Building Pharmacy's Sustainable Impact on Patient-Centered & Community-Based Outcomes: Lessons Learned & Future Directions

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Learning Objectives

- Identify key challenges to creating sustainable change in pharmacist practice behaviors to improve patient-centered and community-based outcomes.
- Describe new opportunities to facilitate pharmacist practice behavior change to improve patient-centered and community-based outcomes.
- Analyze different approaches to improve the sustainability of pharmacist practice behavior change to improve patient-centered and community-based outcomes.

Outline

- Definitions
- Policy-Evaluation- Practice (PEP)
- CPA and Regulation Models of PEP
- Innovation Initiation
- Innovation Implementation
- Innovation Evaluation
- Innovation Sustainability
- Discussion: Challenges and Future

Definition: Patient-Centered Care

- An individual's specific health needs and desired health outcomes as drivers of healthcare decisions and quality measurements.
- Patients-providers as partners.
- Holistic approach to integrating patient's emotional, mental, spiritual, social, and financial perspective.

Definition: Community-based Outcomes

- Population-based outcomes: measures of service delivery optimization and clinical outcomes for a community population. Examples: access to preventive services, access to treatment services, frequency of overdoses, suicides, hospitalizations, etc.

Collaborative Practice Agreements (CPAs)

- Pharmacy practice regulation allows CPAs to be created that formalizes a relationship between a pharmacist and another healthcare provider to perform specific patient care services that are beyond the pharmacist's typical scope of services.
- CPAs are signed and dated by both parties and kept with both parties.

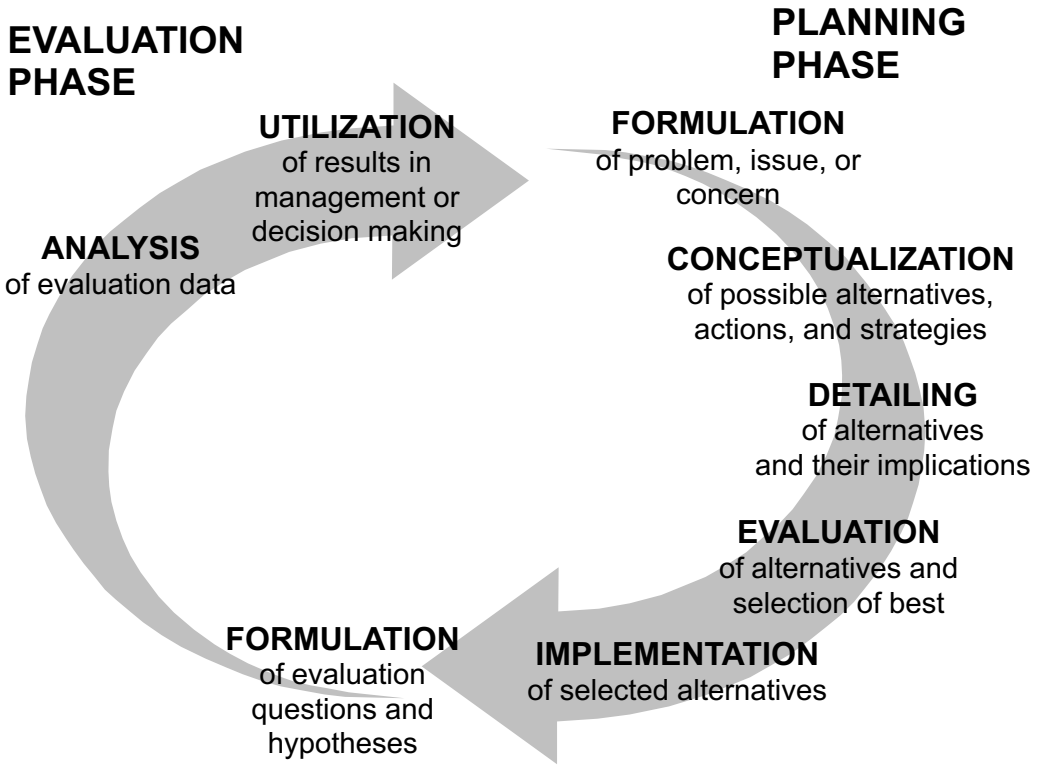
Standing Protocol

- Pharmacy practice regulation allows a more practice protocol to exist that does not require an existing pharmacist-patient relationship.
- Naloxone prescribing by pharmacists to individuals on opioid prescriptions.

