



CONSORTIUM FOR CANCER IMPLEMENTATION SCIENCE

# **Policy Implementation Science: NIH-Funded Case Examples and Lessons Learned**

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# Executive Summary

The [Consortium for Cancer Implementation Science](#) (CCIS) aims to advance the implementation science agenda in cancer control. The CCIS operates through a number of Action Groups, including the Policy and Implementation Science Action Group, which seeks to develop strategies and resources to support the implementation science community in advancing research in policy implementation related to cancer prevention and control. The Consortium annually funds investigators from each Action Group to develop “[public goods](#)” that may be used to build and support the cancer implementation science field. To this end, this report describes the experiences, lessons learned, and unique challenges faced by seven NIH-funded investigators who conducted NIH-funded policy implementation science over the past decade.

Two sets of complementary searches were conducted to identify potential case examples. The primary searches were conducted using the NIH [RePORTER](#) to identify all studies funded under the Dissemination and Implementation Research in Health Program Announcements between 2012 and 2022 that included ‘policy’ or a related term in the abstract or title of the study. Secondary searches were conducted using [PubMed](#) to identify peer-reviewed publications from NIH-funded “policy” and “implementation” studies as indicated in the title or abstract of the PubMed record. ([Appendix A](#) provides the search details and results.)

Ultimately, seven funded projects were selected for the case examples. Projects included studies that examined the implementation of both Big ‘P’ or small ‘p’ policy (see definitions in ‘An [Introduction](#) to Policy Implementation Science’), as well as implementation strategies related to policy. Projects spanned a range of NIH activity codes (e.g., R01, R21) and NIH institutes.

Semi-structured qualitative interviews were conducted with the principal investigator for each of the selected projects (see [Appendix B](#) Interview Guide). Through these interviews, key lessons learned for successful policy implementation science were identified. Major cross-cutting themes identified through the case examples included:

- 1 Building partnerships with policymakers and participating communities is key to success.** All investigators talked about the importance of building early relationships with partners, such as government officials, professional associations, and community members; these relationships were critical to understanding the problem from the “frontlines,” which subsequently informed research questions and study approaches. Researchers discussed the importance of continually asking what products or services are desired by policymakers or community partners.
- 2 The real-world nature of policy implementation requires investigators to be responsive and adaptive.** All investigators discussed disruptions to their studies, for example, due to the COVID-19 pandemic or turnover of key policy officials. Researchers discussed needing to be flexible and preparing to pivot due to real world impacts; for example, to be comfortable adapting their initial study design and plan based on the partners’ requests.
- 3 Theories, models, and frameworks (TMFs) used in policy implementation studies should be versatile and flexible enough to adapt to policy-specific work.** Broad frameworks can do the job for policy implementation science studies—all of the case examples used TMFs such as the Consolidated Framework for Implementation Research, RE-AIM, EPIS, and other overarching frameworks from the implementation science field. Investigators suggested picking a TMF that was versatile enough to fit with policy implementation work.
- 4 Policy-relevant data can be labor-intensive and challenging to collect.** Studies that include policy surveillance or policy mapping and/or policy-relevant primary data collection can pose challenges for research teams. Investigators cautioned about the need to consider study resources and potentially streamline data collection instruments and/or policy data collection scope.





- 5 **Creative grantsmanship is required for policy implementation science proposals.** Investigators discussed the many potential opportunities for funding policy implementation science studies. Several spoke about being flexible to and aware of funding opportunities from across the NIH Institutes to potentially increase funding success.
- 6 **Training and mentorship are crucial for developing a strong policy implementation science background.** None of the case example investigators had public policy backgrounds or formal educational training in public policy. Learning about public policy, policy implementation, and community engagement typically happened via mentoring relationships, and investigators spoke of the importance of mentorship for their success.

The following sections introduce the concept of policy implementation science, describe our methodological approach, and provide details on each of the key lessons learned. Following the report, 3-page profiles are provided for each case that highlight the key themes, resources, and other relevant information about each case. All cases were reviewed and approved by the respective principal investigator. Appendices provide additional details on our study methods ([Appendix A](#)) and the interview guide used for qualitative interviews ([Appendix B](#)).

## An Introduction to Policy Implementation Science

Policy implementation science (IS) research “seeks to understand how the roll out of policies can be optimized to maximize health benefits.”<sup>1</sup> However, methodological advancement in the area of policy IS research lags behind that of the IS field writ large. The lack of a formal sub-discipline of policy IS has created challenges for researchers seeking to conduct research to specifically examine the processes, barriers and facilitators, and outcomes associated with the implementation of both big ‘P’ and small ‘p’ policies. As a result, policy IS researchers are typically applying traditional IS theories, models, and frameworks (TMFs) to policy IS studies which may be inadequate as they do not specifically address the unique drivers or context of policy implementation; using scientific methods from their own disciplines (e.g., econometrics, decision and data sciences, medicine, etc.) rather than policy-specific measures or methods; and often lack formal training (or experience) in public policy or political science. We provide definitions for several key terms used throughout this report in Table 1.

<b>Key Term</b>	<b>Definition</b>
<b>Public policy</b>	Formal decisions made by federal, state, and local governments to act or not to act <sup>2</sup> ; they are “whatever governments choose to do or not to do”. <sup>3</sup> Public policies include laws/legislation, ordinances, rules and regulations, executive orders, administrative procedures, and court decisions that carry the force of law in the given jurisdiction (e.g., U.S., a specific state such as California, a specific local jurisdiction such as Chicago, or across jurisdictions).
<b>Policy implementation science</b>	Science that “seeks to understand how the roll out of policies can be optimized to maximize health benefits.” <sup>1</sup>
<b>Big ‘P’ policy</b>	Public policy, as described above, e.g., “things that governments do.”
<b>Small ‘p’ policy</b>	Includes “organizational guidelines, internal agency decisions or memoranda, social norms guiding behavior” <sup>4</sup> as well as non-codified policies, decisions, or actions made by governmental (e.g., an individual school’s practice governing recess before lunch) or non-governmental bodies or institutions (e.g., a health care system, a non-governmental accrediting body).

# Identifying NIH-Funded Policy Implementation Studies

To identify the universe of potential policy IS case examples, we conducted NIH [RePORTER](#) searches of studies funded under the Dissemination and Implementation Research in Health Program Announcements related to policy implementation that were funded between 2012-2022 as well as a [PubMed](#) search for studies to crosswalk against the NIH RePORTER searches. (See [Appendix A: Overview of Methodological Approach](#) for more details.)

Ultimately, seven NIH-funded grants were included in this review. The grants focused on a range of federal, state, and/or local policies or policies at the organizational level and covered a variety of substantive areas including diabetes prevention, sun safety, mental health treatment, school wellness policies, and smoke-free housing. The grants included a range of NIH activity codes (e.g., R01, R21), NIH institutes, and investigator types (i.e., junior to senior). To develop the cases, background information was compiled for each grant via the RePORTER and PubMed searches, Internet searches, and through semi-structured qualitative interviews with the lead investigator for each project.

An overview of the final cases and descriptions are shown in Table 2; full cases are provided [below](#).

Case PI	Activity Code	NIH Institute	Type of policy-related study	Jurisdiction	Focus of study
<b>Brownson</b>	R01	NIDDK	Local health departments evidence-based policies specific to diabetes prevention and treatment (small 'p')	Missouri	Adoption of evidence-based policies and practices by local health departments
<b>Buller</b>	R01	NCI	Organizational/worksite policies on sun safety practices (small 'p'); state policies on workplace safety around sun exposure (big 'P')	National	Implementation strategy (Sun Safe Workplaces) to facilitate implementation of sun safe policies
<b>Saldana</b>	R01	NIDA	Child welfare system (big 'P')	Tennessee	Implementation strategy to create system-wide changes via training and monitoring
<b>Purtle</b>	R21	NIMH	Earmarked taxes for mental health treatment (big 'P')	National	Exploring presence of earmarked taxes and policymakers' perceptions of taxes
<b>Plunk</b>	R37	NCI	Smoke-free housing policy mandate by the U.S. Department of Housing and Urban Development (big 'P')	Virginia	Design of implementation strategies related to smoke-free housing
<b>Lane</b>	F32	NIDDK	Local school wellness policy mandate by the U.S. Department of Agriculture (big 'P')	Maryland	Implementation strategy intervention to facilitate implementation of wellness policies within schools
<b>Stewart</b>	F32	NIMH	Financial incentive policies for mental health care (Big 'P')	National	Exploring types of financial incentives adopted by payers and policymakers' perceptions of incentives

# Key Lessons Learned

Although each NIH study included in this report was unique in its policy focus, study design, and key issues and challenges, there were several cross-cutting lessons for future policy IS researchers that are highlighted below.

- 1 Building partnerships with policymakers and participating communities is key to success.**
- 2 The real-world nature of policy implementation requires investigators to be responsive and adaptive.**
- 3 Theories, models, and frameworks used in policy implementation science studies should be versatile and flexible enough to adapt to policy-specific work.**
- 4 Policy-relevant data can be labor-intensive and challenging to collect.**
- 5 Flexibility and grantsmanship is required for policy implementation science proposals.**
- 6 Training and mentorship are crucial for developing a strong policy implementation science background.**

## LESSON 1

### Building partnerships with policymakers and participating communities is key to success

Early partner engagement was a crucial component of every study. A wide range of engagement activities with varying levels of partner engagement were discussed by the investigators. Partners facilitated a more comprehensive understanding of the research problem, which was critical to understanding the problem from a policy- and/or practice-based lens, which subsequently informed research questions and study approaches.

In addition to providing a real-world grasp of the problem of interest, partners also helped to endorse the research study; lend trust to the project; and help with logistical activities such as sampling and recruitment. For example, partner organizations can endorse a study or help with recruitment, which can strongly facilitate study participants' trust in the project.

“ **I think it is generally impossible** to get a good read on a policy environment just by reading academic stuff. I mean the internet and reading newspaper stories and organizational websites can get you a decent glimpse into reality. If you limit it to academic literature, you really have no idea what's going on, just because that delay is so long between something being studied and that knowledge getting out there in the literature. So, we always do a lot of informal conversations early on to see if an idea has legs...and then continuing those conversations throughout out the project.

—Dr. Purtle

“ **They [partner organization] promoted the fact** that we [i.e., the study team] were funded by the National Cancer Institute and that we weren't selling anything, oftentimes you show up and they [study participants] think you're selling something.

