

## **Implementation science on the margins: How do we demonstrate the value of implementation strategies?**

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### **Abstract:**

Implementation science (IS) has developed as a field to assess effective ways to implement and disseminate evidence-based practices. Although the size and rigor of the field has improved, the economic evaluation of implementation strategies has lagged behind other areas of IS (Roberts, Healey, & Sevdalis, 2019). Beyond demonstrating the effectiveness of implementation strategies, there needs to be evidence that investments in these strategies are efficient or financially sustainable. Many cost-effectiveness studies in public health and medicine ignore the costs of implementation and scale-up (Salomon, 2019). Two recent reviews on the use of economic evaluation in implementation studies noted a limited number of studies that have used an economic evaluation (only two in primary care settings) and the few that did have a high variance in methodological quality (Reeves, Edmunds, Searles, & Wiggers, 2019; Roberts et al., 2019). Thus, there are many opportunities for IS and economics to collaborate. In this editorial, we lay out conceptual challenges in applying economic evaluation to IS and the implications for conducting economic analyses in integrated primary care research.

**Keywords:** editorial | implementation science | cost analysis

### **Article:**

Implementation science (IS) has developed as a field to assess effective ways to implement and disseminate evidence-based practices. Although the size and rigor of the field has improved, the economic evaluation of implementation strategies has lagged behind other areas of IS (Roberts, Healey, & Sevdalis, 2019). Beyond demonstrating the effectiveness of implementation strategies, there needs to be evidence that investments in these strategies are efficient or financially sustainable. Many cost-effectiveness studies in public health and medicine ignore the costs of implementation and scale-up (Salomon, 2019). Two recent reviews on the use of economic evaluation in implementation studies noted a limited number of studies that have used an economic evaluation (only two in primary care settings) and the few that did have a high variance in methodological quality (Reeves, Edmunds, Searles, & Wiggers, 2019; Roberts et al., 2019). Thus, there are many opportunities for IS and economics to collaborate. In this editorial, we lay out conceptual challenges in applying economic evaluation to IS and the implications for conducting economic analyses in integrated primary care research.

We do not spend time here discussing the types of economic evaluations in depth—there are recent primers on the types of methods available with a focus on IS (Cidav et al., 2020; Dopp, Munday, Beasley, Silovsky, & Eisenberg, 2019; Eisman, Kilbourne, Dopp, Saldana, & Eisenberg, 2020). We also wrote a similar primer for screening and brief intervention, where we have focused much of our research, nearly a decade ago (Cowell, Bray, Mills, & Hinde, 2010). Table 1 provides definitions of various economic evaluation strategies. Broadly, an economic evaluation first focuses on the cost of an intervention by collecting data on resource use and relevant prices. If a comparison group is available, we can compare the costs and outcomes of multiple groups in a cost-effectiveness analysis (CEA)—how many dollars it takes to improve an outcome using one intervention relative to another. CEA can be modified so that the outcome is in utility measures (e.g., quality of life) that can be compared across different types of interventions and outcomes (e.g., diabetes and depression), or the outcome can be monetized so that we have a cost-benefit analysis. Further specializations include return on investment (ROI), a special case of cost-benefit, or budget impact, analyses that weigh the costs relative to the potential revenue gains or losses from a specific payer’s perspective (Barbosa et al., 2015; Cavallo, 2006; Mauskopf et al., 2007). There are a variety of tools economists can offer, but they are not one size fits all (Drummond, Sculpher, Claxton, Stoddart, & Torrance, 2015; Gold, Siegel, Russell, & Weinstein, 1996; Sanders et al., 2016; Severens, Hoomans, Adang, & Wensing, 2020).

**Table 1.** Economic Evaluation Strategies That May Be Useful for IS

Cost analysis	Assesses the cost of an intervention by collecting information on the quantity and prices of resources used
Cost effectiveness analysis (CEA)	Compares the relative differences in costs and outcomes for two or more interventions using the incremental cost-effectiveness ratio, which expresses the additional cost required to improve effectiveness by one unit
Cost-utility analysis (CUA)	CEA with a common metric that reflects overall utility (e.g. quality-adjusted life year)
Cost-benefit analysis (CBA)	Compares the monetary benefits and costs of two or more programs using one or more measures such as the incremental net benefit, or cost-benefit ratio
Return on investment analysis	A special case of CBA comparing the financial return from an initial investment
Budget impact analysis (BIA)	Assesses the financial impact of adopting an intervention from a narrow perspective (e.g., payer)

### Tensions Between Economic Evaluation and IS

Regardless of the type of economic evaluation conducted, there is a tension between traditional economic evaluation methods and IS due to two related points: (a) *implementation strategies are often implemented in stages* (e.g., exploratory, preparation, implementation, sustainment [EPIS] framework; Aarons, Hurlburt, & Horwitz, 2011) and (b) *multiple levels of outcomes are often affected*. Starting with the first point, implementation strategies augment the preparation for and delivery of the services. Much of the investment from an implementation strategy may come during the preparation phase before any service is provided. Economists often use the term *sunk costs* or *fixed costs* to describe costs that occur during the preparation phase before service

delivery starts. We treat these differently when conducting an economic evaluation of treatment services because they do not directly affect the costs of delivering the next service—or the *marginal cost*. Economists disagree on whether to exclude sunk costs in an economic evaluation.

