

Policy implementation science:

Moving beyond binary definitions of tobacco policy

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Tobacco Online Policy Seminar
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Significance

“I mean, I think an unintended consequence on some level is that people thought something was being done in this space and it wasn't. And that's never good. If the public, if the industry, if legislators or other regulators think something is being taken care of because there is a law or policy in place on that, they choose not to take action. When something's not implemented, that's an unintended consequence of that policy.”

-Study participant



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The Vaping Policy Research Study

- Investigate implementation of policies restricting sales and use of e-cigarettes

- State
- Town
- School



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Policy Implementation Science Approach



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Framework for Policy Implementation Analysis

Bullock et al. *Implementation Science* (2021) 16:18
<https://doi.org/10.1186/s13012-021-01082-7>

Implementation Science

RESEARCH

Open Access

Understanding the implementation of evidence-informed policies and practices from a policy perspective: a critical interpretive synthesis



Heather L. Bullock^{1*} , John N. Lavis^{1,2}, Michael G. Wilson^{1,2}, Gillian Mulvale³ and Ashleigh Miatello¹



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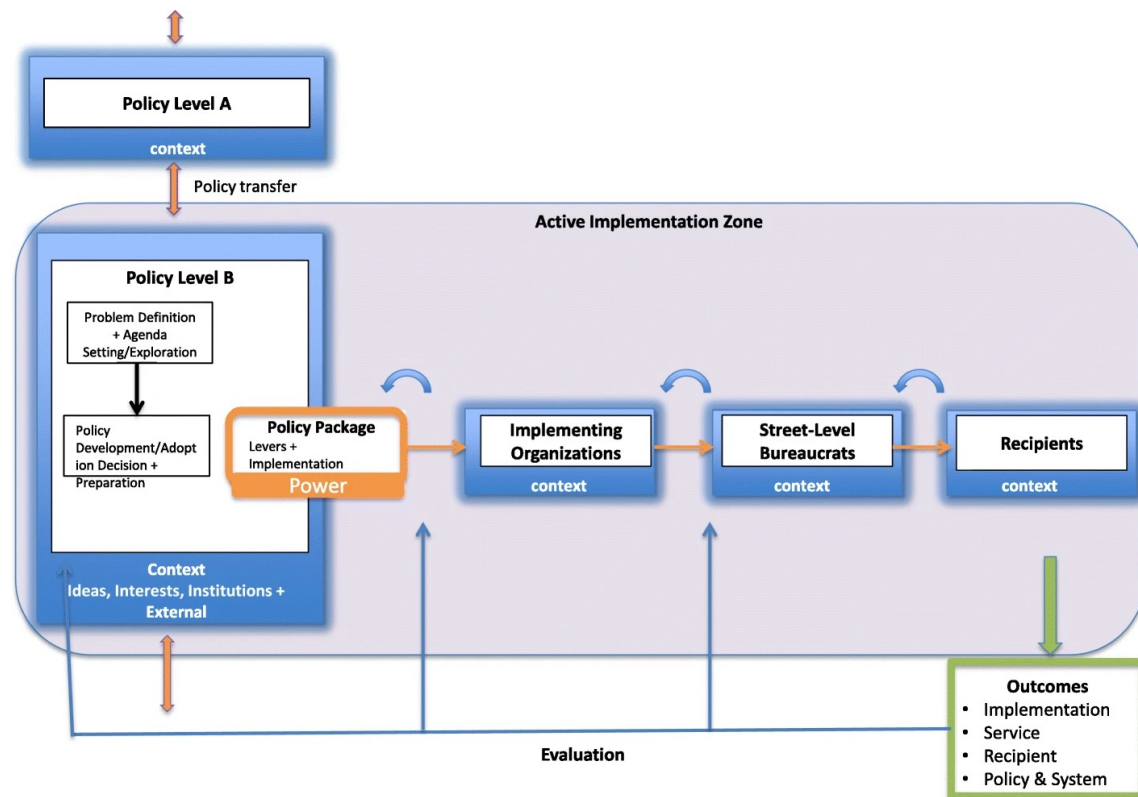
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Bullock Figure 2: Process Model