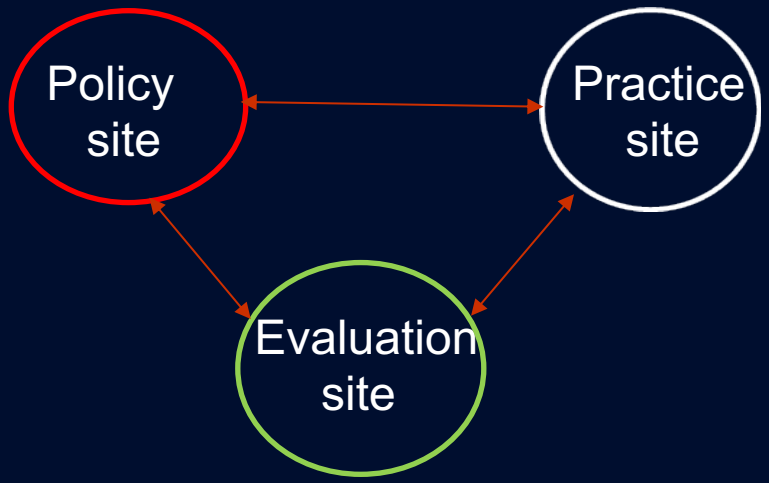
Regulations

- Public health regulation and guidelines yield professional acts that are written in language that is:
  - clear
  - precise
  - enforceable
  - measureable
  - sustainable

The Planning-Evaluation Cycle



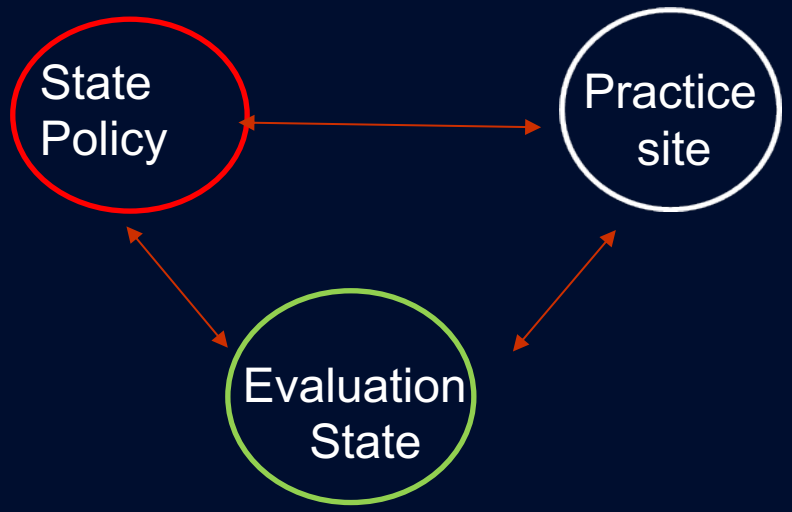
PEP Process: CPA initiation Model A



x N

N= number of sites needed to convert to for broad state implementation and regulation

PEP Process: Regulation Initiation Model B



Policy- Evaluation- Practice (PEP)

- For purposes of presentation, we will focus on:
  - Policy related to public health regulations, specifically those in the pharmacy practice act (and their guidelines), Collaborative Practice Agreements (CPA) related to pharmacist activities, and standing protocols
  - Pharmacy practice service innovation (related to the regulations, CPAs, standing protocols)
  - Evaluation/research related to pharmacy practice innovation

PEP Initiation: Questions

- To what extent did research inform the initial regulation or CPA?
- What initial risks are considered reasonable to initiate a policy without evidence?
- What is an appropriate level of evidence to support the initiation of a policy?
- What are the patient-centered and community outcomes to be achieved by the practice innovation?