In implementation studies, however, the phase of implementation has bearing on what the relevant margin is. If we are starting a service in a completely new health system, then the relevant margin is the health system, and so system-level infrastructure costs may be the relevant marginal cost. But if we are expanding to new clinics within a health system, then the relevant margin is the clinic, and clinic-level startup costs become relevant. And if we are trying to increase the number of patients served within a clinic, then the relevant margin is the patient, and service-level costs become relevant. Every phase of implementation suggests a different relevant decision margin and therefore a different unit of analysis, and in turn a different marginal cost. Regardless of the phase or the relevant margin, almost all implementation decisions involve costs that would be considered sunk costs in traditional economic evaluations. There is not yet a consensus approach for how to apply economic evaluation in a phased implementation framework.

The tension around sunk costs feeds into the second point—that implementation outcomes may also be measured at a patient, staff, site, or higher level. An economic evaluation can accommodate this complexity but requires the researchers to carefully lay out the *perspective* of each analysis, the key outcomes of interest, and the *value*, or economic impact, they want to assess. Perspective answers the question, “Whose costs are counted?” Perspective can be as narrow as the patient or as broad as society. Although the societal perspective is often recommended (Neumann, Sanders, Russell, Siegel, & Ganiats, 2016), many studies focus on the payer or organizational perspective, because they are more relevant for policy and decision-making (Drummond et al., 2015). The type of value is related to the strategy chosen—refer to the table above. One might choose CEA to compare the relative value of one intervention to another, ROI to demonstrate the financial return on investment of an intervention, or budget impact analysis (BIA) if they want to demonstrate the financial impact of implementing an intervention. Therefore, we argue that the key to setting up an economic evaluation is matching the perspective and the type of value you want to demonstrate to the appropriate implementation phase(s) and outcome(s). In the next section, we present two hypothetical examples to illustrate these points.

### **Example 1: Economic Evaluation of a Strategy to Increase Service Delivery**

#### Organizational-Level Outcomes

Consider a hypothetical implementation strategy focused on increasing the number of behavioral health consultations in a given clinic, which includes some activities in the preparation phase (e.g., training, facilitation, workflow design) and implementation and sustainment phases (e.g., ongoing monitoring and support). From a *health system or organizational perspective*, increased consultations may have meaningful impacts on organizational outcomes such as operating budgets or revenue planning, or quality measures or performance incentives. Organizational stakeholders may also want to know whether the financial investment for the strategy is “worth

it” as they consider expansion to other systems or locations. In this scenario, from an organizational perspective, the value of the intervention or implementation strategy lies in the impact on the bottom line and whether it is sustainable. One possibility is that increased behavioral health provider visits could increase revenues relative to the cost of employing more behavioral health providers, or behavioral health providers could reduce time spent per patient by physicians’ allowing physicians to see more patients and generate more revenue; this may be an ideal outcome. The analysis would weigh the implementation strategy and staffing costs for the organization relative to the potential revenue gains or losses. If the focus is on whether the strategy is *sustainable*, we may want to exclude preparation phase costs in a budget impact analysis, because they are not relevant to the decision to continue implementing the strategy—only the strategy-related and service delivery costs postpreparation are the relevant margin. Instead, if the focus is on whether the strategy had a *positive financial return* for the organization using a cost–benefit analysis or ROI, the preparation phase costs are more relevant to the margin of interest.

### Staff-Level Outcomes

Now, what if I am a clinical administrator and I want to choose between two implementation strategies that increase the number of behavioral health consultations *per staff* at the clinic? This is still the organizational perspective, but the outcome is at the staff level. A CEA that compares the staff-level outcomes and costs of the two strategies can help make these types of decisions. Costs for both the preparation and implementation phases should be considered because the margin is the cost of the *next* consultation, and preparation phase activities may contribute to the effectiveness of the strategy. Assume that Strategy A costs \$5,000 per staff across preparation and implementation phases and will increase services delivered per staff by 1,000 patients per year and Strategy B costs \$15,000 and increases services delivered per staff by 6,000 patients per year. How do we choose between them? Strategy B certainly costs more than Strategy A, but Strategy B has a relatively larger effect on consultations provided. We could take the difference in the costs (\$10,000) and divide by the difference in outcomes (\$5,000) to calculate an incremental cost-effectiveness ratio (ICER) of 2. We interpret the ICER such that, relative to Strategy A, for every \$2 spent on Strategy B, service consultations by that staff increase by 1. Strategy B costs more but is also more effective, but is it cost-effective? Well, that is for the administrator to decide whether they are willing to pay for the extra effectiveness of Strategy B at a higher cost.