- Shows one policy level



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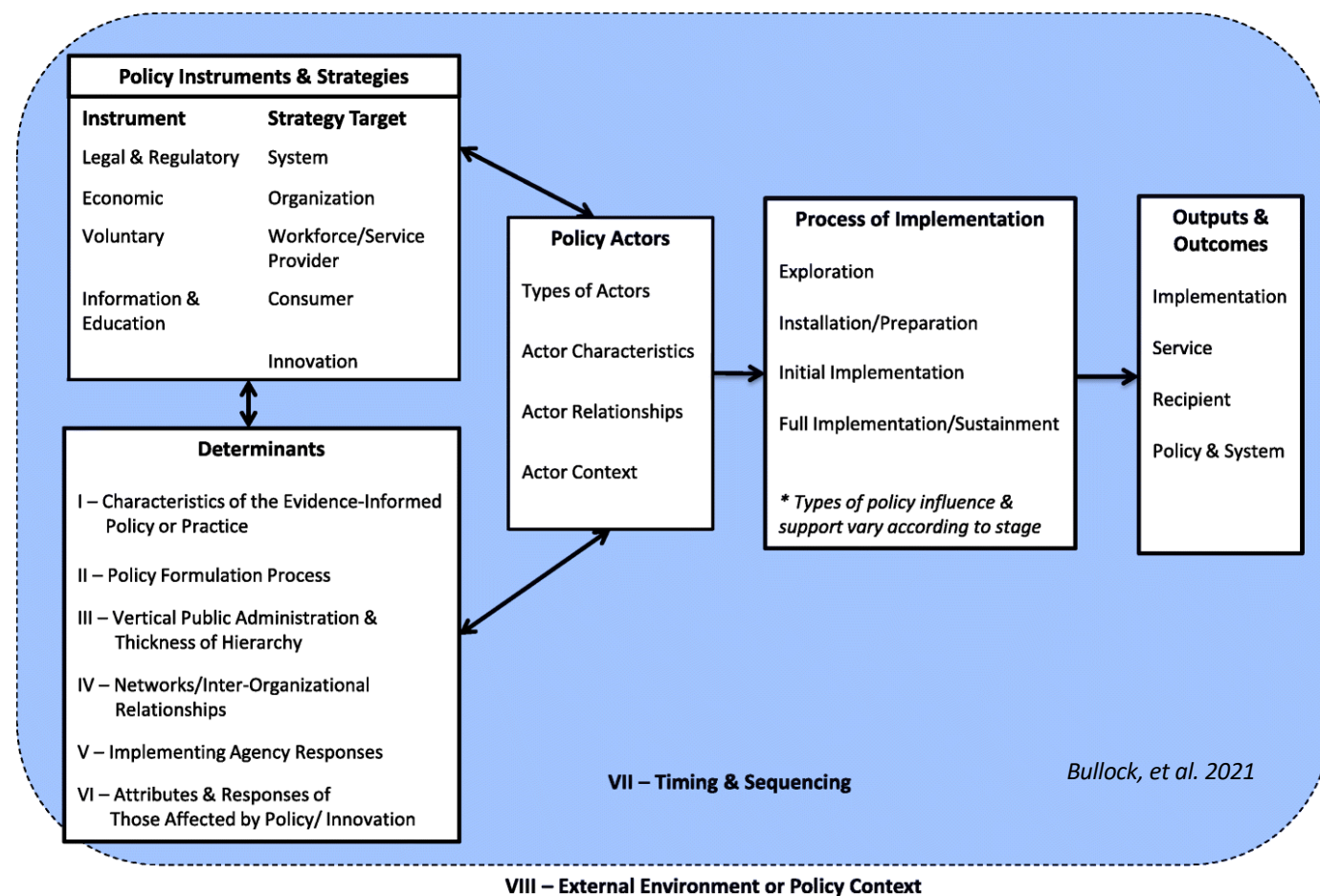
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Bullock Figure 4: Determinants Framework of Implementation

