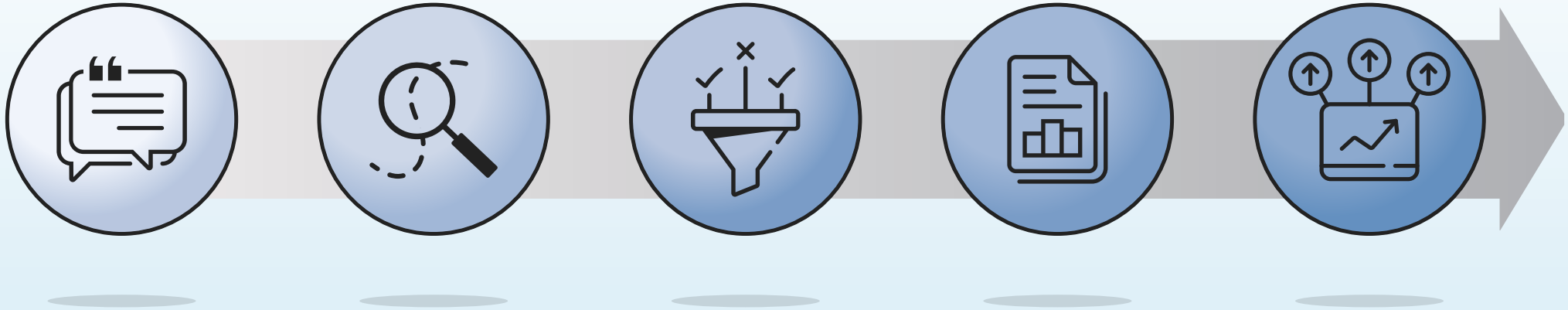
HCPLAN
Health Care Payment Learning & Action Network

Evidence-Based Prevention Continuum

A Pathway to Testing and Scaling Preventive Interventions



Introduction

The Evidence-Based Prevention Continuum **establishes a pathway** to **advance evidence generation** and **implement evidence-based preventive interventions** as part of permanent care delivery and payment models. This pathway focuses on the following key factors which enable an evidence-based preventive intervention to be identified, tested, and scaled:

- Sources of **evidence generation**, particularly for interventions with limited or nascent evidence
- Mechanisms for **scaling and adoption**, particularly for interventions with evidence of significant magnitude and certainty of net benefit

Clinicians, researchers, payers, patients, health systems, and policymakers each play unique roles in advancing evidence-based preventive interventions along the pathway to scale. This resource defines which payers/funders and processes are best positioned to move an intervention along the pathway to scale, from identification, to testing, to broad adoption.

There are many factors which influence whether and how an intervention is moved along the pathway to scale, such as:

- **The strength of the evidence base**, defined as the widely accepted clinical evidence and the implementation evidence (which can be different from one another) supporting the magnitude and certainty of the intervention's net benefit.
    - This document is intended to complement resources developed by organizations which grade evidence (e.g., U.S. Preventive Services Task Force), rather than conflict with or duplicate their efforts.
    - There isn't always a correlation between what is evidence-based and what is scaled.
- **The payer/funder perspective**, including risk tolerance, needs of the target population, and potential health and economic costs and benefits.

Why focus on prevention?

A dedicated continuum for prevention is essential because the standards, risks, and evaluation associated with preventive interventions differ significantly from those of other medical interventions:

- Preventive interventions often are **applied to very broad populations**, meaning decisions about scaling have far-reaching implications, including clinical and financial ones.
- Preventive interventions have a **longer time horizon for assessing health and economic benefits**, and many require sustained engagement with patients, which means the incentive to invest may be influenced by the duration and depth of relationship with the target population.
- Preventive interventions may have upstream impacts on chronic conditions with complex causality.

Preventive interventions may have both short- and long-term effects, both of which should be considered when assessing impact. Preventive interventions are at times adopted without adequate consideration for the downsides (e.g., resources, screenings that result in diagnoses that lead to costly/invasive interventions). It is therefore important to consider the risks and potential economic implications associated with interventions in addition to their potential benefits before they are implemented at scale.

Defining "Evidence-Based"

Preventive interventions can be sorted into one of five levels on the Evidence-Based Prevention Continuum based on the strength of the intervention's evidence. Implementers, payers, and funders generally consider both the **clinical outcomes that indicate the magnitude and certainty of an intervention's net benefit on health outcomes, as well as evidence related to implementation efficacy.** Specifically, the impact on patient health outcomes is of focus when determining which interventions to test and scale. Intermediate outcomes strongly correlated with a long-term health benefit may also be acceptable targets.