—Dr. Buller



## “What’s in it for them?”

In order to build strong partner relations, investigators recommended that researchers prepare to demonstrate their value as an academic partner by asking “*what’s in it for them?*” [see Dr. Stewart case [example](#)]. One way that investigators met partner needs was to include partners in planning and ask what is needed; and second, provide policy-relevant dissemination products (e.g., one page policy briefs) that summarize key research findings for use by the partners during and following the study conclusion.

## Mentorship on partner engagement was key.

Building partnerships is hard to learn from a textbook. Importantly, investigators stated that they often learned about the importance of working with partners from their research mentors, who modeled these activities and helped to make connections and build relationships. Investigators commented on the need for more formalized opportunities for mentorship in academia to ensure skills, such as partnership engagement, are passed on to new investigators or to investigators moving into the policy IS arena. (See related discussion under [Lesson 6](#): Training and mentorship below.)



**Everything that I’ve learned about policy** has been on the ground, working really closely with policymakers. The only reason I know anything about this is because I’ve been lucky to have this community-academic partnership, where we work so closely with policy makers...So watching them [mentors] build relationships, watching them [mentors] negotiate different goals between what the city [policymakers] wants and what we want...So I would say it was mostly mentorship and on-the-ground learning.

—Dr. Stewart

## Partner engagement is a process.

Lastly, partner engagement is not a one-time activity, it requires ongoing efforts and continually “*demonstrating [your] value,*” particularly in the field of policy IS research, where turnover amongst the policymakers or key decisionmakers can be high and leadership/administrative changes are the norm [see Dr. Saldana case [example](#)]. Although this requires considerable effort and emotional labor by investigators, investigators stressed the importance of continually working with partners throughout the study.

## Examples of partners engaged in policy implementation science projects

Investigators forged a wide range of partnerships with government officials and policymakers, non-profit organizations, as well as content experts from multi-sector and disciplinary backgrounds (Table 3).

TABLE 3 Examples of Partnering Organizations	
<b>Government organizations</b>	<ul style="list-style-type: none"> <li>● Federal departments, e.g., U.S. Department of Housing and Urban Development [Plunk]</li> <li>● Local health departments [Brownson]</li> <li>● State health departments and local school districts [Lane/Saldana]</li> <li>● City/county policymakers (e.g., Chief Medical Officer) [Stewart/Purtle/Brownson]</li> </ul>
<b>National associations and organizations</b>	<ul style="list-style-type: none"> <li>● AASHTO (American Association of State Highways and Transportation Officials) [Buller]</li> <li>● SHAPE America [Lane]</li> </ul>
<b>Local organizations</b>	<ul style="list-style-type: none"> <li>● City planners [Brownson]</li> <li>● Community agriculture organizations [Brownson]</li> </ul>



## CASE EXAMPLE **Community-Based Participatory Research to examine a Smoke-Free Housing policy**

Dr. Plunk’s R37 study on Smoke-Free Housing policies engaged a community advisory board (CAB) of roughly 30 public housing residents that met weekly to obtain their perspectives and expertise on study activities. He stressed the importance of engendering trust with CAB members and ensured that the public housing residents’ needs were addressed, at times by writing additional grants for emergent issues that were not met via his R37 study.



**We’re not going to find anything out** [about why policies are not effective] unless we actually go talk to people and we do that in such a way that engenders trust. If we’re not doing that, we’re never going to learn anything and then just be perpetually confused about why nothing ever works.

—Dr. Plunk

This approach also promoted health equity by ensuring that the policy implementation research study—from design to finish—was intimately informed by the desired outcomes of those directly impacted by the policy and/or study findings.

### LESSON 2

## **The real-world nature of policy implementation requires investigators to be responsive and adaptive**

In almost all cases, investigators discussed having to be responsive and adaptive. Concretely, this means that researchers needed to be prepared to pivot throughout the research process—from proposal design through the grant period. Although all research studies may experience unforeseen disruptions, two that are particularly important for policy IS research include pivoting design ideas based on partner feedback and being adaptive to sudden study disruptions due to delays with policy implementation or with staff/decisionmaker turnover.

### **Pivoting to partner needs to reduce burden.**

Investigators spoke about the need to be responsive to partner needs and “*balance the comprehensiveness and rigor*” desired by academic researchers (and NIH reviewers) with the burdens placed on study participants/partners. Since most investigators conducted their research in close partnership with policymakers, organizations, and community members, the needs of these partners were central to the success of research. For example, one investigator described changing the study design after being funded due to partner requests; the study team’s need to be responsive and adapt to the community’s needs was imperative to study success.

In practice, this often involved ensuring that all participants received the benefits of an ‘intervention’ [see Drs. [Brownson](#), [Buller](#), and [Saldana](#) examples]. For example, multiple investigators discussed their use of stepped wedge designs, which provided a balance of academic rigor with partners’ motivations for participation. Stepped wedge designs, however, have implications for power and sample size that investigators should consider.<sup>5</sup>



**We did a step wedge design...**which, wasn’t the original design we wrote in the grant. We decided to convert to that based on input from our advisors, who said, ‘we’d like to participate, but we’d really like to be part of the so-called intervention group for the trial.’ There’s pros and cons to this decision.

—Dr. Brownson

## Being adaptive to sudden study disruptions.

All investigators discussed disruptions to their study activities and timelines. In addition to the COVID-19 pandemic, policy IS research was particularly susceptible to sudden disruptions because partnerships played such a major role in most studies. Partners were crucial for helping investigators have access to data or study sites, and often, changes disrupted partnerships. Changes in government administrations, staffing, and political will (as the result of election results/ administration changes) mean that investigators should be prepared to pivot as needed, especially if their studies depend on policymakers' or community members' buy-in or participation.

### CASE EXAMPLE **Adapting to abrupt changes in government administrations**

Dr. Saldana's R01 study examining an implementation strategy—the R<sup>3</sup> Supervisor Strategy—was strongly supported by partnerships with local and state government leaders. Twice, this team experienced abrupt disruptions to their study due to changing political administrations; in the case of this R01, funding

was cut two years into the five-year grant. As a lesson learned from this experience, Dr. Saldana recommended researchers develop sustainable partnerships with leadership outside of traditional government leaders and to be ready to adjust study design, methods, and goals with changing political climates [see Dr. Saldana [example](#)].

And, after learning these lessons, Dr. Saldana and her team were able to obtain [funding](#) for a follow up study further examining the R<sup>3</sup> Supervisor Strategy with a successful government partnership in another state.



**I think it's important to make sure** that too much of your implementation doesn't hinge at the top because when the top changes, then it's really hard to keep it [the research study]...I really missed the boat in terms of, what are those key sustaining relationships in a system outside of maybe the leadership. So...if I would've had, maybe a really seasoned supervisor, who's been there for 40 years and everybody looks up to...who could have been a liaison to new leadership, that could have been possibly helpful.

— Dr. Saldana

## LESSON 3

### **Theories, models, and frameworks used in policy implementation science studies should be versatile and flexible enough to adapt to policy-specific work**

Theories, models, and frameworks (TMFs) are a key component of IS studies broadly, and policy IS studies are no exception.<sup>6</sup> There are many TMFs that tend to cover three broad areas: process (e.g., describing the process of implementation), determinants (e.g., understanding or explaining what influences implementation outcomes), or evaluation (e.g., guiding the evaluation of implementation).<sup>6</sup> Each of these types of TMFs can guide different components of implementation studies and have their own strengths and weaknesses. Two key considerations when thinking about TMFs for policy IS research are to use broad and flexible TMFs and consider how equity is considered within the TMF.



## Guide policy implementation studies with broad and flexible TMFs.

Broad frameworks can do the job for policy IS studies—many studies in this report applied broad and flexible frameworks such as the Consolidated Framework for Implementation Research (CFIR),<sup>7</sup> RE-AIM,<sup>8</sup> and other classic frameworks from the IS field (Table 4). In addition to broad TMFs, investigators suggested blending and adapting existing TMFs to guide policy implementation studies.

“ **A lot of theories, models, and frameworks overlap** so much that in a way it almost ends up that the constructs are so overlapping. It was definitely a multi-level sort of a study. So it easily could have been a RE-AIM, a PRISM, or a CFIR framework as well. We used theory on the front end to develop our conceptual frameworks, but then we never talk about theory with any of our partners, we just talk about, ‘what is it you need from us and how can we do it to make this work for you?’ And so it’s probably theory-heavy on the grant writing and the front end, and theory light as we go through and try to make that invisible to people if we can.

—Dr. Brownson

## Considering equity when selecting frameworks.

While several investigators spoke about selecting a TMF for a project, they also stressed that it is important to consider the equity implications of using the TMF in the real world. In one example, Dr. Plunk discussed how his team used a framework to guide adaptation of an evidence-based intervention and spoke about the importance of collaboration across all partners [see [Lesson 1](#) above] in the actual adaptation process to maintain equity.

“ **The process of actually adapting the framework** (was through the) collaborative intervention planning framework. (Our partners) originally just proposed one community advisory board and we modified that to two. One of the things that I’ve always found is very important is keeping lay people separate from engaging other stakeholders. Power imbalances are always going to negatively affect the dynamic of community engagement.

—Dr. Plunk

**TABLE 4 Theories, Models, and Frameworks Applied in Case Examples**

Case PI	Theories, models, and frameworks applied
<b>Brownson</b>	Diffusion of Innovations <sup>15</sup> with constructs from Institutional Theory <sup>9</sup>
<b>Buller</b>	RE-AIM <sup>8,10</sup>
<b>Saldana</b>	EPIS and Stages of Implementation Completion (SIC) <sup>11,12</sup>
<b>Purtle</b>	EPIS <sup>12</sup>
<b>Plunk</b>	Consolidated Framework for Implementation Research (CFIR) <sup>7</sup> Collaborative planning framework <sup>13</sup> Procedural legitimacy theory <sup>14</sup>
<b>Lane</b>	RE-AIM <sup>8,10</sup>
<b>Stewart</b>	Diffusion of Innovations <sup>15</sup>

## LESSON 4

### Policy-relevant data can be labor-intensive and challenging to collect

Some policy IS studies involve primary policy data collection in addition to studying the implementation process or factors influencing implementation. Policy-relevant data may not exist in databases (depending on the policy topic and jurisdictions of interest) and therefore can require labor-intensive data collection methods. In addition, policy research often requires complex measurement from multiple levels (e.g., individual and organizational level).

Two of the seven case examples included policy surveillance<sup>16</sup> or policy mapping data for small ‘p’ organizational policies [see Dr. Buller case [example](#)], as well as Big ‘P’ local, county level, and state laws [see Dr. Purtle case [example](#)]. In addition, the studies collected a wide range of policy-relevant outcomes data, such as organizational implementation outcomes data and individual level behavioral change.

