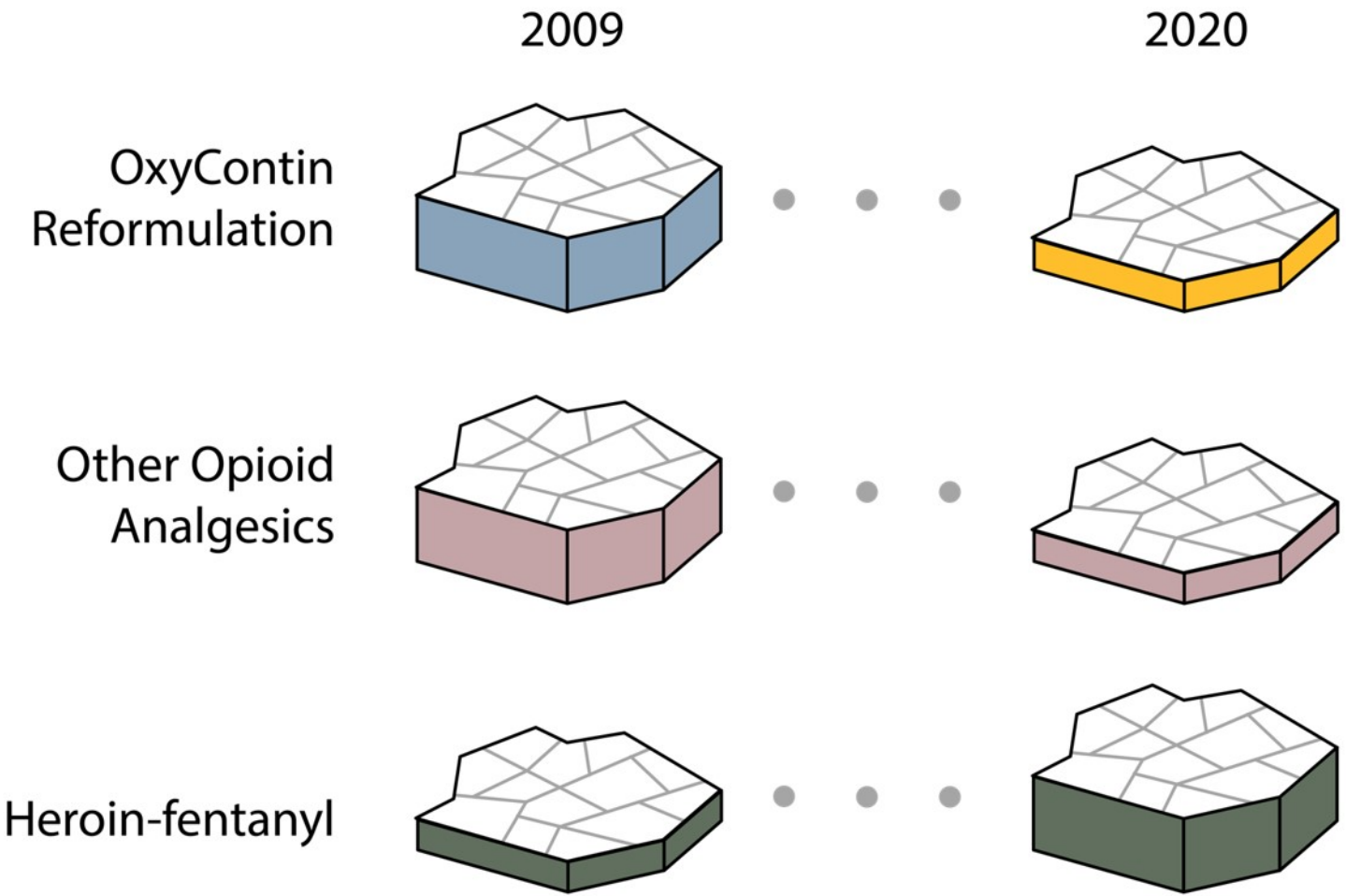
Reformulation



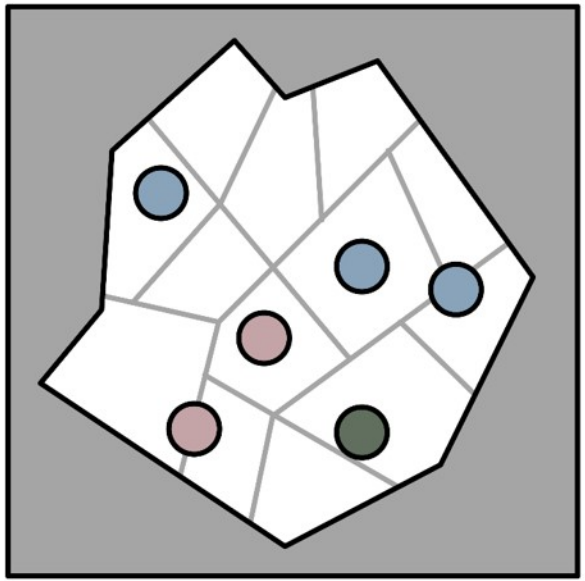
population rate



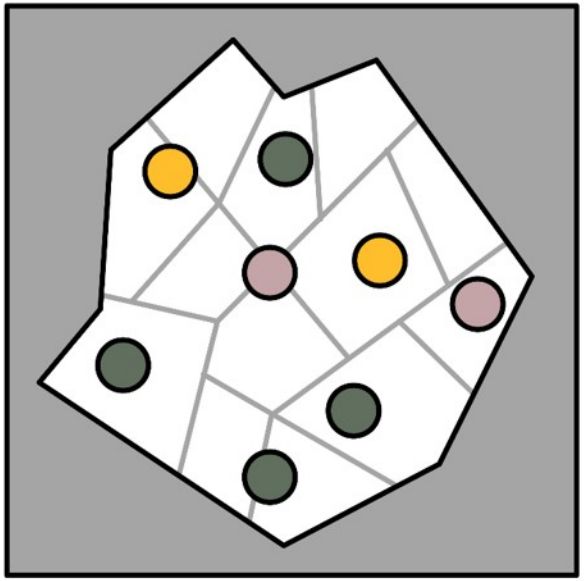
dispensing rate

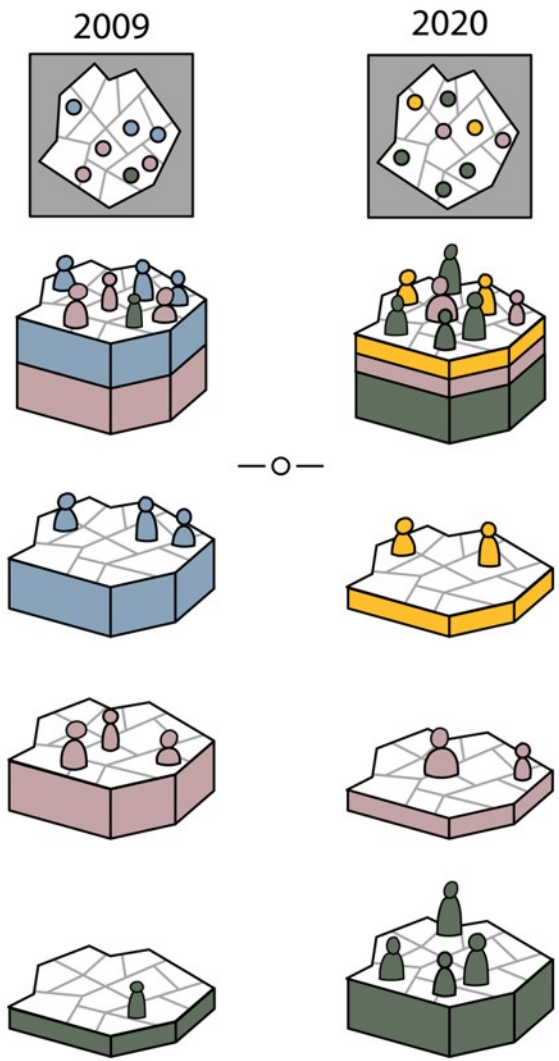

2009
2020
OxyContin Reformulation
Other Opioid Analgesics
Heroin-fentanyl

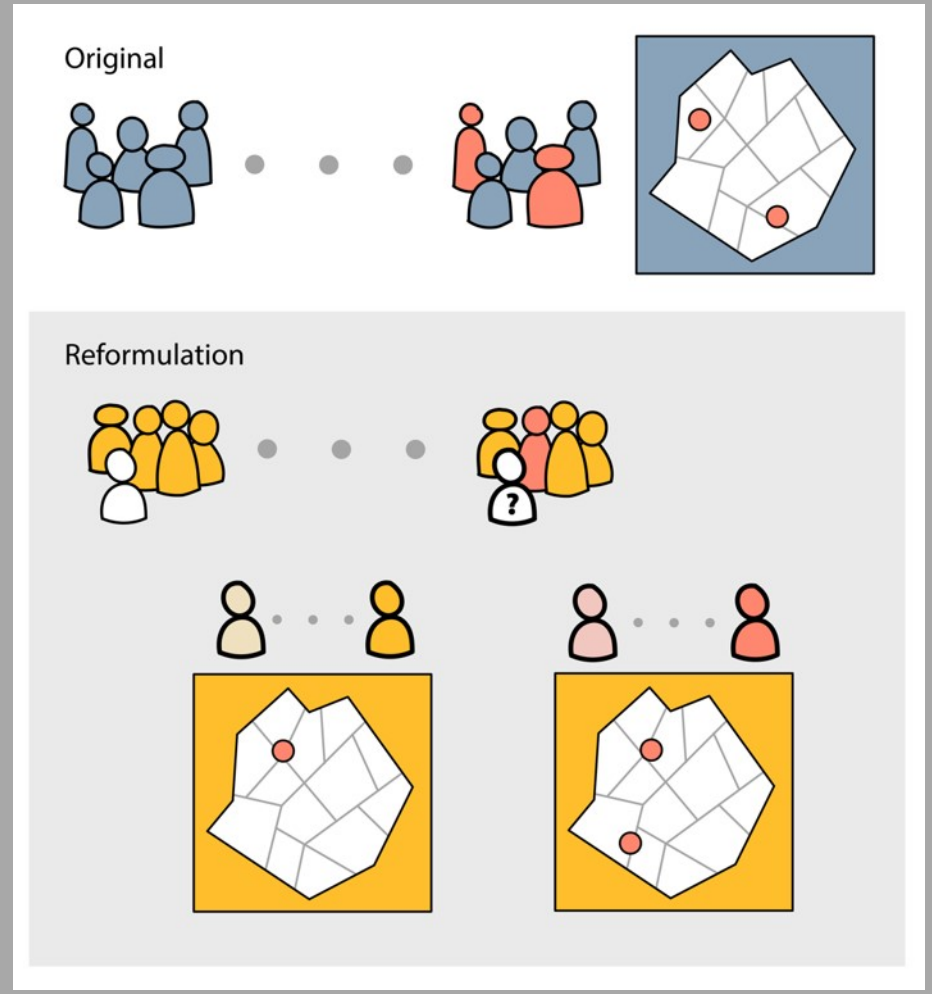