Thinking about innovation initiation more . . .

- Using concepts from multiple health promotion and planning model[1-4], does the policy launch off from collected info on:
- Social assessment: perceived health, social, quality of life needs of population
- Epidemiologic assessment: Identify risk factors contributing to problems identified in social assessment; frequency of problems, and outcomes of problem; greatest problems for the community; who will receive the program?; what health benefit should the population receive?; how much of that benefit should be achieved?

Thinking about innovation initiation more . . .

- Behavioral and Environmental Assessment: Focus on behaviors and environmental influences of importance and that can change from multiple perspectives
- Educational and Ecological assessment:
  - Predisposing factors- factors that precede the behavior and motivate behavior; knowledge and beliefs
  - Enabling factors- enable the behavior
  - Reinforcing factors- consequences of the behavior that provide positive or negative reinforcement
- Administrative and Policy Assessment: Logistics of innovation, determine resources, facilitators, barriers, and consistent with existing policies/regulations.

Background: LAIA & Value

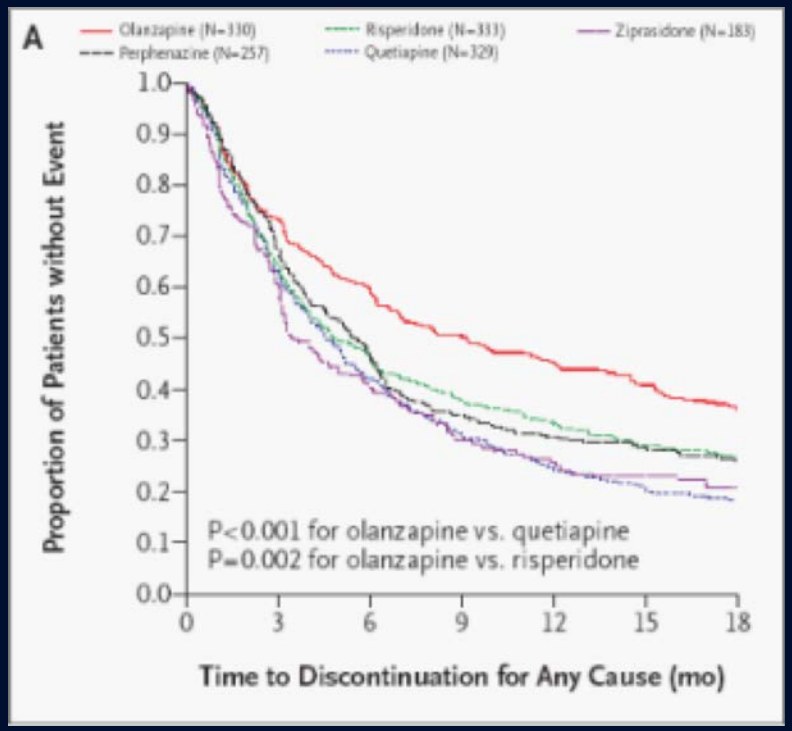
- Antipsychotics are the cornerstone pharmacotherapy for schizophrenia and are used in the treatment of several other psychiatric illnesses (e.g., bipolar disorder). When these individuals are treated with oral antipsychotics, treatment non-adherence occurs at a high rate.
- Long-acting antipsychotic treatments through intra-muscular injections is associated with lower rates of psychotic exacerbation and psychiatric re-hospitalizations. Injections help improve patient adherence to therapies.

Background: The Problem

- By the end of the 2016 calendar year, there were approximately 1,700 individuals in the state of Connecticut receiving long-acting injectable antipsychotic (LAIA) treatments (an estimated 4.7% of all patients with schizophrenia in the state).
- When the rate of LAIA use in the state is discussed with mental health providers, low rates of use and lack of access to injection services are key issues raised.