#### Policy surveillance or policy mapping data.

“Policy surveillance” is the “...‘ongoing, systematic collection, analysis, interpretation and dissemination’ of information about a given body of public health law and policy”<sup>16</sup> typically across jurisdictions or organizations. Policy surveillance (or “policy mapping” as at least one of the investigators referred to it) is inherently challenging and requires a creative and time-intensive approach. In general, there are existing state level legal databases that offer comprehensive policy data but the availability of policies at the local levels (county, municipal, school district) and organizational levels vary widely. The latter requires a wide range of methods, including searching county and/or municipal codes of ordinances and regulatory databases (where available), school district board policies and/or superintendent regulations, sources of ballot initiatives, scouring meeting minutes, and a variety of other time-intensive approaches. Investigators noted the importance of collecting and analyzing policy data, since existing policies can have a strong influence on organizational leaders’ and other partners’ motivations and power to enact changes. However, they cautioned that researchers should understand the scope and effort required to conduct rigorous and comprehensive policy surveillance or policy mapping.

“**Policy-focused implementation science work is messy...**to produce generalizable findings, you have to look across multiple states or levels of government, and data are not collected systematically and uniformly across these geopolitical units. We could have done a 50-state study of tax and legal databases... but we would have missed so much...you need to use more detective methods...if you really want to identify everything relevant to your questions.

—Dr. Purtle

#### Additional primary data collection.

In addition to policy data, collecting primary data requires a balance between gathering multiple levels of data for comprehensiveness (e.g., organizational and individual level data) and participant or partner burden. Investigators recommended trying to consolidate instruments as much as possible to avoid burdening busy study participants. Collaborating with partners to develop final instruments is necessary to strike a balance between goals for data collection and participant burden.

“**One of the things that is consistent across every study** is academic people will want to make the questionnaires long and the data collection processes take a long time. (It’s necessary to) balance the comprehensiveness and rigor with some of the real-world challenges that people face.

—Dr. Brownson



## CASE EXAMPLE **The complexity of data collection in school settings**

Policy IS research in school settings is inherently complex due to the potential for multi-level data collection; researchers may be interested in student level health/behavioral outcomes embedded in school level organizational data, then embedded within district level and community level data and/or policies. Dr. Lane’s F32 study added an enhanced RE-AIM focused implementation evaluation to a larger USDA-funded cluster randomized control trial that examined Wellness Champions for Change (an implementation strategy) [see Dr. Lane case [example](#)]. The larger study assessed the student level impact of training teachers and students to form wellness teams that implement policies. Dr. Lane noted that while some states collect statewide school surveys, Maryland did not have such existing data; therefore, her team was challenged with designing and collecting a wide array of mixed methods data (e.g., surveys, qualitative focus groups and interviews, observational data, document tracking) to triangulate data sources.



**I think that we collected a lot of data** that could have been streamlined into a single instrument or could have been streamlined to something that... multiple people at the school filled out. The other thing is developing methods to assess what schools are already doing... a lot of our schools...came in and already had a wellness team, for example.

—Dr. Lane

In hindsight, Dr. Lane noted that many of the instruments could have been streamlined to consolidate the assessment and reduce burden on busy school professionals and student participants. In addition, she noted that in the future, she would consider conducting baseline readiness assessments to better understand schools and tailor the intervention.

## LESSON 5

### **Creative grantsmanship is required for policy implementation science proposals**

NIH has increasingly funded policy-focused studies, reflecting the ongoing shift in public health toward promoting policy and systems changes. However, investigators shared that still, policy IS work can require creative grantsmanship because it may not be fully understood or appreciated by NIH reviewers.

Investigators recommended that researchers find an NIH Institute or other funders that are interested in policy implementation; tailor application language to educate reviewers; and make a strong theoretical case for the health outcome implications of policy implementation.



**I think one of the things that we’ve had to learn to do** is to really make the case (in NIH grants and with academic audiences) for policy... and how difficult and challenging it can be to get policy in place, but how important it is once it’s there.

—Dr. Buller

#### **Find an NIH institute or funders that are interested in policy implementation.**

Investigators noted that some NIH institutes are more interested in policy implementation work than others (e.g., the National Cancer Institute (NCI), the National Institute on Mental Health (NIMH), and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)). Researchers are encouraged to align their aims with the interests of the institutes, with a focus on those that already support policy work, so there is a shared understanding and appreciation for the work.



## Tailor application language to educate reviewers.

Due to the smaller number of policy IS applications to the NIH (compared to clinical or behavioral research-related IS applications, for example), reviewers may not be as familiar with policy-specific terms or methods that are common in policy work. Investigators recommended that researchers save “*some real estate*” in the application for educating reviewers about the rigor and utility of methods. For example, investigators recommended that researchers anticipate some of the criticisms of policy work such as limited familiarity with non-randomized control trial study designs.

“**We’re using a difference-in-difference approach** with which I think a lot of reviewers get, but there are more old school classic reviewers who, if it’s not an actual randomized control trial, they think, ‘you can’t know anything.’ So it’s kind of dead on arrival...[you may write] ‘these methods are widely used in field, A B and C, they’ve been used for 75 years...these are the limitations and these are all the things we’re doing to address this inherent limitation.’

—Dr. Purtle

## Make a strong theoretical case for the health outcome implications.

Often the mechanisms of policy change to health outcomes involve lengthy trajectories. For example, a policy that intends to decrease the sales of sugary beverages on school campuses may be expected to have short-term influences on student intakes of sugary beverages, medium-term influences on dental caries, and long-term influences on chronic disease outcomes like Type II diabetes. However, these mechanisms are highly complex and confounded by a number of structural and multi-dimensional influences. Investigators discussed the challenge of making the case for behavioral or health outcomes to NIH reviewers, particularly when a proposal is focused on policy implementation. As discussed above, ideally there will be a more widespread understanding and appreciation for policy change as prioritized outcomes in the future. In the meantime, investigators recommended that researchers rely on available literature to make a cogent theoretical case for potential or anticipated outcomes of the policy.

### LESSON 6

## Training and mentorship are crucial for developing a strong policy implementation science background

None of the case investigators had formal academic training in public policy. Most investigators’ training about policy, policy implementation, and community engagement happened via mentoring and ‘on the ground’ experience.

### Mentoring.

Traditional doctoral and postdoctoral mentoring was mentioned in multiple cases, though these mentoring relationships were often broad and not specific to policy IS. This often involved observing how mentors modeled community engagement and building relationships and learning how mentors brought policy considerations into their research.

Investigators noted that, when possible, researchers may consider leveraging grant proposals to formalize mentorship roles. Two investigators were awarded F32 (postdoctoral research training) grants [see Drs. [Lane](#) and [Stewart](#) case examples], which allowed them to include policy IS experts on mentoring teams. Dr. Stewart commented that the mentorship and training allowed her to learn about and take on the often “*overwhelming*” challenge of policy implementation research that is focused on influencing structural barriers to health. In particular, mentors gave her access to policymakers and modeled successful partnership building for policy implementation research.

These lessons were invaluable to Dr. Stewart’s training and allowed her to obtain a [K23 Mentored Patient-Oriented Research Career Development Award](#) to advance her research agenda and continue examining financing as a policy implementation strategy, as well as other develop additional skills.



Other types of academic training grants can support mentorship relationships. For example, as a junior faculty member, Dr. Purtle received internal funding to establish a mentorship relationship with an expert outside of Drexel University. He used this opportunity to connect with Dr. Ross Brownson, a renowned expert in IS, particularly policy implementation research. This relationship supported Dr. Purtle’s early success in the policy IS field.

## ‘On the Ground’ Experience

Overall, many investigators learned about building partnerships ‘on the ground’ and mentioned their perception about a lack of formal training opportunities on this topic aside from specific academic training grants.

This is particularly important for investigators who may not be able or eligible to apply for academic training grants, or who may not have had formal educational training in public policy or experience working in policymaking settings.



**I probably had one formal policy course in my training, but I came at (policy IS) from the real-world experience of working with the state legislature and the governor’s office on both budget issues and on legislation around chronic disease, cancer prevention, and tobacco use.**

—Dr. Brownson

## Formal Training.

There are a few formal policy IS-related training opportunities. One unique example of a formal training opportunity specific to policy IS is a two-day [Policy-Focused Implementation Science Institute](#) led by Dr. Purtle and colleagues, and hosted by the Global Center for Implementation Science (GCIS) at New York University. Two other formal IS training opportunities that include policy IS modules are [The Institute of Implementation Science Scholars](#) at Washington University St. Louis led by Drs. Haire-Joshu and Brownson, and the [Training Institute for Dissemination and Implementation Research in Cancer \(TIDIRC\) Course](#) hosted by the National Cancer Institute’s Division of Cancer Control and Population Sciences.

## Conclusion

This report describes NIH-funded policy IS projects, funded across a variety of mechanisms and institutes. The goal for this “public good” was to respond to the [CCIS Policy and Implementation Science Action Workgroup’s](#) call for examples of successful policy IS projects to serve as “exemplars” for researchers who are interested in exploring policy IS research in the future.

Using NIH RePORTER and PubMed, we identified seven case examples of funded policy IS research projects and conducted in-depth interviews with the lead investigators for each project. This report summarizes six key lessons learned about the unique challenges of proposing and conducting policy IS research. Investigators shared the critical importance of partnering with policymakers, organizations, and community members, as well as being able to pivot and adapt to partner needs. Strategic partnerships were also key to sustainability and avoiding sudden disruptions due to changes in political will. Investigators also discussed the use of flexible TMFs in guiding studies and the challenges of collecting policy-relevant data, including the need to consider and balance academic rigor with participant burden. Investigators offered concrete tips for researchers when crafting their NIH applications and discussed the importance of mentorship and training opportunities in building the policy IS field. The lessons learned and guidance provided in this report can help policy IS researchers successfully propose and conduct a policy IS study, as well as anticipate potential barriers.



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# **CCIS Policy Implementation Science Case Examples**



# Enhancing Evidence-based Diabetes Control Among Local Health Departments



## Study details

### Principal investigator

Dr. Ross Brownson, Distinguished Professor at the Brown School at Washington University in St. Louis

### NIH grant number and reporter link

[R01DK109913](#)

### Project dates

Jul 15, 2016 – Jun 30, 2022

### Policy studied

Evidence-based programs and policies (EBPPs) in diabetes control

### Stage of implementation

Adoption

### Implementation science theory/framework

Diffusion of Innovations and Institutional Theory

## Study aims

**Phase 1:** Refine and test measures to assess the adoption of EBPPs in local health departments (LHDs), building on pilot work.