2009



2020



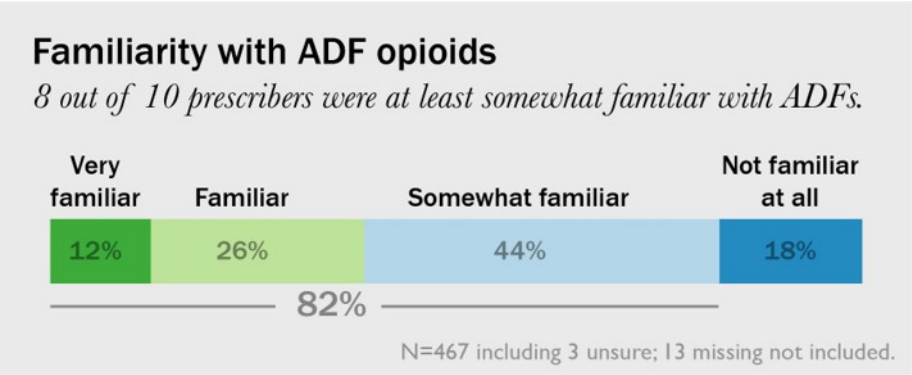

2009
2020

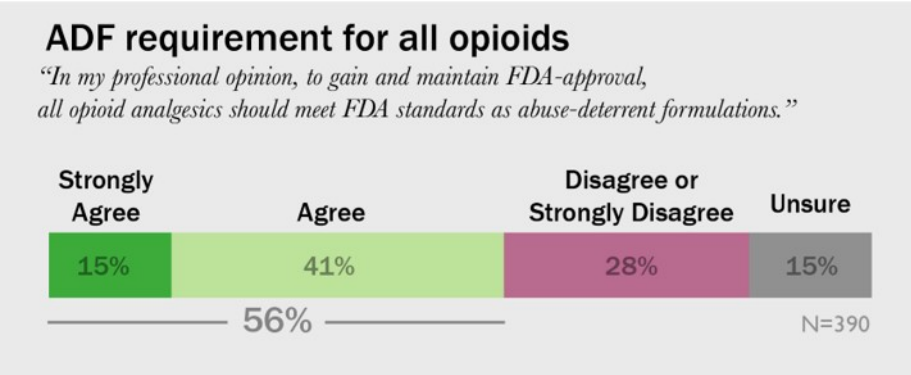

Original
Reformulation
?

Perceptions that influence ADF prescribing

Methods

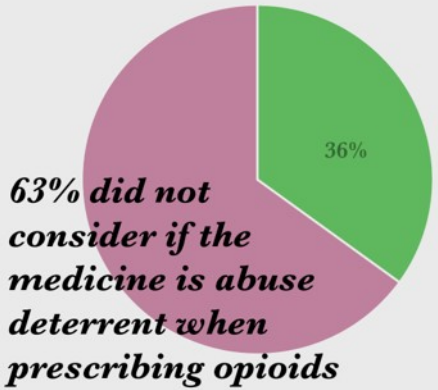
Electronic survey sent via medical licensure board to all DEA prescriber registrants in