- In context of
 - A process by which policies are developed
 - The IS continuum of Exploration, Planning, Implementation, and Sustainment (EPIS)



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Applying Policy IS to the VAPOR Study



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E-cigarette control policies

- Restrictions on sales of “flavored” products
- Minimum legal sales age (“Tobacco 21”)
- Licensure requirements for tobacco product retailers
- Excise taxes
- Clean indoor air laws



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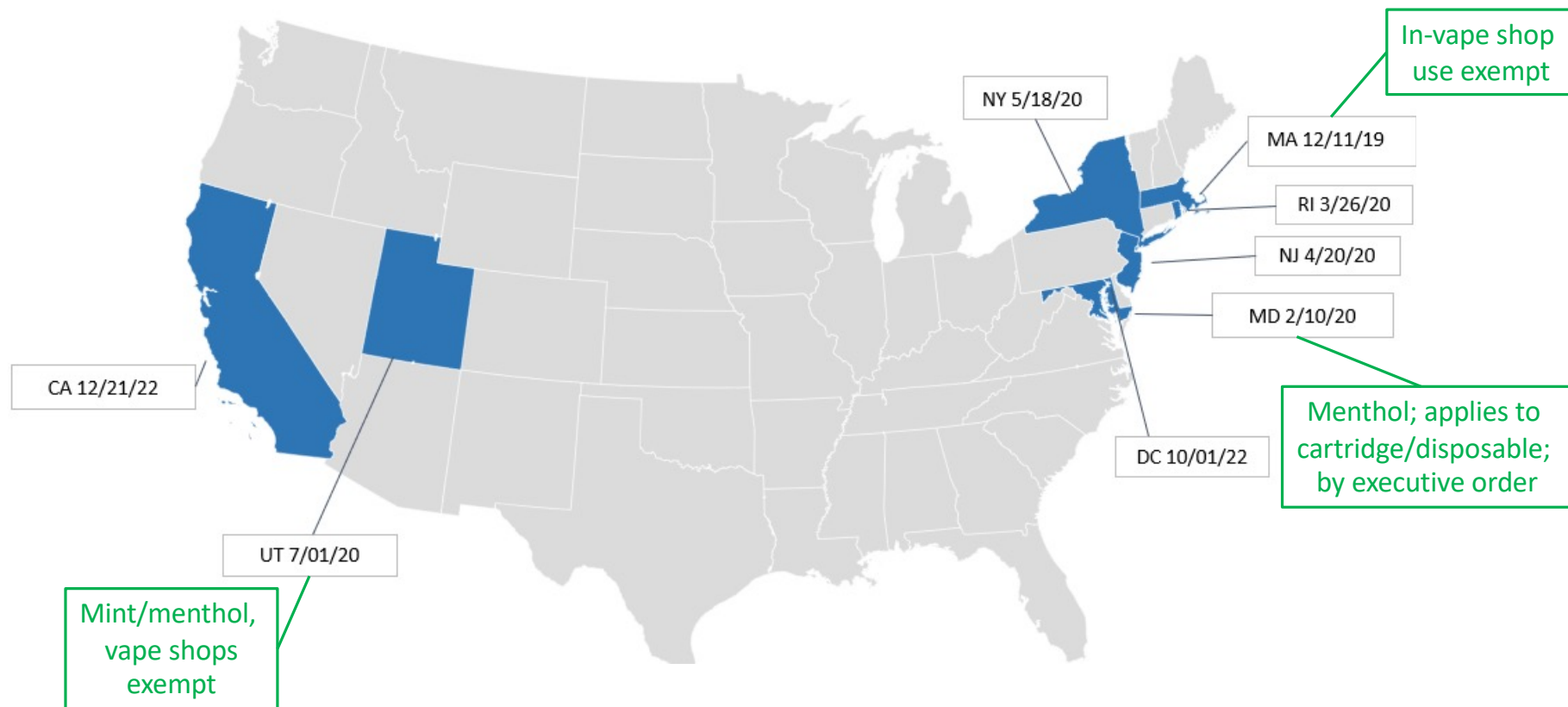
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7 states & DC have current flavor restrictions