**Phase 2:** Conduct a qualitative needs assessment of 15 LHDs in Missouri to understand factors influencing the adoption of diabetes control EBPPs. Next, conduct a pre/post, experimental (group-randomized) study of 30 LHDs in Missouri to evaluate the effectiveness of active dissemination and implementation (D&I) approaches. The intervention arm of this study (15 LHDs) received a flexible “menu” of D&I approaches that accounted for local contextual and organizational factors. The control arm (15 LHDs) received a minimal “usual care” intervention.

## Study at a glance

This project sought to reduce the burden of diabetes by increasing adoption of evidence-based programs and policies (EBPPs) among local health departments (LHDs) in Missouri. The study focused on comprehensively understanding the factors that influenced the adoption of EBPPs; to do this, they developed a measure to assess adoption and conducted needs assessments with LHD officials to understand the local contexts. This information informed the intervention tested, which was a ‘menu’ of possible approaches to improve the adoption of EBPPs for diabetes prevention, tailored to local context. The intervention was tested using a stepped wedge design that allowed for all participating LHDs to receive the locally tailored intervention while also ensuring appropriate comparisons across intervention and control groups. While a stepped wedge design was not originally planned, the study team pivoted based on partner and participant engagement and input received. This case uniquely highlights the importance of considering local context and adaptations while being responsive to partner needs.



This series of ‘public goods’ case examples was developed for the [Cancer Consortium for Implementation Science \(CCIS\)](#) to highlight NIH-funded policy implementation science studies and the key lessons learned in conducting this type of research. The cases presented demonstrate the many creative and unique ways that both big ‘P’ and little ‘p’ policies have been rigorously investigated to advance public health.

## Key policy implementation science lessons learned

1

Build a strong interdisciplinary team with policy expertise

2

Consider the challenge of collecting policy-relevant outcome data

3

Balance the comprehensiveness and rigor desired by academic researchers with participant incentive and burden

4

Ensure findings are disseminated back to partners and participants

## Key policy implementation science lessons

### Build a strong interdisciplinary team with policy expertise

Study teams for policy implementation research should be built with the study objectives in mind. In addition to involving collaborators with content expertise, partnering with those who understand the policy environment and local context is critical.

Dr. Brownson has partnered with community members impacted by policies, City Council members, retired and current public health department officials, and a range of other former or current policymakers and practitioners to build strong research teams. He recommends taking a tailored approach to build a team that reflects the study objectives and policy-specific goals.

“ **If we’re working on a mental health policy study,** then I will look for someone who understands the complexities of the mental health system...on the studies for big P policy, I bring on board someone with formal policy training and someone working in the policy setting.

### Consider the challenge of collecting policy-relevant outcome data

Unlike clinical research where projects can rely on existing outcomes data in electronic medical records, policy implementation research in community-based settings is often challenged by a lack of existing data sets. Dr. Brownson describes that the lack of validated standard outcome measures is an ongoing challenge that he’s faced in this and several policy related projects, and one that other researchers should consider in designing policy implementation research. Researchers may need to factor in developing, psychometrically testing, or creatively considering other forms of measurement in order to measure policy-relevant outcomes.

“ **There’s definitely a challenge** and of course a clinician would say, ‘well, there are all these errors in the electronic medical record as well,’ but there’s not even anything parallel to that in public health practice....This makes it difficult to identify “gold standards” for a lot of the outcomes we’d like to be measuring, like use of an evidence-based policy or practice and organizational capacity for evidence-based decision making.

### Balance the comprehensiveness and rigor desired by academic researchers with participant incentive and burden

Policy implementation research must balance the comprehensiveness and rigor desired by academic researchers with partners’ motivations for participation. This study was originally proposed as a group randomized design but pivoted to a stepped wedge design with input from partners early on. This decision then required additional tradeoffs between sample size, power, and participant and research burden.

“ **Talking to our partners early on,** there was a strong interest in making sure everyone had the benefit of the intervention group...And so I think the other design issues that came into play were sort of the pragmatic ones around how many local health departments we could really handle, how many we could staff, how many of these courses we could pull off and what intervention period timeframe is reasonable for waves given the study design and nature of the intervention. And then the trade offs, ideally you’d have a large enough number...you might have eight data collection points, but of course that’s a big burden on people to be collecting data every time. In a group randomized design, we’d only have pre and post data collection. This impacts the research team, too, in being able to collect, manage, and analyze all the data.

## Ensure findings are disseminated back to partners and participants

In this study, the team provided local tailored reports for each local health department partner. In addition, they presented study findings at practitioner meetings, such as the conference for the National Association of County and City Health Officials, and also developed infographics and one-pagers to summarize their findings to be disseminated more broadly. Dr. Brownson highly recommends that efforts are taken to communicate findings back to partners in understandable and meaningful ways (following principles of [Designing for Dissemination](#)). He notes that dissemination can also be a way to improve subsequent research study practices by asking for feedback on what is particularly useful to partners and policymakers on what they'd like to see in future dissemination products.

## Additional Resources/Readings

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# Using Technology to Scale-Up an Occupational Sun Protection Policy Program



## Study details

<b>Principal investigator</b> Dr. David Buller, Senior Scientist & Director of Research at Klein Buendel		<b>NIH grant number and reporter link</b> <a href="#">R01CA210259</a>	<b>Project dates</b> Aug 1, 2019 – Jul 31, 2023
<b>Policy studied</b> State and organizational level workplace sun safety policies	<b>Stage of implementation</b> Adoption and implementation	<b>Implementation science theory/framework</b> RE-AIM	

## Study aims

**Aim 1:** Estimate the program reach (number and representativeness) and implementation rates (i.e., adoption of policies and delivery of education on occupational sun protection) achieved by the evidence-based occupational sun protection intervention, Sun Safe Workplaces (SSW), comparing in-person program delivery methods (SSW-IP) to a lower-cost dissemination method that utilizes Internet technology (SSW-T), i.e., virtual meetings, social networking, online training, and program materials, in a model of national distribution to public safety and public works industries.

**Aim 2:** Estimate the costs associated with the SSW-IP and SSW-T (i.e., intervention costs and induced employer costs) and compare the estimated program benefits (i.e., policy and education) to cost.

**Aim 3:** Estimate the effect and cost-effectiveness of SSW-IP and SSW-T in secondary outcomes of a) changes in workplace environments and procedures for sun safety and b) workers' sun safety practice.

## Study at a glance

This R01 study builds upon a pilot trial of Sun Safe Workplaces (SSW) with public employers in Colorado. SSW is an implementation strategy that includes tailored training and technical assistance to facilitate the adoption and implementation of organizational sun safe policies (small 'p' policies). Importantly, many states also have codified workplace safety policies that include employee sun protection; these policies were also collected and analyzed as part of the intervention. This study compared reach, implementation rates, and effectiveness - on a national scale - between an in-person intervention (SSW-IP) vs. a virtual intervention (SSW-T). The primary outcome of interest was cost effectiveness, to test whether the virtual intervention could be

This series of 'public goods' case examples was developed for the [Cancer Consortium for Implementation Science \(CCIS\)](#) to highlight NIH-funded policy implementation science studies and the key lessons learned in conducting this type of research. The cases presented demonstrate the many creative and unique ways that both big 'P' and little 'p' policies have been rigorously investigated to advance public health.

## Key policy implementation science lessons learned

1

Consider NIH goals and different institutes in writing a policy implementation study proposal

2

Collect and analyze small p policies (as applicable) for important context

3

Conduct readiness assessments and ensure local adaptations to ensure effective policy implementation strategies

4

Think about "what's in it for them" when bringing policy-relevant partners on board

delivered cost-effectively to an expanded group of worksites. This study uniquely highlighted a collection of small p policies to inform a tailored implementation strategy and the testing of an adaptation of an implementation strategy for national scale up.

## Key policy implementation science lessons

### Consider NIH goals and different institutes in writing a policy implementation study proposal

In presenting policy work to academic audiences, Dr. Buller noted frustration with ongoing resistance or consideration of policy as “secondary interest” unless there is clear focus on individual level health behavior change. He noted that policy adoption and implementation should be considered a *“legitimate outcome for the kinds of intervention and health promotion work that we do.”*

With this challenge in mind, Dr. Buller provided a few suggestions for successfully obtaining NIH funding for policy-related research:

- 1) Build a strong evidence-informed case for policy impact.
- 2) Stick to study designs and rationales (e.g., randomized pre-post test designs) that are familiar to NIH reviewers.
- 3) Shop the study idea and find NIH Institutes that are interested in policy implementation research (e.g., NIAAA, NCI, NIMH).

“ **If I can get a whole state department of transportation** to adopt a policy, I mean, in North Carolina, that’s 11,000 workers. That has a huge possibility of potential for (individual-level) impact.

### Collect and analyze small p policies (as applicable) for important context

The SSW intervention first collected and analyzed any relevant organizational and state policies for each study site as important context for implementation. Locating the organizational policies was often challenging because they were in Employee Handbooks, Safety Manuals, and/or across several organizational policy documents. State policies were also collected because they often facilitated the implementation of SSW and buy-in from the study sites.

“ **They [district managers] don’t run into as much resistance** among fellow employees or managers who they might otherwise run into resistance without the [state] policy...once the policy is there, it’s a communication about what the state sees as important.

### Conduct readiness assessments and ensure local adaptations to ensure effective policy implementation strategies

The SSW intervention teams developed a “readiness change” matrix before working with each participating site and then heavily adapted the intervention accordingly. These components allow for a tailored approach to *“meet them where they are.”* After analyzing both organizational and state policies, the study team tailored each intervention to incorporate the policies as training tools during the readiness assessment:

“ **We incorporate [relevant policies] into our intervention....** Then, when we’re communicating with them [study participants], we...know what they’re starting with. We give them a report to say...‘Here’s what you’re already doing in your policy that you might be able to easily make changes in, or here’s where the gaps are.’

This process required a dedicated ‘coach’ who intimately understood the local settings’ readiness and provided a tailored approach.

## Think about “*what’s in it for them*” when bringing policy-relevant partners on board

When connecting with partners in new sectors, Dr. Buller suggested that researchers first think about what they are offering to partners. He recommended that researchers have supporting data ready from similar jurisdictions or examples to show that there is potential for success in advancing policy implementation. This can foster confidence that “*there is something in it for them.*”



**I think you have to go into it,** not just thinking about what’s in it for you as the researcher, but what’s in it for them. These folks [partners], they want to help their industry. I think it’s important to be able to show them that you’ve worked with their industry or similar industries...So we could show them that we were sensitive to the work environments that we were likely to encounter.