Kentucky, Oct/Nov 2019. Response proportion (8.5%) was similar to other unincentivized health care provider surveys (N=480 eligible). Some analyses limited to prescribers who prescribe controlled substances.





Perceptions that influence ADF prescribing

Few clinicians consider abuse deterrent properties when selecting opioid analgesics.

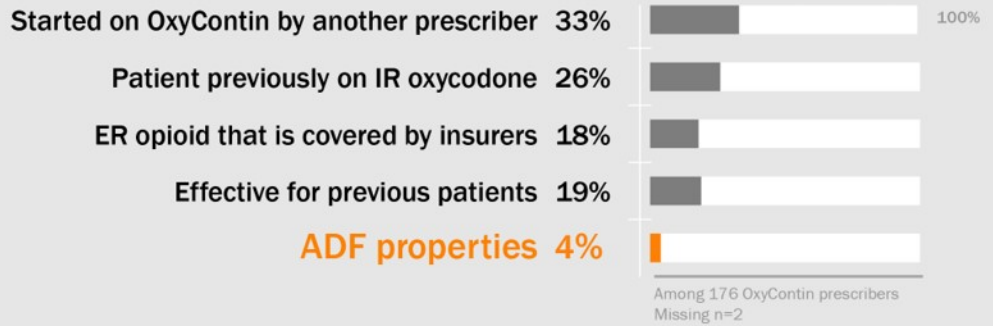


Survey of KY opioid prescribers, Autumn 2019 N=381

ADF properties are not top of mind when considering which opioid to prescribe. This phenomena may limit the extent of patient selection bias with reformulated OxyContin. But it may also limit direct comparisons with other ADFs.