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Key informant interviews

- Participants and Recruitment
 - Work with the Tobacco Control Network (TCN) of the Association of State and Territorial Health Officials to identify potential respondents
 - Generally, Directors of Tobacco Control or equivalent
 - If Director is not the appropriate interviewee, the Director will help identify the right person
 - Study staff worked to identify alternate or additional interviewees as necessary
- Semi-structured interview guides designed to probe all aspects of Bullock model
 - Zoom interviews, one interviewer and one note taker, recorded and transcribed



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Qualitative Analysis

- Deductive coding based on Bullock model (primary)
- Inductive as necessary (secondary)
- Analysis process
 - 2 coders per transcript
 - Consensus coding to ensure rigor
 - Each domain analyzed separately to identify themes



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Recruitment Results

- 7 of 8 states/districts interviewed in 2023
- 9 interviews completed
 - 2 additional interviews for completeness where first interviewee was not fully knowledgeable
 - Approximately 1hr each
- Total of 129 pages of transcript and ~75,000 words



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Policy analysis results

What did we learn about implementing restrictions on sales of flavored e-cigs?



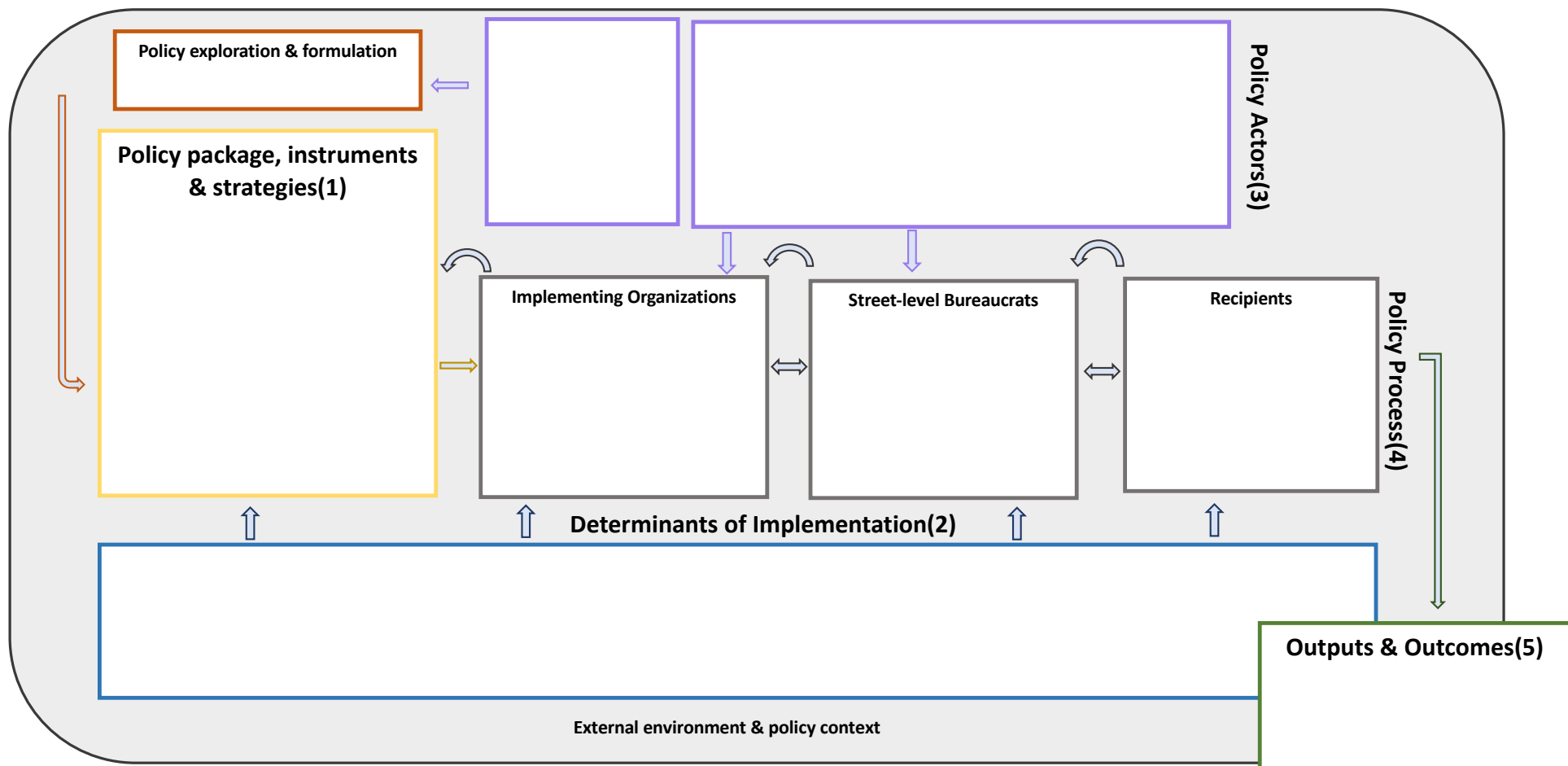
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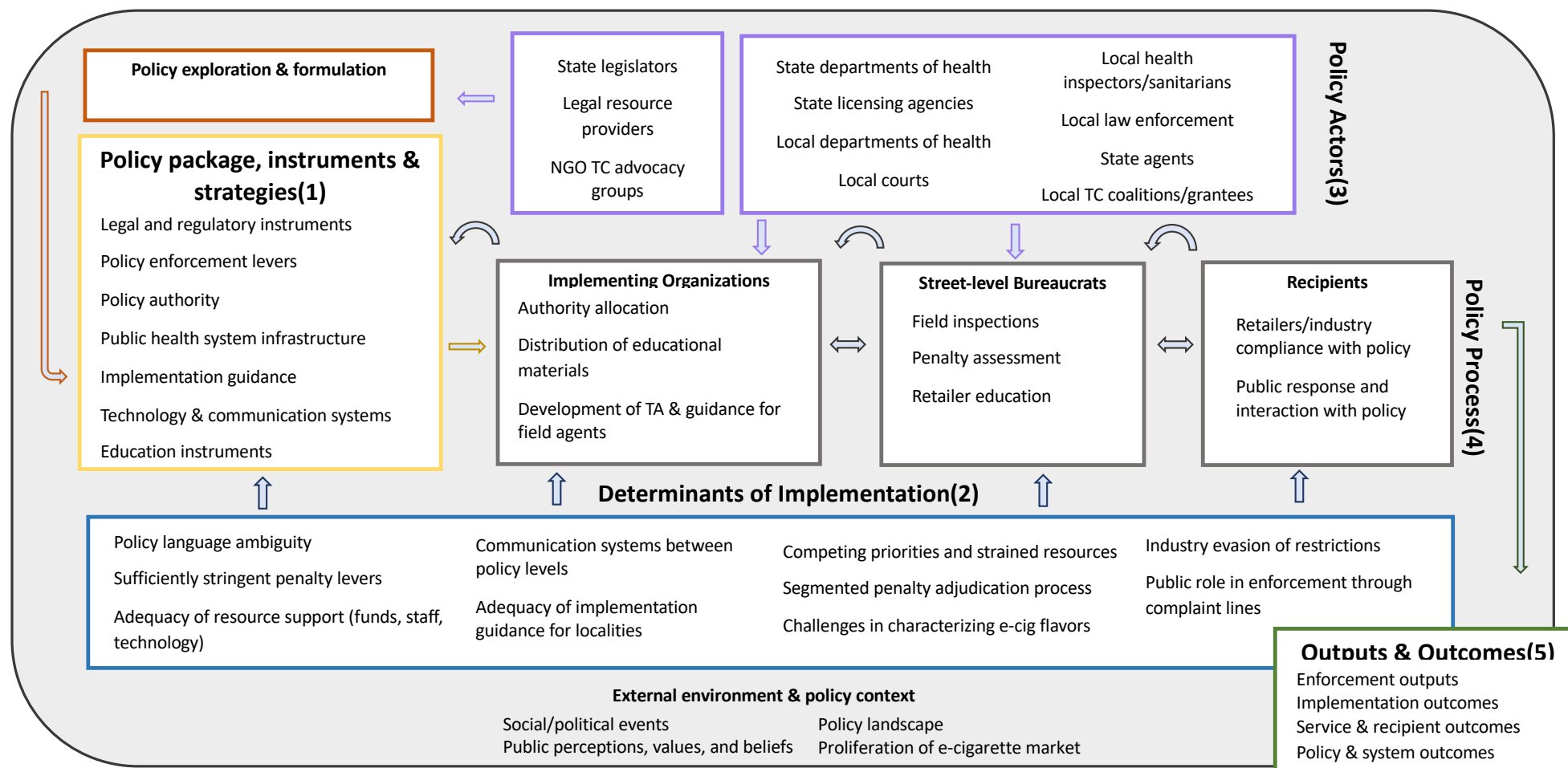
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Results