## Additional Resources/Readings

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# Supporting Sustainable Positive Interactions in the Child Welfare System: The R<sup>3</sup> Supervisor Strategy



## Study details

<b>Principal investigator</b> Dr. Lisa Saldana Senior Research Scientist at the Oregon Social Learning Center		<b>NIH grant number and reporter link</b> <a href="#">R01DA040416</a>	<b>Project dates</b> Sep 15, 2015 – Jul 31, 2021
<b>Policy studied</b> Child Welfare System	<b>Stage of implementation</b> Implementation	<b>Implementation science theory/framework</b> Stages of Implementation Completion (SIC) and EPIS	

## Study aims

**Aim 1:** Examine the potential of R<sup>3</sup> to influence supervisor interactions with caseworkers and subsequent family outcomes.

**Aim 2:** Examine the impact of R<sup>3</sup> on organizational characteristics known to impact staff retention and the successful adoption of innovations such as climate, leadership, readiness, and citizenship.

**Aim 3:** Examine the potential for maintaining fidelity standards to the R<sup>3</sup> strategy as consultation and coaching are fully transferred to the system.

## Study at a glance

This study focused on testing an implementation strategy, the R<sup>3</sup> Supervisor Strategy—via a Hybrid Type II trial—of a public child welfare system (CWS) in the United States. The implementation strategy aimed to create multi-level and system-wide changes in the CWS via training, consultation, and fidelity-monitoring to supervisors who oversee caseworkers. This case uniquely highlighted the challenges of conducting policy implementation research in dynamic, real-world environments where political leadership (and with it, political will) changed and shifted priorities and support for the study.

This series of 'public goods' case examples was developed for the [Cancer Consortium for Implementation Science \(CCIS\)](#) to highlight NIH-funded policy implementation science studies and the key lessons learned in conducting this type of research. The cases presented demonstrate the many creative and unique ways that both big 'P' and little 'p' policies have been rigorously investigated to advance public health.

## Key policy implementation science lessons learned

1

Develop sustaining partnerships upfront to survive in changing political climates

2

Balance analytic rigor (and study designs) with partner needs

3

Consider blending implementation science frameworks to match the complexity of implementation strategies

4

Design implementation strategies that target multiple levels of influence

## Key policy implementation science lessons

### Develop sustaining partnerships upfront to survive in changing political climates

Policy implementation research is often subject to the dynamic nature of political leadership and political will. Being able to pivot and adapt was critical for this research team. Initial development of the R<sup>3</sup> Supervisor Strategy took place in partnership with and at the request of NYC child welfare system, but a change in administrations led to disinterest in the evaluation study. Next, a southern state became the original partner for this R01 study, but again, changing administrations required a sudden stop in the middle of the grant. As Dr. Saldana recalls, *“It was a pretty abrupt hard stop. It wasn’t like ‘okay we can sort of see how it goes.’ It was like, ‘we want you done by this date’ type of thing.”*

In hindsight, Dr. Saldana reflected that she would have developed strategic relationships with key partners (in addition to government leaders) in order to ensure sustainability of the project.

**“ I think it’s important to make sure** that too much of your implementation doesn’t hinge at the top because when the top changes, then it’s really hard to keep it [the research study]...I really missed the boat in terms of what are those key sustaining relationships in a system outside of maybe the leadership. So...if I would’ve had, maybe a really seasoned supervisor, who’s been there for 40 years, and everybody looks up to...who could have been a liaison to new leadership that could have been possibly helpful.

Learning from this experience, however, the next state that Dr. Saldana and her R<sup>3</sup> team entered sustained beyond the initial grant period.

### Balance analytic rigor (and study designs) with partner needs

Conducting policy implementation research with local government sites often requires compromises to make the study enticing given partners’ limited time and resources. Dr. Saldana noted that they elected for a randomized stepped wedge design, which was optimal for analytic rigor but also allowed local government participants to receive “the thing” (i.e., the R<sup>3</sup> Supervisor Strategy intervention).

**“ We were able to use a stepped wedge design** that for us, we knew was going to be able to provide that sort of analytic rigor that we needed, but for them, we were presenting it to them in terms of capacity and convenience...And we have really found that the stepped wedge or dynamic wait list design, which are very similar, that both of those are really useful when we’re working in environments where everybody has to get “the thing.”

### Consider blending implementation science frameworks to match the complexity of policy-relevant implementation strategies

Policy-relevant implementation strategies require a framework that considers the complexity of implementation in policy and community contexts. Dr. Saldana developed the [Stages of Implementation Completion \(SIC\)](#) model that guides researchers to consider implementation processes and milestones. As an author of SIC, she found that this framework paired well with the broader [EPIS \(Exploration, Preparation, Implementation, Sustainability\)](#) framework to aptly guide their understanding of ‘how’ the R<sup>3</sup> implementation was being implemented. Specifically, EPIS’ domain of “bridging factors” was particularly helpful in thinking about how the R<sup>3</sup> Supervisor Strategy linked the inner and outer contexts, and ultimately advanced implementation. She recommended that researchers consider pairing broader and more specific frameworks in this way to align with the complexity of policy work.

## Design implementation strategies that target multiple levels of influence

Policy implementation research inherently calls for targeting multiple levels of influence, particularly on levels beyond individual behavior change, which is traditionally the focus of public health research. Dr. Saldana reflected that if one wants to make a sustained impact, it is important to design implementation strategies that influence structural levels of change. She also noted that this type of work is time and labor intensive but necessary for policy work.



**I think one thing I've learned** is doing things at the policy level, it absolutely takes more time than just doing something at an individual agency level. That seems like it should be a no-brainer, but I really didn't think that through, in terms of all of the different layers of time that it would take.

## Additional Resources/Readings

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# Policy Implementation Research on Earmarked Taxes for Mental Health Services



## Study details

<b>Principal investigator</b> Dr. Jonathan Purtle Associate Professor at NYU School of Global Public Health		<b>NIH grant number and reporter link</b> <a href="#">R21MH125261</a>	<b>Project dates</b> Dec 1, 2020 – Nov 30, 2022
<b>Policy studied</b> Earmarked taxes for mental health services	<b>Stage of implementation</b> Pre-implementation/ Exploration	<b>Implementation science theory/framework</b> EPIS	

## Study aims

**Aim 1:** Identify all jurisdictions in the U.S. that have implemented earmarked taxes for mental health services and catalogue information about tax design.

**Aim 2:** Characterize county mental health agency leaders' experiences implementing earmarked taxes, understand the determinants of decisions about tax-funded services using the EPIS framework, and assess the acceptability and feasibility of different types of implementation strategies.

**Aim 3:** Develop a conceptual policy implementation framework to improve earmarked tax design, inform the selection of implementation strategies to increase the taxes' reach of EBPs, and disseminate the framework to relevant policy audiences.

## Study at a glance

Earmarked taxes — taxes where the revenue is flagged for specific activities — are a potential implementation strategy that could be used to provide funding for evidence-based public health practices. In this two-year exploratory study, the team focused on the landscape of earmarked taxes to fund mental health services. They worked to identify where earmarked taxes have been implemented throughout the U.S., understand barriers and facilitators to implementing earmarked taxes, and develop strategies to improve the implementation of such taxes. This case uniquely highlights the application of rigorous policy mapping and qualitative inquiry with policymakers to understand determinants of decisions about tax funded services.

This series of 'public goods' case examples was developed for the [Cancer Consortium for Implementation Science \(CCIS\)](#) to highlight NIH-funded policy implementation science studies and the key lessons learned in conducting this type of research. The cases presented demonstrate the many creative and unique ways that both big 'P' and little 'p' policies have been rigorously investigated to advance public health.

## Key policy implementation science lessons learned

1

Be conceptually clear about policy as “intervention” vs “implementation strategy”

2

Design policy implementation studies with NIH goals in mind

3

Be prepared to tackle low response rates when surveying policymakers

4

Apply an equity lens while knowing your audiences

## Key policy implementation science lessons

### Be conceptually clear about policy as “intervention” vs “implementation strategy”

This study focused on earmarked taxes *as an implementation strategy* to improve the implementation of mental health services through increased funding. This kind of conceptual clarity was noted as crucial to policy implementation work.

The study team published [a manuscript](#) to set the stage for how they are conceptualizing this implementation strategy and to provide a rationale for this R21 study. Conceptual clarity is important because the rest of the study design and analysis flows from whether a policy is the intervention itself, or an implementation strategy. Because this study was an exploratory grant, it also set the stage for future work on implementation strategies to test, improve, and evaluate the impacts of the use of earmarked taxes.

**“ I think that’s a challenge with policy-focused work and implementation science: What’s the evidence-based ‘thing’?”**

### Design policy implementation studies with NIH goals in mind

When writing policy implementation proposals to the NIH, it was important to consider how policy work fits within the goals of the target institute and NIH broadly. Dr. Purtle recommended that researchers: 1) anchor the study aims to an evidence or knowledge translation gap to avoid the misconception about it being advocacy work; 2) *“dedicate a little more real estate and application to educating [reviewers]”*, particularly for reviewers who may be less-informed and concerned about the rigor of common policy implementation science methods and statistical techniques, such as difference-in-differences analyses. He recommended that researchers prepare well-referenced rationales that demonstrate the wide application of such methods and techniques in other disciplines; and 3) clearly delineate the theoretical pathways linking policy to health outcomes. Since the causal link between policy adoption to population health outcomes likely requires long and often unknown time lags, Dr. Purtle recommended citing to existing literature that supports the theoretical case: *“based on studies x,y,z, we can say this policy would [be] beneficial...from a population health perspective.”*

### Be prepared to tackle low response rates when surveying policymakers

Policy implementation work involving policymakers poses unique challenges for recruitment and response rates because of the limited ‘universe’ of possible respondents with relevant expertise. Anticipating and planning for this concern upfront in grant proposals will help to address reviewers’ potential criticisms. For example, Dr. Purtle’s team compared their response rates to prior surveys of policymakers and tried to assess how responders and non-responders differ. Additional suggestions included developing partnerships with organizations to request partners’ support in endorsing data collection efforts, as well as including other forms of data, such as social media, where policymakers’ comments are publicly documented:

**“ Think about what you can observe instead of ask about.** So in a lot of my other work, we do news media content analysis, we analyze what legislators say on Twitter and Facebook about different issues to get a sense of how policymakers are thinking about different health issues. So, observe, instead of ask, whenever possible or in addition to asking. I think it’s hard to get strong responses from surveys from policy makers, but a lot of what they do and say is on the public record.