ADF properties rarely primary reason to prescribe OxyContin

One-third of OxyContin prescribers did not to initiate the original prescribing decision.



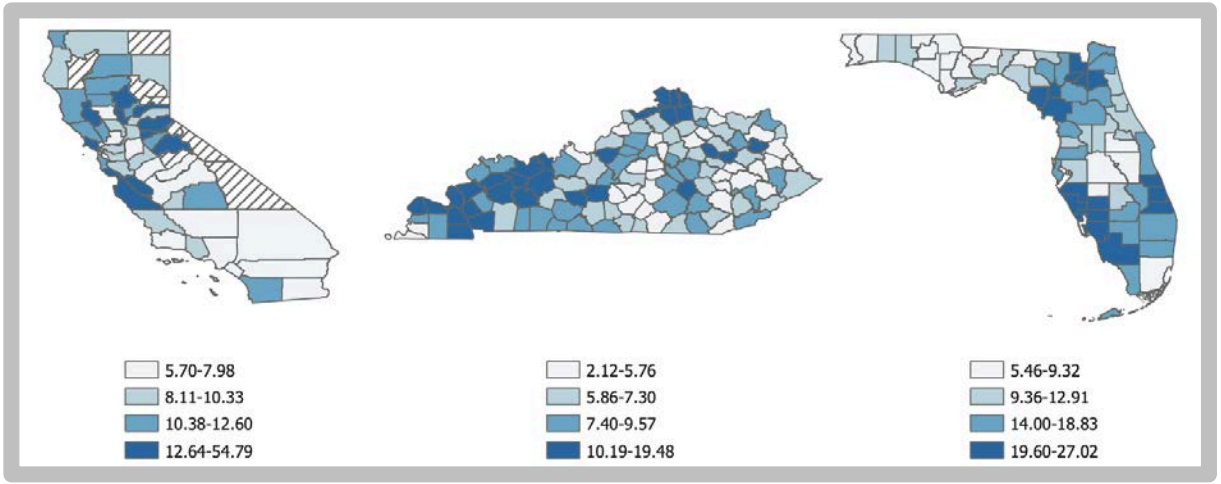
ADF dispensing varies by location

Methods

Analysis of Prescription Monitoring Program data from CA, FL, KY for outpatient opioid prescriptions dispensed to adult residents in 2018. ADFs included: OxyContin, Hysingla ER, MorphaBond, Embeda, and Xtampza ER.

ADF dispensing shows pockets of concentration. Areas with high rates of opioid prescribing and overdose do not necessarily have greater ADF penetration.

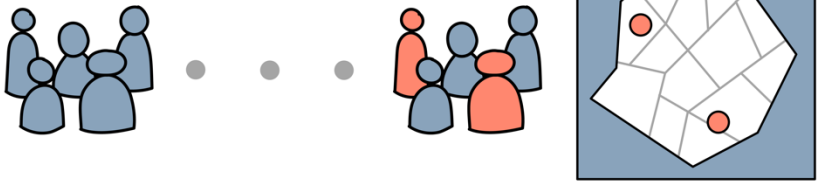
Annual rate of ADF dispensing per 1,000 Adult Opioid Patients



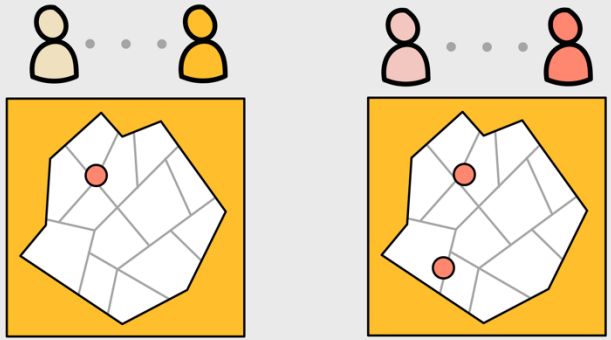
Brown JR, Oh GY, et al. 2020 – *Journal of Rural Health*. 10.1111/jrh.12496