- What is/is not written into policy
- How do agencies and other organizations work together
- Additional determinants (barriers and facilitators)



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Authority (1)

- Often based on how tobacco/e-cig/flavor law is situated within agencies' existing authorities based on state laws
- Horizontal integration
- *“There were conversations at the state level between the [Department of Health], the [Tobacco Control Program], the [Attorney General's Office], and then the state [Department of Revenue]. I would say we were the three agencies that were trying to figure out, when this law went into effect, who would actually be implementing it.”*
- *“But our inspectors – so there's no teeth for them to make themselves be let in. They also have no power to seize product. So if a store is illegally selling, they can cite them, they can fine them, but they can't take that product with them.”*



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Licensure

- Determines what stores can legally sell products → where to go inspect, who is in violation
- Provides a lever for enforcement (licenses can be taken away)
- *“We have a database system that each one of our funded programs use and even some [localities] that aren't funded use to record all of their inspection data and all of their underage sale data. And it's updated and they all update it with any new retailer that is licensed in their area. And every time they do an inspection, we can see the level of violations.”*
- *“We've worked together-- the [Department of Revenue], they've just got pretty much everything up on their website, but we know how many licenses they have, and we keep track of any folks who are selling that don't have a [Department of Revenue] license and make sure that we get that information to the [Department of Revenue].”*



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Wholesale/Online /Retail Sales

- Policy language creates loopholes in online/wholesale/retail space
- *“Our retailers can still sell flavored vapor products out-of-state. So they could have a website where they're selling out-of-state. So the fact that they have these products, for example, maybe behind the counter or in their storeroom - they can say, "Well, we're not selling them to anybody here, but we have them back there because we're shipping them out to wherever." So one of the things that we've identified as a loophole that really needs to be addressed is to sort of look up the chain to the wholesaler, perhaps, to prohibit distribution in addition to retail sales.”*
- *“So, wholesalers can do business in [State] on flavored tobacco products...And they can sell to retailers, too. So retailers can have a huge stockpile and continue to buy, and there's nothing illegal about that. It's when the product exchanges hands between the retailer and the customer that the law is broken.”*



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Defining flavored products

- Many, though not all, states found defining and identifying flavored e-cigs to be challenging
- *“They have created a list of products that are included in the prohibition that you cannot sell these products, but they do mention that it is not exhaustive.”*
- *“The way the statute is written, it's like if it's specifically a flavor or aroma, or if it's advertised like cherry..., it's banned because the statute says that you can't use those terms in your advertising and selling of those products. The problem that local health departments have noticed is that a lot of times, they don't use those terms. So for instance, they may call it a star electronics flavor. And star doesn't have a characterizing flavor.”*
- *“...Sometimes felt like they have to take it to a lab or have it analyzed to that degree to find out if it's a flavor or not. But when it gets to vague areas and mixing behind-the-counter stuff, mixes, I guess, it gets a little difficult.”*
- *“And there's not really clear guidance in our code about what would count or what wouldn't count. So we have just internally set a precedent with our local health officers.”*
- *“So what we've said is anything other than tobacco flavor is not okay as opposed to the approaches that some other states have taken where you get into the whole concept flavors. Anything other than tobacco is not allowed...I think in particular, the way that language was defined here have been extremely helpful.”*