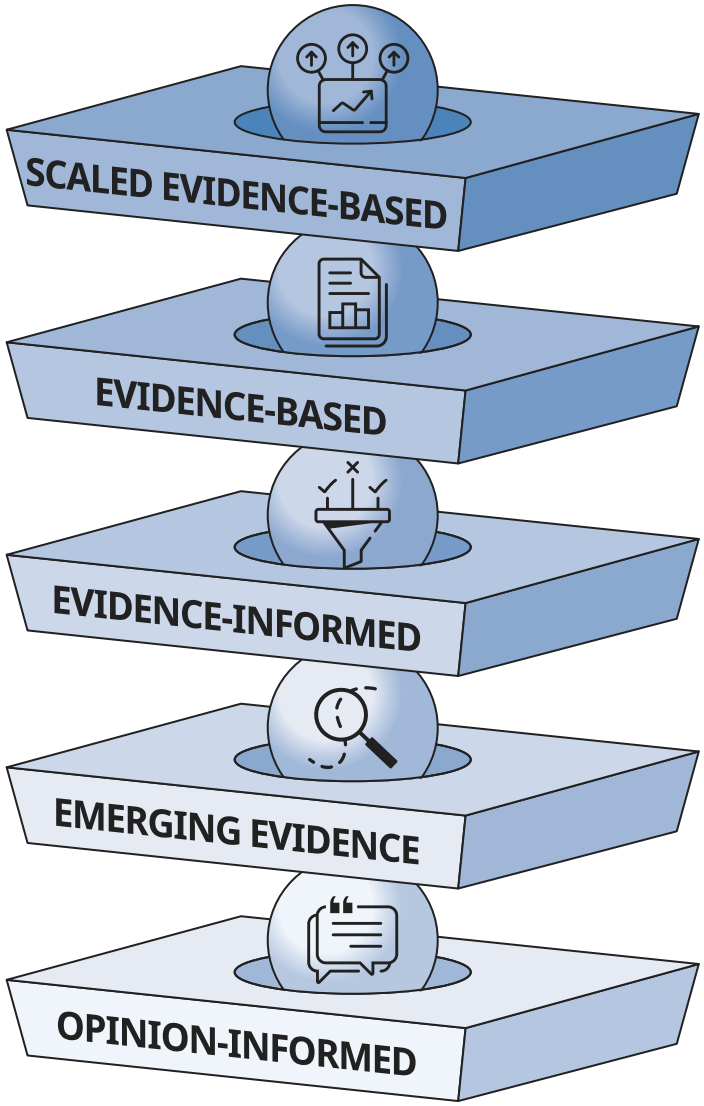
Some interventions may have clinical evidence and implementation evidence that would be categorized at different levels. Assessing the strength of implementation-focused evidence may be challenging because it is highly context-dependent. A given strategy may manifest or perform differently depending on the specific context. Even in cases where a clinical intervention is evidence-based, more implementation-focused evidence may be needed to deploy a new or innovative version of the intervention (e.g., in-person vs. virtual).

Regardless of where an intervention falls on the Continuum, evaluating its impact is beneficial. When implementing an intervention, it is important to ensure the necessary infrastructure is in place to evaluate it effectively.

Resource

The NIH's Stage Model for Behavioral Intervention Development can be used to assess the level of maturity of an intervention's implementation-focused evidence base.

The Evidence-Based Prevention Continuum



Existing evidence is robust, multi-centered, and widely scaled: Evidence may allow for the comparison and measurement of the effectiveness of different implementation strategies on health and implementation outcomes

Existing evidence is convincing: Evidence may be comprised of sufficient well-conducted studies of appropriate design that demonstrate consistent and precise results focused on health outcomes, and are generalizable to the intended U.S. population and setting

Existing evidence is adequate: Evidence may support the intervention's impact on health outcomes but have one or more significant limitations, such as the appropriateness of study design, quality of studies, applicability of results, overall precision, and/or heterogeneity of the outcomes

Existing evidence is nascent: Interventions in this category may require greater appropriateness of study design or quality, applicability of results, overall precision, reliability, and replicability

Reported claims are suggestive of a possible health benefit: Support for interventions in this category is based on factors such as satisfaction surveys, personal experience, testimonials, or clinical observation in a routine case