## Apply an equity lens while knowing your audiences

Understanding the potential equity impacts of policies is of utmost importance. Dr. Purtle noted that although equity was a central consideration in this R21 study (e.g., “*So what are the priority populations? Where are the locations of the direct service organizations that spend this money, and how is equity coming into play?*”), the term ‘equity’ can be perceived as polarizing with some partners or research participants and thus he may use terms such as “*distributions of benefits*” or other terms to get at the same ideas in nuanced ways, depending on the geopolitical location. In this way, Dr. Purtle recommends knowing ones’ audience: gaining a strong understanding of the local nuances and geopolitical perspectives, particularly during data collection efforts.

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## Additional Resources/Readings

- Purtle J, Stadnick NA. Earmarked taxes as a policy strategy to increase funding for behavioral health services. *Psychiatric Services* 2020;70(1):100-104. [doi.org/10.1176/appi.ps.201900332](https://doi.org/10.1176/appi.ps.201900332)
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# Using Differences in Perceived Legitimacy and Resident Compliance to Promote Fair and Effective Implementation of Smoke-Free Housing



## Study details

### Principal investigator

Dr. Andrew Plunk, Director of Outreach and Community Partnerships at Eastern Virginia Medical School

### NIH grant number and reporter link

[R37CA245716](#)

### Policy studied

Smoke-Free Housing (U.S. Department of Housing and Urban Development)

### Stage of implementation

Implementation

### Project dates

Aug 7, 2020 – Apr 30, 2025

## Implementation science theory/framework

Consolidated Framework for Implementation Research (CFIR) • Collaborative planning framework • Procedural legitimacy theory

## Study aims

**Aim 1:** Establish (1) who exhibits lower perceived legitimacy of Smoke-Free Housing (SFH), and under what circumstances, and (2) what property and organizational factors that differ between and within housing authorities could affect SFH implementation and resident compliance.

**Aim 2:** Test associations between perceived legitimacy, SFH implementation strategy, and several markers for SHS (fine particulate matter, airborne nicotine, and exhaled CO). They hypothesized that: (a) perceived legitimacy will be related to differences in SFH implementation, (b) differences in SFH implementation strategy will affect SFH compliance, as measured by SHS, and (c) low perceived legitimacy of SFH will mediate the impact of implementation strategy on SFH compliance.

**Aim 3:** Develop a scalable implementation strategy for SFH to improve resident compliance and perceived legitimacy. Community advisory boards will be used to inform this process to ensure that solutions are grounded in real-world experiences.

This series of 'public goods' case examples was developed for the [Cancer Consortium for Implementation Science \(CCIS\)](#) to highlight NIH-funded policy implementation science studies and the key lessons learned in conducting this type of research. The cases presented demonstrate the many creative and unique ways that both big 'P' and little 'p' policies have been rigorously investigated to advance public health.

## Key policy implementation science lessons learned

1

Evaluate health policies with an eye toward unintended consequences

2

Adapt and apply a 'package' of theories, models, and frameworks to guide policy implementation studies

3

Engage community in a way that engenders trust

## Study at a glance

The [U.S. Department of Housing and Urban Development \(HUD\) Smoke-Free Housing policy](#) required that "each public housing agency (PHA) must implement a "smoke-free" policy banning the use of prohibited tobacco products in all public housing living units, indoor common areas in public housing, and in PHA administrative office buildings." This policy was an unfunded mandate with limited guidance, leaving a wide range of policies that were implemented by individual housing agencies. In a previous HUD-funded study (2017), Dr. Plunk found that some versions of the

policy, particularly property-wide smoking bans, could lead to a range of unintended consequences, such as increased incidences of residents smoking in their homes. As a result, this NIH R37 study proposed to develop community-generated implementation strategies that would facilitate the implementation of the Smoke-Free Housing policy. This case uniquely highlights a rigorous Community Based Participatory Research (CBPR) approach to investigate *how* to design implementation strategies to enhance uptake of the policy in a non-punitive and community-engaged manner.

## Timeline



This NCI study was built upon an existing research study—titled, *\*Assessing the Impact of Smoke-Free Public Housing on Smoking Behavior, Environmental Tobacco Smoke, Third Hand Smoke, Other Tobacco Use, and Smoking-Related Disparities*—examining the Smoke-Free Housing policy funded by HUD. The earlier study identified that the policy did not improve air quality. The PI was awarded this current NCI R37 study that is actively engaging public housing residents to identify implementation strategies to promote effective uptake of the policy.

## Key policy implementation science lessons

### Evaluate health policies with an eye toward unintended consequences

As a public health policy, the Smoke-Free Housing mandate intended to decrease smoking and exposure to second-hand smoke in public housing; however, Dr. Plunk's HUD-funded evaluation revealed property-wide smoking bans and a high reliance on punitive measures to enforce adherence.

“When the policy went into effect, property managers started telling them [public housing residents] not to smoke outside the building anymore, they had to go off property. Well, they don't want to have anything to do with it and they're not going to walk across the property, so they just go in their apartments. Because of that, indoor smoking actually increased, which is kind of a perverse consequence of having a smoking ban.

Health policies often have unintended consequences or outcomes. Identifying these outcomes and implementation challenges were critical to the success of designing and obtaining the R37 study, which employs a community-engaged process to understand more effective implementation strategies to facilitate policy adherence.

### Adapt and apply a 'package' of theories, models, and frameworks to guide policy implementation studies

Since there are few policy-specific theories, models, and frameworks to guide policy implementation, Dr. Plunk recommended using a broad framework (e.g., [Consolidated Framework for Implementation Research, CFIR](#)) and then adapting more specific theories and models. This study applied a package of theories and frameworks to guide components of the inquiry. First, **CFIR** provided a comprehensive, overarching framework. Second, the **Collaborative Intervention Planning Framework**, which “brings together researchers and community stakeholders through the creation of a CAB to work on shared health concerns and direct the adaptation process.” Finally, **procedural legitimacy theory** aptly explained the phenomenon of the erosion and undermining of institutional trust and the resulting impact to policy adherence. In addition, the latter theory guided importance of residents seeing themselves as being in the same moral community with the public housing agencies. Combined, this 'package' allowed for a comprehensive understanding of how to inform the development of implementation strategies.

## Engage community in a way that engenders trust

Since the earlier study identified limited effectiveness of the Smoke-Free Housing policy, Dr. Plunk applied a community based participatory research (CBPR) approach to understand *why* the policy was failing and *how* strategies could lead to better implementation. A critical piece of this community-engaged process was continually engendering trust with public housing members.

“**And I think we’re not going to find anything out** [about why policies are not effective] unless we actually go talk to people and we do that in such a way that engenders trust. If we’re not doing that, we’re never going learn anything and then just be perpetually confused about why nothing ever works.

Even for those without formal training in CBPR or other community-engaged approaches, Dr. Plunk recommends engaging with a “*diverse group of folks, with respect to their voice...You need to engage people who will actively disagree with you.*” It is also recommended to be sensitive to power dynamics across community members, as well as between researchers and community members.

## Additional Resources/Readings

- Wray JA, Sheehan BE, Rees VW, Cooper D, Morgan E, Plunk A. A qualitative study of unfairness and distrust in Smoke-free Housing. *Am J Health Behav* 2022;30(5);798-809. doi: [10.5993/AJHB.45.5.1](https://doi.org/10.5993/AJHB.45.5.1)
- [Collaborative planning framework] Cabassa LJ, Druss B, Wang Y, Lewis-Fernandez R. Collaborative planning approach to inform the implementation of a healthcare manager intervention for Hispanics with serious mental illness: A study protocol. *Implement Sci* 2011; 6:80. <https://doi.org/10.1186/1748-5908-6-80>
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# Student Wellness Champions for Change: Engaging Student Leaders in Enhancing Wellness Policy Implementation through Participation and Advocacy



## Study details

<b>Principal investigator</b> Dr. Hannah Lane Medical Instructor Duke University		<b>NIH grant number and reporter link</b> <a href="#">F32DK115146</a>	<b>Project dates</b> Sep 1, 2017 – Aug 2, 2019
<b>Policy studied</b> Local school wellness policies (U.S. Department of Agriculture policy mandate)	<b>Stage of implementation</b> Implementation	<b>Implementation science theory/framework</b> RE-AIM	

## Study aims

**Aim 1:** Assess the extent to which involvement on student wellness teams improve students' individual health behaviors, weight status, health and public health literacy, and youth advocacy skills.

**Aim 2:** Assess the extent to which student wellness teams make environmental changes in their school. Additionally, the study aims to describe factors, including reach, adoption, implementation and maintenance, that are necessary to inform translation of this intervention strategy to diverse schools across Maryland and beyond.

## Training aims

**Aim 1:** Gain skills in cultural competency and health equity.

**Aim 2:** Assemble a mentoring and advisory team of scientists across disciplines (psychology, nutrition, communications, epidemiology, education).

**Aim 3:** Gain didactic training in multi-level modeling and mixed methods data analysis.

## Study at a glance

This NIDDK F32 (Ruth L. Kirschstein Postdoctoral Individual National Research Service Award) training grant provided an opportunity for Dr. Lane to obtain training and to evaluate an implementation strategy to facilitate implementation of the U.S. Department of Agriculture (USDA) local school wellness policy mandate (hereafter: wellness policies). The training grant was embedded within a larger USDA-funded cluster randomized controlled trial, Wellness Champions for Change. Wellness Champions for Change sought to assess the student-level impact of an intervention to train and provide technical assistance to teachers and students, and to enable them to form wellness teams that implement

This series of 'public goods' case examples was developed for the [Cancer Consortium for Implementation Science \(CCIS\)](#) to highlight NIH-funded policy implementation science studies and the key lessons learned in conducting this type of research. The cases presented demonstrate the many creative and unique ways that both big 'P' and little 'p' policies have been rigorously investigated to advance public health.

## Key policy implementation science lessons learned

1

Obtain mentorship about how to build diverse academic-community partnerships

2

Balance the collection of rigorous policy-relevant data in community settings with study team resources and participant burden

3

Conduct robust readiness assessments before testing implementation strategies

4

Apply an equity lens to understand "successful" policy implementation

policies. This F32 added an enhanced RE-AIM-focused implementation evaluation to this trial in order to describe the training and technical assistance as an implementation strategy. This case uniquely highlights the testing of evidence-based implementation strategies in diverse school settings.