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Funding

- *“I think this policy was certainly an unfunded mandate. There were no additional resources attached to the implementation of this policy.”*
- *“So there's no additional monetary resources to help with this as far as developing media campaigns. Nothing of that nature.”*
- *“And as you may expect, there are larger [localities] that have more means that are just forging right ahead and finding ways to actually enforce this law, and others - I mean, it's been [a good long time now] - haven't done anything, just don't have the capacity. There's no funding written into the law or anything.”*
- *“But once the policy was into effect, we added that extra step to their inspection log and to the guidelines. But then they also were receiving additional funding to go through that, which was really helpful. So I do feel like the resources were there.”*



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Fines/Adjudication

- Some localities struggled with applying the penalties
- *“And it wasn't clear if the \$X was on-- you walk into a store. There's multiple flavored products. Is it, every flavored product is \$X fine? Or it's like: we went in one time; we see that you violated the law in this instance, so that's one fine? Not clear.”*
- *“So by the time a person goes to administrative hearing, they very likely could have racked up three or more fines. And then the administrative judge could say, ‘Yeah. I'm going to knock this down to one fine.’”*
- *“But by and large, our local jurisdictions will not take any action in the tobacco space and now broadly construed as including vapes, because they don't want to get sued. They don't have time and energy for that.”*



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Results

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Guidance/Coordination

- A common, central role of state [Departments of Health] and [Tobacco Control Programs] was providing guidance to staff, local health departments, and retailers
- *“My role, the other aspect is just sometimes, we get questions on statutes pertaining to tobacco from the general public and from local health departments. And I'm not allowed to interpret the statutes. I'm just allowed to direct them to where they are and basically go over the principles as stated in the statutes.”*
- *“I really do think that having these workgroup calls where everyone's on board has been extremely beneficial. And I think that's probably been the best thing that's come out of it, and the collaboration that we're seeing from the local level and the state level with what we have to work with.”*



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Interorganizational relationships

- Health departments worked with retailers and community members to communicate/educate about the policy
 - *“I think the main strengths of implementation, ... is ... the overall education of the community and the retailers [I]t's individual connecting and contact with retailers.”*
 - *“Well we have grantees that work with prevention. And this is one of the areas where they go out into the general communities, coalitions, et cetera to make retailers aware that the law has changed. They have a website. And they alert retailers to the changes in the laws.”*
- Industry (retailers, manufacturers) attempted to influence/water down policy/implementation
 - *“The wholesalers are telling the vendors, ‘Oh, this is fine. You can sell this. Don't listen to the enforcement agency. They don't know what they're talking about.’”*



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Timing and sequencing

- Several states had experience restricting sales of flavored products during the 2019 EVALI crisis
 - *“I want to say like [XX localities] had some type of flavor restriction in their local regulations....[H]aving those local regulations in place is a good facilitator of implementing the state law. “*
- In some instances, the policies were implemented very rapidly leaving agencies and retailers little time to organize compliance
 - E.g., develop implementation processes with local health officials, communicate policy, sell off products, set up ability to comply
- For some states, there were other policies enacted at the same time
 - *“[T]here were a lot of policy things that were quickly put into place that affected the retail environment in addition to flavors.”*
- COVID



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Responses of those affected

- Public support for flavor restrictions reported to be high
- Some retailers tried to evade the policy (under the counter sales, rename products, curbside/app purchases, sell flavors separate from devices)
- Industry introduces products that are not clearly affected by flavor restriction



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Methodological results

What did we learn about applying Bullock's framework in this setting?