Levels of Evidence	Illustrative Study Types	Illustrative Sources of Evidence Generation	Illustrative Interventions
 **SCALED EVIDENCE-BASED**	• Type 3 hybrid implementation science studies	• Examining the impact of different implementation models and payment incentives to scale broadly (public, private, etc.)	• Nutrition-focused: Home-delivered meals for seniors • Screening-focused: High blood pressure screening programs
 **EVIDENCE-BASED**	• Multiple RCTs or other similarly rigorous studies with aligned results (i.e., n>1,000, multicenter, more than five in number, in different environments including non-academic settings, etc.)	• Rapid-cycle testing • Testing and scaling interventions through payment models	• Nutrition-focused: Nutrition counseling • Screening-focused: School-based health center screening programs
 **EVIDENCE-INFORMED**	• Pre-post studies with a comparison cohort • Pre-post with control or difference-in-difference models • Small RCTs (n<100, single-center, and fewer than five in number) demonstrating benefits in health outcomes • Real-world evidence	• Rapid-cycle testing • Clinical trials	• Nutrition-focused: Medically Tailored Meals (MTMs) for patients with heart failure • Screening-focused: Mobile health clinics providing health screenings
 **EMERGING EVIDENCE**	• RCTs demonstrating benefits in intermediate or process outcomes (without studies showing improved health outcomes) • Evaluations without a control group (e.g., pre-post) • Real-world evidence	• Clinical trials • Health system or claims-based hospital-specific reports	• Nutrition-focused: Food insecurity screening and referral • Screening-focused: Coronary calcium screening
 **OPINION-INFORMED**	• Case series	• Opinion-informed claims collected through independent practitioners or clinicians, clinical groups, or consumer/patient groups • Consistent with biologically plausible mechanisms	• Nutrition-focused: Nutrigenomics • Screening-focused: Whole-body wellness CTs or MRI screenings

Illustrative Study Types: This column contains examples of study designs that correlate with each level of evidence. Notably, study types in the Scaled Evidence-Based level are not necessarily "better" or more rigorous than those in lower levels of evidence. For example, type 3 hybrid implementation science studies are suited to testing interventions in the Scaled Evidence-Based category due to their focus on implementation. This does not mean that this study type is better than having multiple RCTs, which appear as an illustrative study type in the Evidence-Based category. Interventions in the Scaled Evidence-Based category are assumed to have the clinical evidence expected of interventions in the Evidence-Based category, which may include multiple RCTs.

Illustrative Sources of Evidence Generation: This column contains examples of opportunities to generate evidence at each level. These are not the only examples of evidence generation. The Pathway to Scale highlights likely mechanisms for generating additional evidence.

Illustrative Interventions: This column contains sample interventions at each level of evidence across two common prevention domains. Notably, the interventions which fall into the lower levels of evidence do not necessarily have evidence suggesting that they are not effective; they simply do not have sufficient evidence to be categorized in a higher level of evidence. Interventions can move into higher levels if and when sufficient, appropriate evidence is generated.

Resource

Evidence-Based Interventions Without a Randomized Controlled Trial (RCT)

- In some cases, it may not be logistically feasible or ethical to conduct a RCT. In some of those instances (e.g., multi-modal lifestyle interventions), consideration may be given to real-world evidence.
- The resources below offer guidance on assessing when real-world evidence would be considered sufficient for an intervention to be considered evidence-based or cost-effective:
  - From PCORI: Guidance on the Design and Conduct of Trials in Real-World Settings: Factors to Consider in Pragmatic Patient Centered Outcomes Research
  - From the FDA: Framework for FDA's Real-World Evidence Program

The Pathway to Scale

Scaling Stage	IDENTIFY & INVEST Identify and monitor interventions of interest; Invest in early evidence generation	PILOT & TEST Test promising interventions among target populations through well-evaluated pilot programs	SCALE BROADLY Scale interventions through more permanent mechanisms to broader populations
Aligned Levels of Evidence	OPINION-INFORMED	EMERGING EVIDENCE; EVIDENCE-INFORMED	EVIDENCE-BASED; SCALED EVIDENCE-BASED
Scaling & Testing Mechanisms			
Medicaid	• N/A - Further evidence generation needed	• Medicaid 1115 Waivers • In Lieu of Services (ILOS)	• Medicaid State Plan Amendments
Medicare	• N/A - Further evidence generation needed	• Limited Medicare APMs from the CMS Innovation Center (e.g., grant-based models)	• Most Medicare APMs from the CMS Innovation Center (e.g., ACOs, bundles) • Prevention-focused quality measures
*Investors/ Funders**	• Early-stage private equity or venture capital • Early-stage research funded by NIH, FDA, ARPA-H	• Later-stage private equity or venture capital • Philanthropic investment • Research funded by NIH, FDA, ARPA-H	• Funders may enable broad implementation and/or new and innovative implementation methods
*Private Health Plans***	• Low-risk supplemental benefits to increase beneficiary satisfaction or employee engagement	• Low-risk supplemental benefits to increase beneficiary satisfaction or employee engagement • Payment flexibilities (e.g., up-front lump sums) to pilot promising interventions	• Broad integration into private health plans • Prevention-focused quality measures • Payment flexibility (e.g., up-front lump sums) for providers to scale promising interventions