Interactive maps available at http://tiny.cc/ADFmap

Original

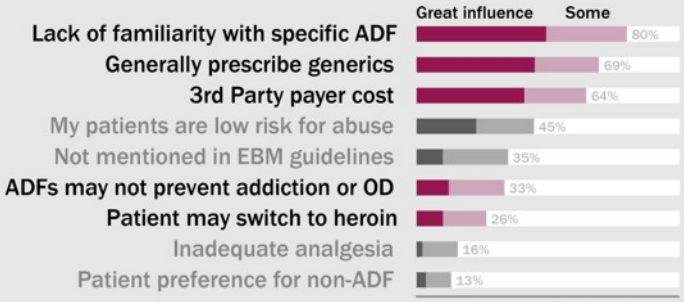


Reformulation



Lack of familiarity, generic preference, and cost limit ADF presscribing

Only a quarter were influenced by concerns of pushing patients to heroin by prescribing an ADF.

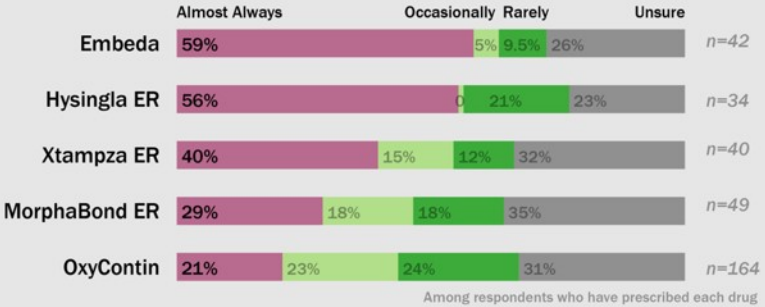


Survey of Kentucky-registered controlled substance prescribers, Autumn 2019

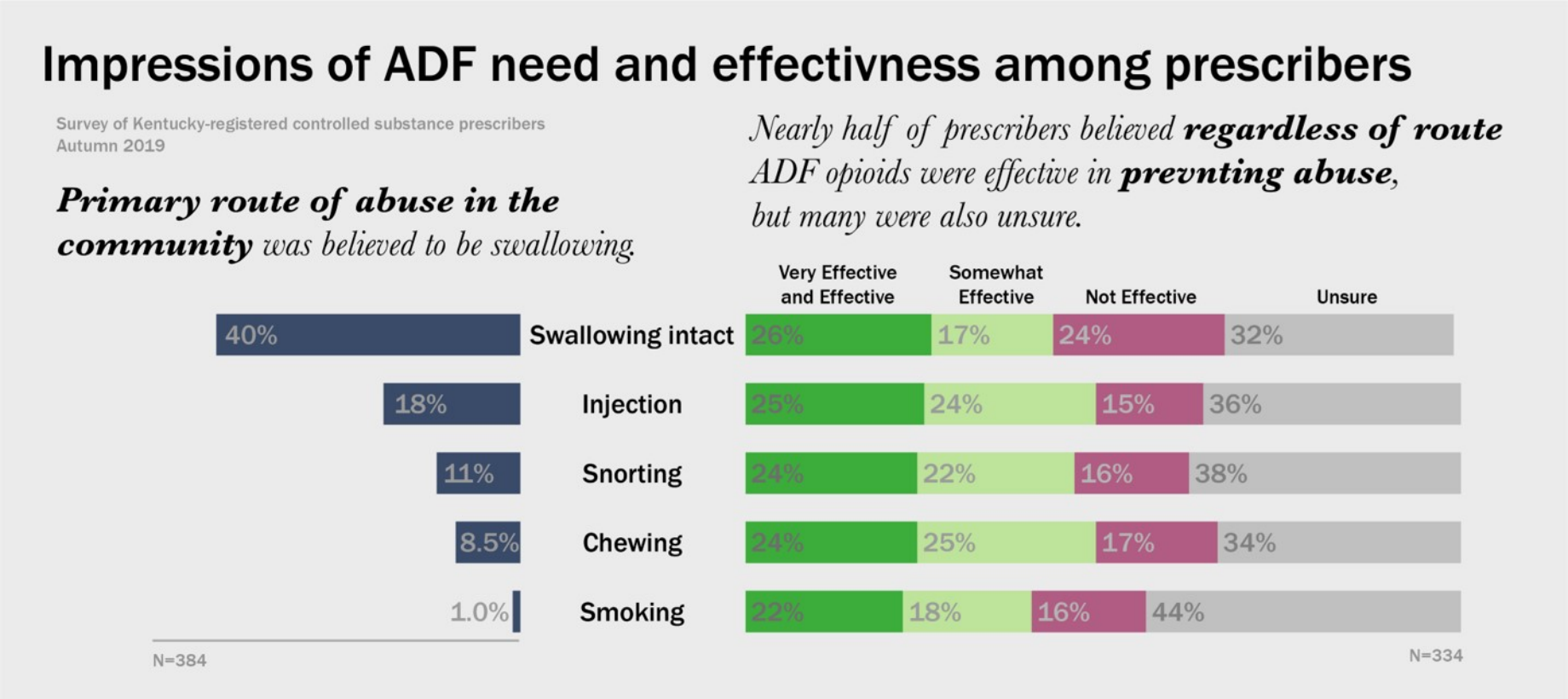
Point-of-prescribing requirements by third-party payers not uniform across ADFs