Issues of Non Adherence

- Clinical Antipsychotics Trial of Intervention Effectiveness (CATIE)
  - 1493 subjects
  - Treated with 1 of 5 oral antipsychotics
  - Primary outcome: discontinuation for any reason
- Results:
  - High rates of discontinuation (74% before 18 months)



Lieberman JA, et al. NEJM 2005;353:1209–23.

Background: Pharmacists

- Community pharmacists have been identifying new and varied services to provide a higher level of care for their patients. The impact of community pharmacists providing these services has been seen in several research papers and reviews over the last several decades.
- Community pharmacists, due to their accessibility in the community, are well positioned to administer the LAIA to enhance patient convenience of where the injection is given, further promoting medication adherence.

Does innovation emerge from planning framework?

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Model A- Long-Acting Injectable CPA[5] in CT

- CT allows pharmacists to administer LAIA injections and naltrexone injection via signed Collaborative Practice Agreement (CPA) between pharmacist and prescriber.
- The CPA specifies:
  - Collaborating pharmacists must complete necessary injection and disease state training before permitted to provide LAIA administration services.
  - Certification and/or training in: (1) CPR, (2) first aid, (3) vaccine administration, (4) OSHA, (5) Blood-borne pathogen, (6) Completed manufacturer specific training for each product, (7) minimum of 2 hrs of annual CE credits focused on antipsychotics and/or disease states that are FDA approved for LAIA use, & (8) trained on proper procedures for documentation and physician follow-up.

Model A Initiation (Cont.)

- Checklist of drugs MD allows RPh to administer
- Specific language about not being authorized to initiate, modify, monitor, refill, or discontinue drug therapy not described in protocol, or order any lab tests for referred patients.
- Specific procedures: Examples:
  - May administer LAIA therapy to patients with new prescription for any approved protocol antipsychotics. “Injections may be given by pharmacist” written on prescription.
  - Physician or designate of physician should obtain signed consent from patient and schedule appointment to receive first injection from collaborating pharmacist. Copy of CPA kept in patient’s medical record.

Model A Initiation (Cont.)

- Scheduling of appt and keeping staff up-to-date on LAIA appts.
- Patient information verified prior to injection;
- Injection procedures specifically outlined
- 15-minute waiting period to observe adverse events
- Specific procedures on how to manage adverse events
- Documentation on a specific encounter form, copy sent to prescriber
- Missed appointments, notification to prescriber, develop an action plan
- File CPA at site and made available to Drug Control

Model B Initiation
105 CMR 700.004[6]

- MA legislation supporting pharmacists administering behavioral health and substance use disorder medications. Guidelines are still pending. Regulation proposes that “a pharmacist or pharmacy intern is authorized to dispense by administration FDA approved mental health or substance use disorder treatment drugs to person 18 years or older provided that:

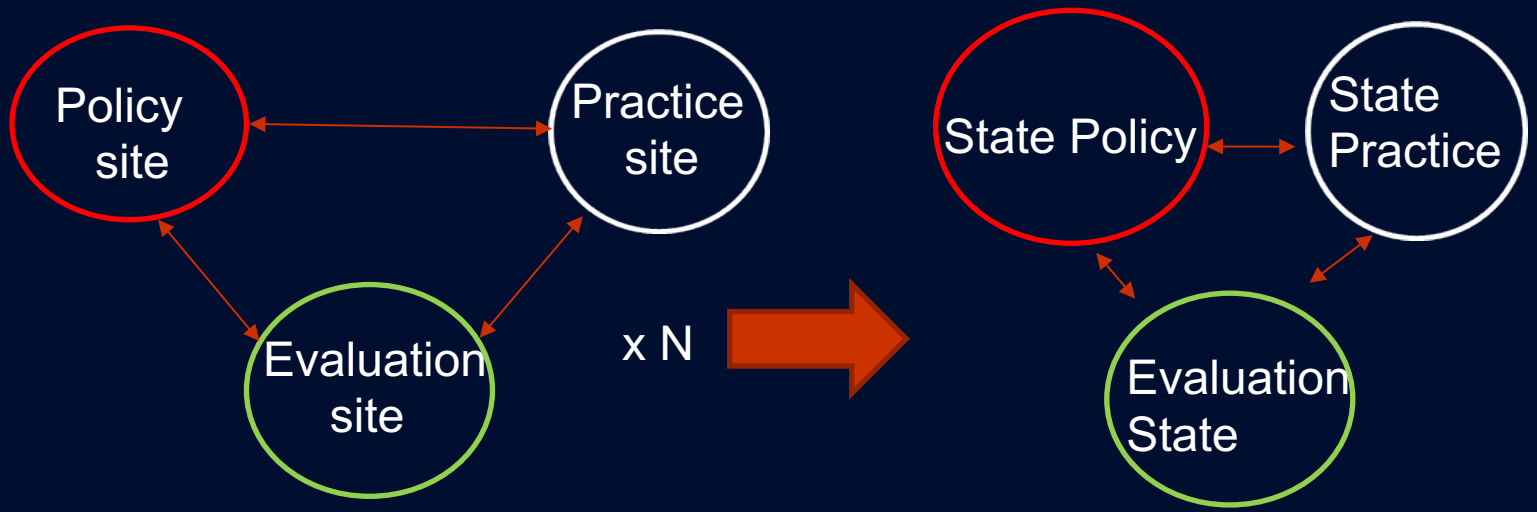
Model B Initiation (Cont.)

- (a) Pharmacist or pharmacy intern is authorized to dispense controlled substances in accordance with MGL c112;
- (b) Such administration is conducted pursuant to a valid prescription;
- (c) Such dose is not the first dose of such agent the person has received;
- (d) Such prescription is subject to reassessment by the prescriber at appropriate intervals as determined by such prescriber; and
- (e) Such activity is conducted in accordance with guidelines adopted by the Department, which shall include, but not limited to, requirements for:

Model B Initiation (Cont.)

- 1. Specific drugs permitted to be administered pursuant to this section;
- (2) Training specified and maintenance of competency;
- (3) Pre-administration patient counseling;
- (4) Dosing and administration of the medicines only in accordance with manufacturer approved labeling;
- (5) Administration of medication, including administration of controlled substances as necessary for the management of medical emergencies;
- (6) Record keeping; and
- (7) Reporting of adverse events

PEP Framework: CPA Implementation-Evaluation



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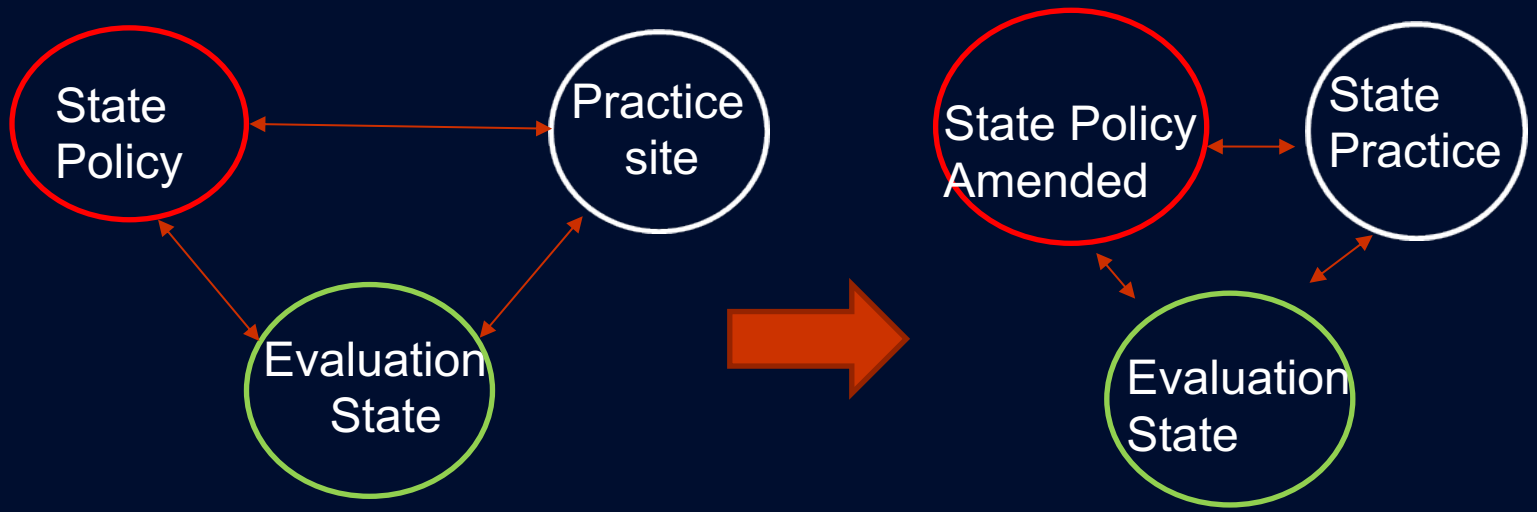
PEP Framework: Regulation Implementation-Evaluation