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Coding process

- There is a steep learning curve
 - Not all concepts in the framework are well-defined (require returning to source material on which framework was built)
 - Definitions can be subtle
 - The scope of the framework means there is a lot to keep in mind when coding
- The framework is comprehensive
 - We did not identify many codes inductively



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Applicability

- Advantage → purpose-built for studying policy implementation
 - Other frameworks (e.g., CFIR) may work to some extent, but require broader thinking
- Some concepts/domains are underdeveloped in framework
 - E.g., outputs and outcomes defined somewhat differently in tables and text



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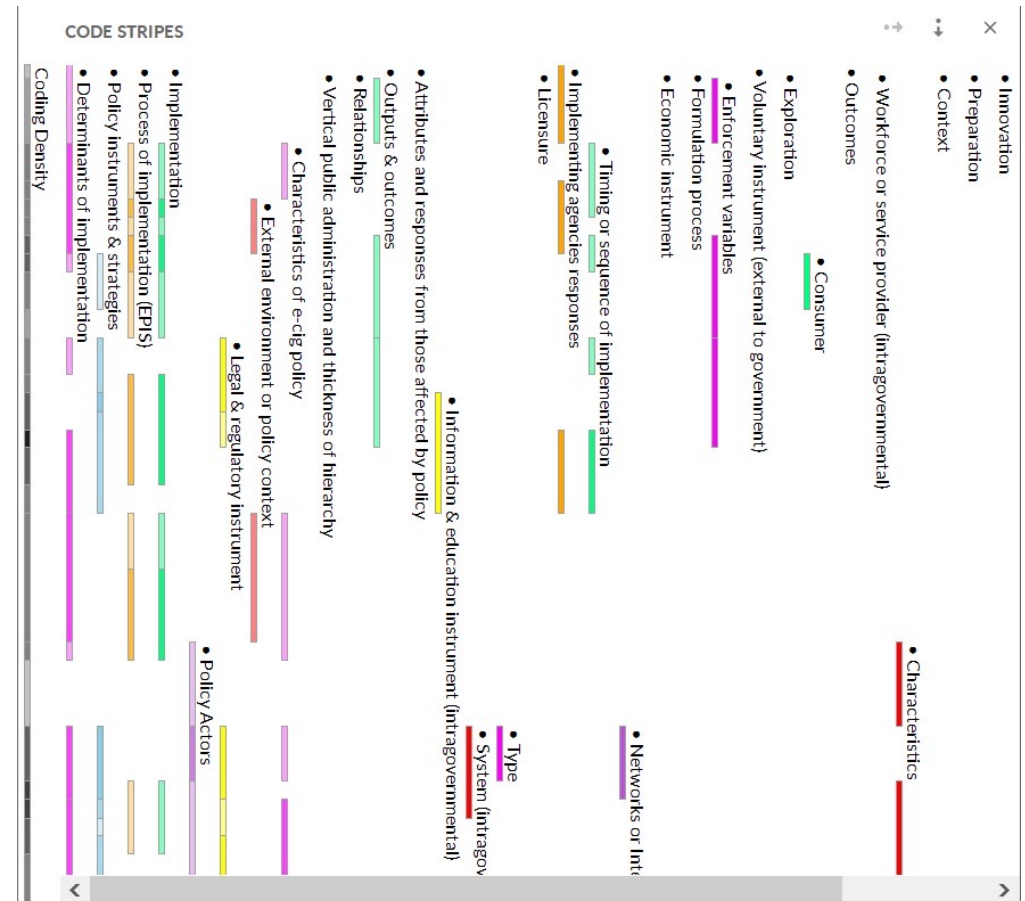
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Coding density

- Single data elements revealed information relevant to multiple aspects of policy implementation
- There are elements that are conceptually distinct (e.g. policy authority and actors) that consistently overlap



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Interviewees

- Health department employees generally willing to speak
- As government employees, some were constrained by communications policies
 - Despite assurances (interviewees and their states not identified), some were hesitant to share flaws in state's implementation
- Two employees from the same state could have different perspectives on implementation



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Limitations

- Single policy context (e-cigarette regulation)
- 1-2 interviews per state
 - Expertise of interviewees varied, different personnel had different takes on implementation, they had varied insight into local activities
- Findings represent the breadth of experience – not how common the experiences are
- No interviews with federal personnel; local interviews not yet incorporated
- Represents first few years of implementation
- We don't yet know the relationship between implementation details and [flavored] e-cigarette use



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