For the training component, several topics, including policy, systems and environmental change (PSE) approaches and mixed methods were included. Some examples of trainings that Dr. Lane found helpful included: 1) **Mixed Methods training at the University of Michigan**, 2) a Pathways to Prevention (P2P) **NIH training** on evaluating natural experiments in obesity; and 3) **Research Talk's Qualitative Research Summer Institute**, for example, the rapid analysis and implementation data analysis trainings; and 4) lastly, participating in working meetings with collaborators involved in various PSE change approaches.

## Key policy implementation science lessons

### Obtain mentorship about how to build diverse academic-community partnerships

Building strong academic-community partnerships is an essential activity for policy implementation researchers. Dr. Lane credits mentors from her doctoral and post-doctoral training, who modeled how to engage partners effectively. Through these mentors, she was able to connect to a diverse range of partners, including community advisory boards, state education department officials, state health officials, non-profit organizations (e.g., Shape America), and local school district officials, including those in neighboring cities.

**“ I would say that...a key thing that one must be able to do in policy implementation work...is to engage and bring the right people to the right table. I think the only way to really get at that skill is through mentorship.**

Notably, Dr. Lane reflected that not all research trainees have equal opportunities to access mentors and there is a need for academic institutions to formerly support mentoring networks and other mentoring opportunities.

### Balance the collection of rigorous policy-relevant data in community settings with study team resources and participant burden

Unlike in healthcare settings where data may sit in existing repositories (e.g., electronic medical records), gathering policy-relevant data in community settings can require labor-intensive primary data collection. To assess effectiveness of Wellness Champions for Change, the parent RCT involved extensive student-level quantitative data collection, including height, weight, accelerometers, and surveys. The school-level data collection, which was expanded through Dr. Lane's F32 award, involved environmental audits, observational data on curriculum fidelity, and administrator surveys. The study team also collected qualitative data, including pre- and post- student interviews and focus groups, and implementation process data, such as communications records. In hindsight, Dr. Lane noted this was overwhelming for the study team and burdensome for busy school professionals; many of these organizational and process measurements could have been streamlined and consolidated. For example, multiple instruments could have been shortened and combined into one, or they could have asked multiple professionals at each school district to complete together based on their area of expertise.

### Conduct robust readiness assessments before testing implementation strategies

A key challenge that Dr. Lane encountered in her study is that schools seem to vary in their starting points—that is, some may have been more 'ready' than others for the changes promoted through the intervention. Dr. Lane reflected on the importance of considering readiness first so that strategies can be tailored and adapted to *“meet schools where they are”* in order to facilitate more successful implementation.

**“ We launch into these implementation strategies when it is not a one size fits all. It's not prescriptive, like 'training and technical assistance to build teams' and that'll do it. Some schools, that's not going to work for them.**

## Apply an equity lens to understand “successful” policy implementation

Closely related to the lesson learned about conducting readiness assessments, Dr. Lane asserted the need for researchers to “take a step back” and more sincerely engage the communities that this research is intended to benefit. This is particularly important given drastically changing organizational climates during the COVID-pandemic. In doing so, she noted that researchers could first gain an understanding of the historical and structural causes of existing implementation inequities; and secondly, better understand how organizational partners may define “successful” policy implementation, driven by the perspectives of those impacted by the policy.

“**The majority of the evidence for these practices has...** also not been examined through an equity lens. And so, the policies themselves just may not be what those schools desire or need or would prioritize. And then in addition to that, the way that we define what a successful implementation of those policies is also may not be what those schools desire or need or could achieve ever. I think we...also need to do more...listening and engaging with school folks, especially post COVID where just everyone is stretched thin.

## Additional Resources/Readings

- Lane, HG, Deitch R, Wang Y, et al. “Wellness Champions for Change,” a multi-level intervention to improve school-level implementation of local wellness policies: Study protocol for a cluster randomized trial. *Contemp Clin Trials* 2018;(75): 29-39. DOI: [10.1016/j.cct.2018.10.008](https://doi.org/10.1016/j.cct.2018.10.008)
- Lane HG, Driessen R, Campbell K, et al. Development of the PEA-PODS (Perceptions of the Environment and Patterns of Diet at School) survey for students. *Prev Chronic Dis.*, 2018 June; 15(88). DOI: [10.5888/pcd15.170561](https://doi.org/10.5888/pcd15.170561)
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- Kuhn AP, Kim E, Lane HG, et al. Associations between elementary and middle school teachers’ physical activity promoting practices and teacher- and school-level factors. *Int J Behav Nutr Phys Act* 2021; 18(1):66. DOI: [10.1186/s12966-021-01129-4](https://doi.org/10.1186/s12966-021-01129-4)

# Investigating the Payer Role in the Implementation of EBP in the Public Sector



## Study details

<b>Principal investigator</b> Dr. Rebecca Stewart Assistant Professor at the University of Pennsylvania	<b>NIH grant number and reporter link</b> <a href="#">F32MH103960</a>	<b>Project dates</b> Nov 16, 2014 – Nov 15, 2017
<b>Policy studied</b> Incentives to increase evidence-based mental health practices	<b>Stage of implementation</b> Implementation	<b>Implementation science theory/framework</b> Diffusion of Innovations

This series of 'public goods' case examples was developed for the [Cancer Consortium for Implementation Science \(CCIS\)](#) to highlight NIH-funded policy implementation science studies and the key lessons learned in conducting this type of research. The cases presented demonstrate the many creative and unique ways that both big 'P' and little 'p' policies have been rigorously investigated to advance public health.

## Study aims

**Aim 1:** Systematically identify, document, and describe incentives employed by payers in the public mental health system to increase the use of evidence-based practices among community mental health providers.

**Aim 2:** Examine potential barriers and facilitators to the implementation of incentives proposed in the literature.

## Training aims

**Aim 1:** Develop expertise in implementation science and payer incentives in community mental health and broader fields.

**Aim 2:** Gain relevant experience in the design, methods, and analyses appropriate for the proposed project and future research in implementation science and community mental health.

**Aim 3:** Establish a network of collaborative and cross-disciplinary relationships to assist in current and future research endeavors.

## Study at a glance

This F32 grant built upon a strong academic-community partnership with policymakers at the City of Philadelphia and researchers in Community Psychology. For the study portion, financial incentives used by payers were considered the implementation strategies that facilitated the implementation of evidence-based practices to improve mental health care. This study sought to understand the landscape of different financial incentives used by payers across the country (a state-by-state comparison was desired by policymakers), and then understand facilitators and barriers to these strategies, as perceived by policymakers. In doing so, the study seeks to inform how policy change can address the "chronic underinvestment and underfinancing of behavioral health," which is a large structural problem to tackle: "it's a lot easier to train clinicians and look at the outcomes of that than change these huge structural systemic barriers to quality of care."

## Key policy implementation science lessons learned

1

Seek mentors in policy implementation

2

Build early academic-community partnerships that center partners' needs

3

Be prepared to continuously demonstrate your value

4

Disseminate study findings in a format that holds "currency" with partners



## Key policy implementation science lessons

### Seek mentors in policy implementation

Despite policy implementation being a “sexy” topic, there were few formal training opportunities when this F32 grant started in 2014 and still the topic is not widely taught in academic settings. Dr. Stewart obtained policy implementation training from mentors at the [University of Pennsylvania Center for Mental Health](#), which specializes in research built upon community-academic partnerships (for example, with policymakers in the City of Philadelphia). In this capacity, she learned both about policy work and the importance of partnerships in conducting rigorous, policy-relevant research.

“**Everything that I’ve learned about policy** has been on the ground, working really closely with policymakers. The only reason I know anything about this is because I’ve been lucky to have this community academic partnership, where we work so closely with policy makers...So watching them [mentors] build relationships, watching them negotiate different goals between what the city [policymakers] wants and what we want...So I would say it was mostly mentorship and on-the-ground learning.

### Build early academic-community partnerships that center partners’ needs

Forging strong academic-community partnerships is critical to successful policy implementation work but requires patience, continuous collaboration, and importantly, centering the partners’ needs. Dr. Stewart frequently trains other researchers and noted the challenges that new researchers may have given the time and resources that partnership development requires.

“**I would say bring your partners in as early as possible**, but it’s hard because early researchers have to, a lot of times, build their relationships. I think what’s important first and foremost is to demonstrate your value as early as possible. Often I see that junior people think that community partners are just here to service their laboratories or research agenda instead of thinking of it as, ‘what can I give you?’

In the same line, research designs should also balance the partners’ needs. Dr. Stewart recalled advice from her mentor, who recommended that her policy implementation study designs be *“as rigorous as your community partner will allow.”*

### Be prepared to continuously demonstrate your value

When working with policymakers and community partners, there is often turnover in leadership and staffing, particularly since COVID-19, requiring that researchers continuously forge new partnerships with policymakers. While this can be *“emotionally taxing,”* it is often necessary in this field to continue to conduct policy-relevant research. Dr. Stewart recommended that researchers be prepared to constantly demonstrate their value to new policymakers, leaders, and other partners.

### Disseminate study findings in a format that holds “currency” with partners

While academic researchers focus on publications in peer-reviewed journals, policy implementation researchers need to be skilled in disseminating products that speak to policymakers and community leaders. Often these products are brief (e.g., one-page infographics) “distilled” versions that highlight the policy and practice implications. For example, for this F32 study, state partners requested a one-page brief that summarized how states were financing incentives to improve quality of care in mental health treatment: *“I think everyone is working in their silos and wants to know if other states and counties have figured it out.”* Other policymakers have asked her for 1-3 PowerPoint slides that summarize the findings. In this way, Dr. Stewart suggested that researchers should first ask their partners what types of products are desired. Offering this form of dissemination can also enhance recruitment because potential participants may be more inclined to participate if they know they will receive valuable data to inform their policymaking.

## Additional Resources/Readings

- Stewart R, Marcus SC, Hadley TR, Hepburn B, & Mandell DS. State adoption of incentives to promote evidence-based practices in behavioral health. *Psychiatr Serv* 2018;69(6):685-688. doi: [10.1176/appi.ps.201700508](https://doi.org/10.1176/appi.ps.201700508).
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# Appendix A: Overview of Methodological Approach

Case examples were identified via a systematic process and a multi-pronged approach. To identify potential cases, we conducted NIH RePORTER searches and a PubMed search for big P studies to crosswalk against the NIH RePORTER searches.

- **NIH RePORTER search:** We searched NIH RePORTER for all Dissemination and Implementation (D&I) Research in Health Program Announcements (PARs) within the past 10 years (2012-2022) for both big P and small p funded studies (see additional details below).
- **PubMed search:** PubMed was searched for U.S.-based papers published in the last 10 years that included the terms “policy OR policies OR law\* OR legislation OR tax OR ordinance OR regulation” AND “implementation” in the title and/or abstract. Of the 3,110 records returned, 20 met our criterion of “policy” and “implementation” and were funded by NIH (see additional details below).