PEP Implementation: Questions

- To what extent is innovation is feasible?
- To what extent does implementation achieve stated intent of policy/innovation?
- To what extent does infrastructure exist to make implementation sustainable?
- What are the barriers and facilitators of implementation to ensure policy is successful?

Thinking about innovation implementation more

- Health Promotion and Planning models[1-4,7] highlight the following implementation considerations:
  - Procedures clearly stated and can be followed; how will adherence to protocol be measured during implementation?
  - Measures of innovation protocol deviations and why deviations
  - Identification of innovation infrastructure facilitators and barriers- looking at the extent to which innovation is considered consistent with perceived needs, organizational values, personal values, etc.
  - Examining the extent to the innovation is simple and more likely to be adopted more consistently

Opportunities to Facilitate Implementation

- 1:1 pharmacist support of innovation
- Use of electronic checklists to ensure program fidelity
- Access to documents to modify for sites
- Use of existing billing infrastructure to simulate billing and payment of services
- Use of grants to fund pilots
- Team-based, flexible care provision to prevent gaps

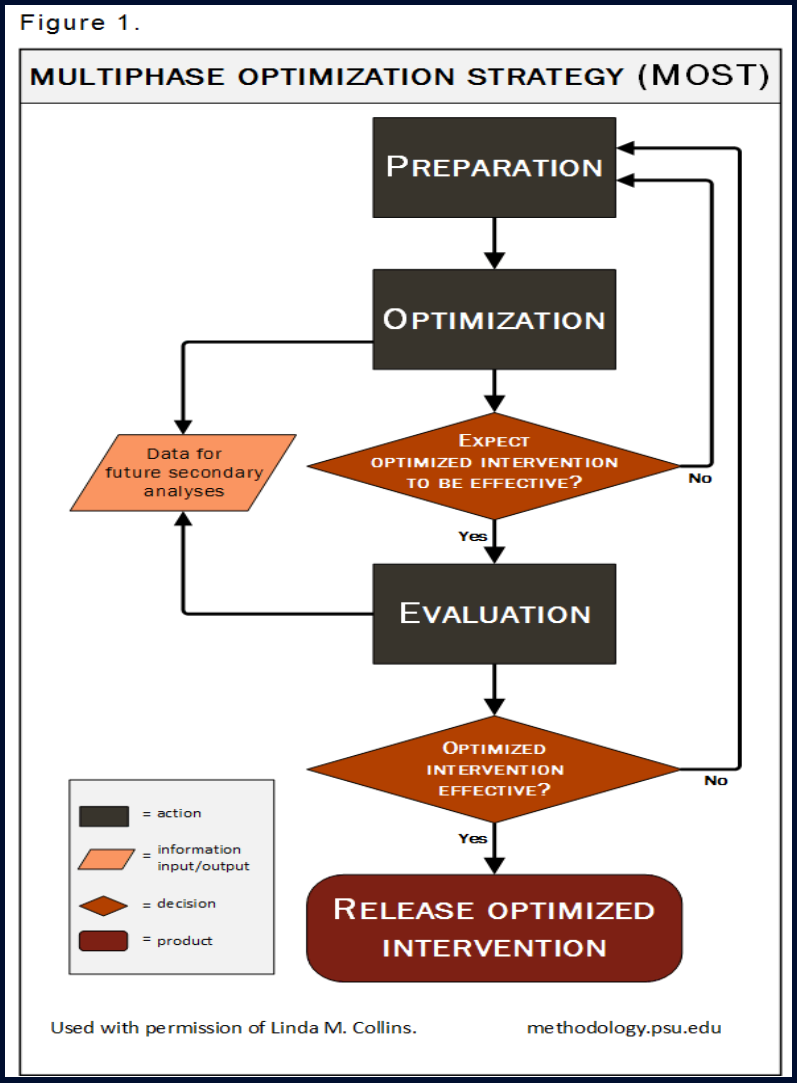
Innovation Models A & B: Evaluation/Research