Survey of Kentucky-registered controlled substance prescribers, Autumn 2019

Prior authorization restrictions may be a stronger source of selection bias for some ADFs.



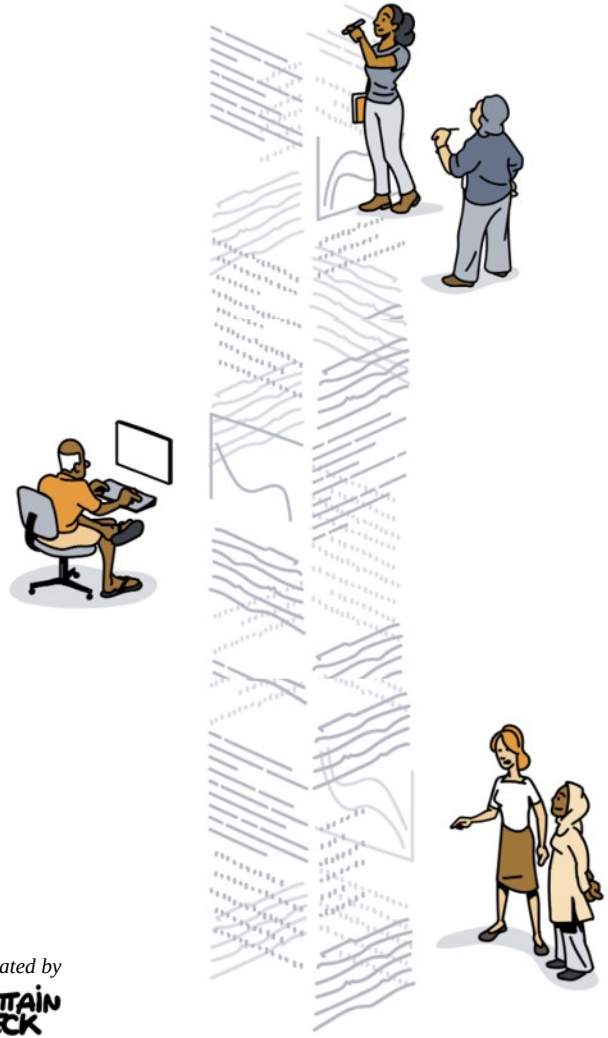
Prescriber perceptions of routes of abuse



Conclusions

The [NOMAD] study leads us to consider whether abuse deterrence is an inherent property of the drug itself, or if its intended effect lies in an interaction with social context.

If we accept that abuse deterrence in the community is more than a biochemical property, label language becomes becomes all the more challenging, albeit with the potential to be more scientifically accurate.



Illustrated by
BRITTAIN PECK

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OpioidData.org

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