The study team reviewed the final list of cases together and discussed potential cases and a ‘backup’ list of cases. We discussed each cases’ policy (big P or little p) and field, type of funding mechanism (e.g, R21 vs R01s), NIH Institute (e.g., NIMH, NCI), the type of setting and study design, and the overall approach, to create a purposive case sampling list. We aimed for diversity of investigators (junior to senior) as well as the research study’s stage of the policy implementation lifecycle and research focus, as our goal was to include a range of cases that showcased variety across these different areas.

We reached out to investigators of identified studies via email invitation. Our initial goal was to include 10 investigators in the study; we succeeded in completing 7 key informant interviews.

Once our key informants were identified, we conducted background research to pull their project narrative from NIH RePORTER as well as published peer-reviewed manuscripts, reports, conference presentations, and other relevant material (e.g., government reports, websites, etc.). We developed a profile for each project to summarize the policy “intervention” being studied, the jurisdiction where the policy was implemented, the study period, the timeline for implementation, the study design, and key research questions and outcomes. A semi-structured interview guide was developed and adapted for each key informant to glean perspectives and lessons learned in conducting policy implementation research; for example, what worked, what challenges were encountered, and recommendations of best practices. The focus of the interviews was less about outcomes of the research and more about the process of conducting policy IS research (e.g., study designs, challenges with conducting this type of work, lessons learned, etc.).

This project was deemed to be ‘Not Human Subjects Research’ by the Harvard University Institutional Review Board where the CCIS Policy Action Workgroup chair is based.

**Study Search Details:** As described earlier, we conducted NIH RePORTER searches and a PubMed search for big P studies to crosswalk against the NIH RePORTER searches.

- **NIH RePORTER search details:** NIH RePORTER was searched for all Dissemination and Implementation (D&I) Research in Health Program Announcements (PARs) from 2012-2022 for both big P and small p funded studies. Of the 110 funded studies that mentioned ‘policy’ or a related term (policy, policies, law, legal, legislation, ordinance, statute, regulation, regulatory, code, rule) in the abstract or title, 16 (14.5%) were studies designed to understand factors affecting policy implementation, understand the mechanisms of implementation, or test strategies to improve policy implementation, and were included in our sample of potential case examples.
- **PubMed search details:** PubMed was searched for U.S.-based papers published in the last 10 years that included the terms “policy OR policies OR law\* OR legislation OR tax OR ordinance OR regulation” AND “implementation” in the title and/or abstract. Of the 3,110 records returned, 20 met our criterion of “policy” and “implementation.” 506 (16.3%) were studies of the impact or effects of a given policy on a particular outcome and not studies of policy implementation; the remaining studies included commentaries, protocols, and other studies related to policy and implementation but not on point. In nearly all cases, the manuscript authors considered the fact that the policy took effect as equivalent to it being implemented (and referred to it as a study of policy implementation).



**Interview Details:** An interview guide (see [Appendix B](#)) was developed and reviewed by study team members. Due to time constraints, we piloted the guide and received feedback on questions from our first case example, [Dr. Brownson](#), a renowned expert in policy IS and implementations science broadly. Revisions were made to the guide following Dr. Brownson’s case and each guide was tailored to cases’ unique features. Interviewers reviewed the NIH RePORTER record for each case and familiarized themselves with related study publications prior to interviews. Each interview was conducted via Zoom by one of the study investigators with a notetaker. All interviews were digitally recorded and professionally transcribed using Temi.com (an AI transcription service). Study team members reviewed notes, initial impressions, and emergent findings after each interview.

**Case and Report Development:** Study team members individually reviewed transcripts and identified key lessons learned in Word; we then met to iteratively discuss and refine lessons learned from each interview. Each case example was drafted by a lead team member, revised by other team members, and then sent to the respective investigator for review and approval. For the full report, study team members met to discuss lessons learned and themes from each case and created an Excel matrix to document cross-cutting themes. These were iteratively refined and discussed over several team meetings and multiple drafts of findings.

Inclusion Criteria for Studies		
Inclusion	Explanation	Notes
<b>Policy</b>	Study of implementation of a specific policy(ies) in a government jurisdiction or organization. This is a MUST	Defining policy broadly to include law, legislation, regulation, taxes, incentives eg SNAP food bucks, guidelines eg DGA
<b>IS Protocol</b>	IS Protocol from NIH-funded study	
<b>IS TMF</b>	Clearly mentions IS theory/ methods/frameworks	
<b>Implementation Strategies</b>	Testing implementation strategies	
<b>U.S.-based study</b>	Study is conducted in the U.S.	

Exclusion Criteria for Studies	
Exclusion	Explanation
<b>Not policy</b>	Not a study of a specific public policy(ies)
<b>Policy impact (not IS) study</b>	May include secondary data analyses of the impact or association of a given policy on outcomes OR a qualitative study of factors influencing policy implementation without reference to IS TMFs and/or strategies
<b>Policy effects (not IS) study</b>	
<b>Review Paper</b>	
<b>Non-U.S.</b>	



# Appendix B: Interview Guide

PI NAME, INTERVIEW DATE	
PROJECT START DATE	
PROJECT TITLE AND FUNDING OPPORTUNITY	
POLICY STUDIED	
STUDY OBJECTIVES	
STAGE OF POLICY IMPLEMENTATION	
STUDY DESIGN	
TMF USED	
OUTCOMES	
RELEVANT PUBLICATIONS	
AUDIO RECORDING ID	
INTERVIEWER	
NOTETAKER	

## INTRODUCTORY QUESTIONS

1. To start, could you tell me about your current role at [university, etc.] and your areas of interest or research?
  - 1.1 How did you become interested or involved in [topic, e.g., cancer research]?
  - 1.2 Tell us about your educational background. Did you study public policy, policy implementation or a related field formally?
  - 1.3 Who on your research team has training or expertise with public policy or policy implementation?
2. As we described in the email, we are interested to learn more about your project titled, [XYZ]. The research objectives for your project state [fill here]. I'm interested in discussing objective [XYZ] that focus more specifically on the [adoption/implementation/sustainability] aspects of the policy. Can you tell me about how you settled on these specific aims/objectives?
  - 2.1 How did your objectives evolve while you were planning the study?
  - 2.2 Was anyone else involved in refining these objectives?



## TIMELINE

*We'd first like to learn a little bit about the timeline of events for both the policy that you're studying, as well as the timeline for your research study.*

3. We understand that you studied [XYZ policy name]. Can you walk us through the timeline of the policy [adoption/implementation] and the research study timeframe?
  - 3.1 When was policy adopted, effective dates [as applicable], implementation phase?
  - 3.2 When was your study funded, data collection phase, analysis
  - 3.3 Are there any other significant dates over the course of policy implementation or study processes?
4. What, if any, challenges have you encountered with these timelines?
  - 4.1 How, if at all, did these challenges impact your research timeline e.g., design, staffing, funding issues
  - 4.2 What, if any, lessons learned arose from navigating the policy timeline with your research timeline?

## RESEARCH PARTNERSHIPS

5. Did you engage with community, government, or other partners *in the development* or design of the study?
  - 5.1 [If applicable] How did you identify partnerships with community and/or government partners?
  - 5.2 When did you first reach out to partners? Please tell us about this process.
6. Did you engage with community, government, or other partners *in conducting* the study?
  - 6.1 How did working with partners advance your project?
  - 6.2 What were some of the challenges of working with partners (e.g., politics)?
7. What lessons learned do you have from working with community and/or government partners?

## THEORIES, MODELS AND FRAMEWORKS

*Next, I'd like to ask you about theories, models, and frameworks.*

8. Could you tell us more about the use of [insert type of TMF used]; how did you decide on this particular TMF?
  - 8.1 How was this suitable for your design?
  - 8.2 In what ways, if at all, have you had to adapt the TMF or add in additional TMF as the study proceeded?

## STUDY DESIGN, METHODS AND OUTCOMES

*Next, I'd like to ask you about the study design, methods and outcomes*

9. I see that you employed an [xyz (e.g., retrospective, quasi-experimental mixed methods)] study design. Can you tell us more about the early stages of study design?



**9.1** Who was engaged in study design discussions and decisions?

**9.2** [If applicable – qual] How did you decide to employ rapid qual methods/analysis vs traditional qual methods/analysis?

**9.3** What, if any, were lessons learned about study design [after/in the process of] conducting the study?

**10.** Did your analysis follow a proposed statistical analysis/qual analysis plan, or did it evolve as the study progressed? If it deviated, what were the reasons for the changes?

**11.** [As applicable] Can you tell us more about how you identified [xyz health] outcomes?

**12.** [As applicable] Can you tell us about how you identified [xyz adoption/implementation] outcomes?

**12.1** Were there any barriers to data collection?

**13.** Was a cost-related analysis [considered or] conducted? [specify cost-effectiveness vs other]

**13.1** To what extent did it consider the cost incurred, adjusted costs?

## SUSTAINABILITY AND DISSEMINATION

*Next, we have some questions about [sustainability and] dissemination.*

**14.** [If applicable] I see that you're measuring [xyz – to address sustainability] can you tell us more about why this was included?

**15.** [If applicable] Do you have plans to, or are you currently measuring, longer-term study outcomes or impacts?

**16.** [If applicable] In what ways, if any, were you able to see if the policy's intended impacts will be sustainable?

**17.** We see that you've published [xyz, as we've discussed]. Are there any other dissemination products that we've missed (e.g., grey paper).

**17.1.** In what other ways did you/do you plan to disseminate your findings? (e.g., manuscript, webinar, etc)

**17.2.** [If applicable] Did you partner with any community groups/government to disseminate findings?

## EQUITY-FOCUSED QUESTIONS

Ask these questions for studies that explicitly call out an equity focus in the NIH reporter abstract or in peer-reviewed work.

*We noticed that your study [e.g., mentioned equity-focus in any way, used equity TMF, targeted a historically disadvantaged population, discussed equitable implementation].*

**18.** Can you tell us about your process of developing equity-focused research questions?

**19.** In working with [xyz 'historically disadvantaged group' as identified] to what extent, if at all, did you consider the sites/stakeholders' resources or strategies to overcome implementation barriers?

**20.** Were key actors involved in your study to help develop equity-sensitive recommendations?

**21.** To what extent was fidelity measured with a specific consideration for the historically disadvantaged populations' adherence to the policy?