- When and how do you evaluate if LAIA CPA or Regulation innovation is having impact?
- Data Collection- At the start of the innovation
- What are your target outcomes ?
  - # pharmacist LAIA injections over a specified time period
  - LAIA Adherence over a specified time period
  - Measure patient acceptance; Ease of access to injection
  - Patient knowledge of LAIA
  - Pharmacist-patient relationship
  - Team communication regarding LAIA
- How to do evaluation?
  - Validated measures if available; patient-reported outcomes; prescriber and pharmacist outcomes; community-based outcomes
  - RCT or more basic experimental designs- pre-post assessments

Consideration in Innovation Evaluation

- What evaluation design makes sense?
- Do you test the whole innovation together or do you test components of innovation?[8]
- Is it better for policymakers to know specific components of innovation work or that entire innovation works? Is it more efficient to know what components work well (optimize the intervention) first and then later test the whole innovation?

Evaluation of Innovation Components[8]



Condition	Factor 1	Factor 2
A	X	0
B	X	X
C	0	X
D	0	0

Factor 1: Intervention Component 1
Factor 2: Intervention Component 2

Innovation Models A & B: Sustainability

- Previous implementation and evaluation considerations lead to questions about sustainability/maintenance of innovation. These questions include:
  - Are there coaches and facilitators to ensure efficacy and support with innovation initially and periodically thereafter (check in)?
  - Does innovation allow for pharmacist reimbursement? If not, what is the viability of innovation being sustainable?
  - If there is reimbursement, is there a clear and easy pathway to reimbursement through billing codes?
  - Is the innovation simple enough, flexible and work within the practice flow to allow easy maintenance of innovation?
  - Is there an organizational culture that supports the continuation of the innovation beyond the initial supporters of the innovation?
  - Does changing innovation model based on evaluation lead to greater innovation sustainability and success?

Discussion: Challenges & Future

Discussion: Challenges & Future

- Does it matter how the innovation came about- CPA vs. Regulation and how that might effect innovation efficiency?
- Should public health policy support more focused, stepwise implementation vs. broader regulatory initiatives that may not have been adequately explored?
- Can pilot programs, CPAs or regulatory pilots, have strong evaluation components built within their language that specifies when a high quality evaluation needs to be done and how results can lead to a quicker path for incorporation into regulation (thus avoiding the sink hole of pilots that never get into regulation)?
- Is innovation regardless of PEP pathway viable when infrastructure doesn't exist to make it sustainable? To what end do policymakers have a responsibility to all involved in the innovation that innovation can be

Discussion: Challenges & Future

- Do pharmacists initiate and continue LAIA injections without a funding model and possibly not being able to ensure continuity of service?
- What are your thoughts on the future of practice innovation, regardless of PEP pathway, without a sustainable model? Is it necessarily good for patient-centered care and optimizing community outcomes when practitioners engage in models that are not sustainable?

Questions

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