** For the purposes of this Pathway to Scale, "Investors/Funders" includes private equity, venture capital, philanthropic groups, and research funders (e.g., NIH, FDA, ARPA-H)*
*** For the purposes of this Pathway to Scale, "Private Health Plans" includes commercial plans, employer-sponsored plans, Medicare Advantage, and Medicaid Managed Care*

The vast majority of funders require an intervention to have strong evidence demonstrating the magnitude and certainty of the net benefit on health outcomes and economic impacts before it is scaled. Interventions across the Continuum generally fall into different levels of readiness for implementation:

- Interventions that are **Opinion-Informed** require further evidence generation before taking on the risk of scaling to broader populations.
- Interventions which fall into the **Emerging Evidence** or the **Evidence-Informed** categories generally require additional clinical and implementation evidence before they can be scaled broadly. However, some funders may implement these interventions in limited trials or pilots in targeted populations as a means of developing further evidence.
- Interventions which fall into the **Evidence-Based** or the **Scaled Evidence-Based** categories are generally seen by funders as being ready for broader scaling.

Some interventions will progress along the Pathway to Scale as further evidence is generated. Others will never have sufficient evidence to be scaled broadly.

Testing and Scaling Mechanisms

The Pathway to Scale demonstrates how scaling entities play different roles in advancing evidence-based prevention. The above categories on the Pathway to Scale are generalizations for which there are exceptions. Funders make their own market-driven assessments of which interventions they are willing to invest in, often with consideration for funding streams and likelihood of health and economic benefit. When selecting interventions to scale, a funder's aims may influence how they prioritize the strength of the evidence base and their risk tolerance for scaling things that are less evidence-based.

The Pathway to Scale seeks to define how funders generally move an intervention along the Pathway to Scale, not suggest an ideal state. For example:

- Interventions in the Emerging Evidence and Evidence-Informed categories are more likely to be funded by organizations with a relatively higher risk tolerance around the certainty of the financial outcomes and health benefits of an intervention. These funders may have the capacity to conduct rapid-cycle testing or pilot interventions in a specific context and for specific populations, thereby generating more evidence in the process.
- Interventions in the Evidence-Based and Scaled Evidence-Based categories are more likely to be funded by organizations with a relatively lower risk tolerance and desire for greater certainty of the financial outcomes and health benefits of an intervention. These organizations have the capacity to implement interventions for a larger and/or broad population.
- Government payers may have a higher standard than private payers for the level of evidence they require before an intervention can be implemented due to the use of public resources. The CMS Innovation Center, which has a government mandate to produce cost savings, tends to test enhanced scaling of interventions through their alternative payment models (APMs) that are Evidence-Based, but may require additional testing before they can be scaled broadly across Medicare and/or Medicaid. However, CMS does test some interventions that fall into the Emerging Evidence or Evidence-Informed categories. For example, Section 1115 Medicaid waivers are used to test new or existing ways to deliver and pay for health care services; approved waivers are required to have a comprehensive, CMS-approved evaluation.

- Typically states retrospectively evaluate the impact at the end of the waiver period. Consideration could be given to more nimble innovation approaches that would accelerate learning. For example, serial A/B testing of alternatives early in the waiver period would provide important insights that could then guide what to scale and test across the state.
- This could potentially accelerate learning and enable states to develop more nimble, cost-effective interventions. If the program generates sufficient evidence of the program's benefit on health outcomes, the intervention may be scaled more permanently through a Medicaid State Plan Amendment (SPA).

Other Factors Impacting the Feasibility of Scaling

It is important to recognize that most health care interventions are not evaluated based on financial returns, but rather whether they improve health. Given this, it is important to evaluate preventive services using a similar framework: do they significantly improve health at a reasonable cost? Many preventive services may be more cost-effective than currently covered medical interventions, but aside from vaccinations, smoking cessation, and certain cancer prevention tests, few are directly cost saving.

The strength of the evidence base is not the only factor which enables an intervention to be scaled. Other factors that may be required for an intervention to be scaled successfully include:

- Availability of and access to a payment mechanism/financial reimbursement (Note: Payment is not just important for feasibility and sustainability, but also can help track whether an intervention is being furnished.)
- Certified providers and provider referral pathways
- Quality measures
- Sufficient degree of financial, leadership, and time investment from key stakeholders
- Interoperability and functional data sharing mechanisms
- Provider value-based maturity (e.g., infrastructure, culture, track record)

Common impediments to scaling successfully include:

- Workforce barriers
- Payment misalignment
- Delivery system fragmentation
- Infrastructure and technology limitations
- Cost-effectiveness relative to currently covered medical interventions
- Data security and privacy issues

Key Contributors

The HCPLAN Operator Team wishes to thank members of the Evidence-Based Prevention Workgroup for sharing their insights to help inform the development of the Evidence-Based Prevention Continuum.

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