### Patient-Level Outcomes

Now consider assessing the impact of the strategy on patient outcomes during the implementation phase. We could design a study that compares patients of staff participating in the strategy versus patients of staff who did not participate. A potential difference in patient outcomes during the implementation phase occurs through the investments in the preparation phase. This poses a dilemma. One could argue that the preparation phase costs should factor into a patient-level CEA if we are evaluating starting a new program because we cannot start the program without incurring those costs. However, if the program has been in place for a year and we are trying to decide whether we should continue the service, the costs from the preparation

phase are sunk costs that have no bearing on the decision and so should be excluded. Thus, whether preparation costs should be included in the CEA depends on the perspective.

Because preparation phase costs do not vary at the relevant margin for patient outcomes in the implementation phase—the next patient served—their inclusion can be challenging. For example, if we spend \$5,000 training a single staff in the preparation phase, we would allocate the fixed costs of training by dividing \$5,000 by the number of patients seen by that staff in the implementation phase; the average cost of training per patient. For 100 patients seen, we would allocate \$50 of the cost of each patient, and for 1,000 patients the allocation would be \$5. For staff with smaller patient pools, the fixed costs may greatly inflate the total costs per patient, whereas the costs may be understated in larger patient pools. We are more likely to conclude the strategy is cost-effective in a larger practice than in a smaller one simply because we have lower average fixed costs. In this example, because the end goal is to increase the number of consultations, it is not particularly informative that serving more patients lowers costs.

## **Example 2: Economic Evaluation of a Complex Strategy to Increase Both Service Delivery and Quality**

Now, consider another example: a more complex implementation strategy that aims to increase not only the *number* of services but also the *quality* of services provided, such that services are more likely to be delivered as intended or with high fidelity to an evidence-based intervention. The increasing complexity opens up new outcomes in the preparation and implementation phases.

### Staff-Level Outcomes

First, there could be staff-level outcomes that occur in the preparation phase: Did the implementation strategy improve the proficiency or the time to proficiency of the staff? If the focus is on staff outcomes that occur at the end of the preparation phase, then all the costs incurred during the preparation phase are direct inputs for the relevant margin and should be considered for an economic evaluation of staff outcomes. In this case, the costs are the training and support, and the outcomes are proficiency or time to proficiency. We could compare the costs and outcomes of staff who participated in the strategy and staff who did not to determine the marginal value of the implementation strategy: How much does it cost to improve proficiency or speed up time to proficiency? Both the costs and outcomes occur in the same phase, and the CEA is standard.

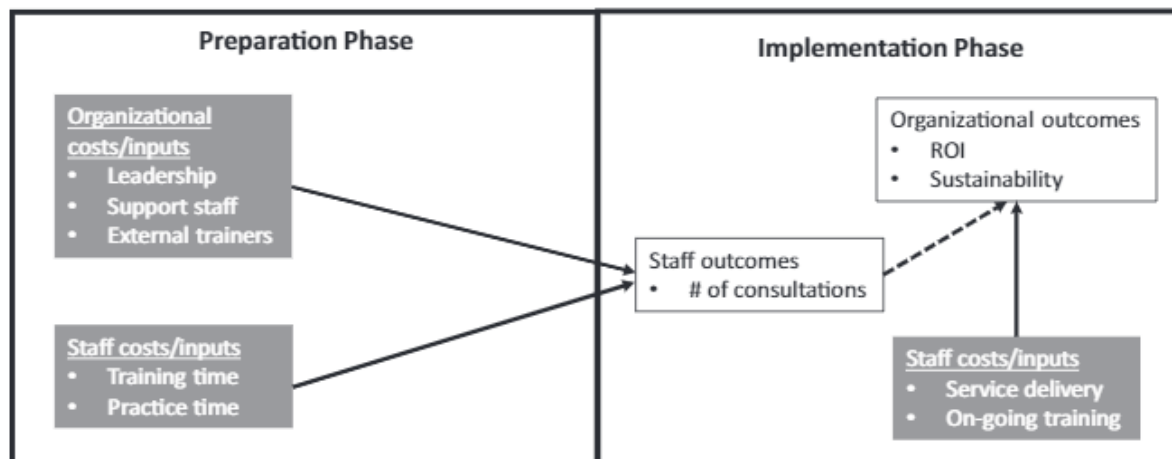
### Patient-Level Outcomes

But what about the effect on patients' health? In addition to seeing more patients, the amount of time staff spend with patients during the implementation phase could change because of preparation phase investments to improve quality. The time differential in the implementation phase is highly relevant to the margin for patient outcomes. We could record the time spent by staff with patients and directly assess how implementation phase costs vary because of the quality of activities. The implementation phase costs and patient outcomes are aligned with our standard approach to CEA. However, like the first strategy, staff-level costs in the preparation

phase impact the ability to achieve good patient outcomes and should thus be included. Otherwise, excluding the preparation phase costs would lead to a biased patient-level CEA. Ultimately, we may want to aggregate the patient outcomes to the staff level. By aggregating patient outcomes to the staff level, we may better align the staff-level costs in both the preparation and implementation phases to the staff-level impact on patients at the appropriate margin for both the number of patients served and patient health.

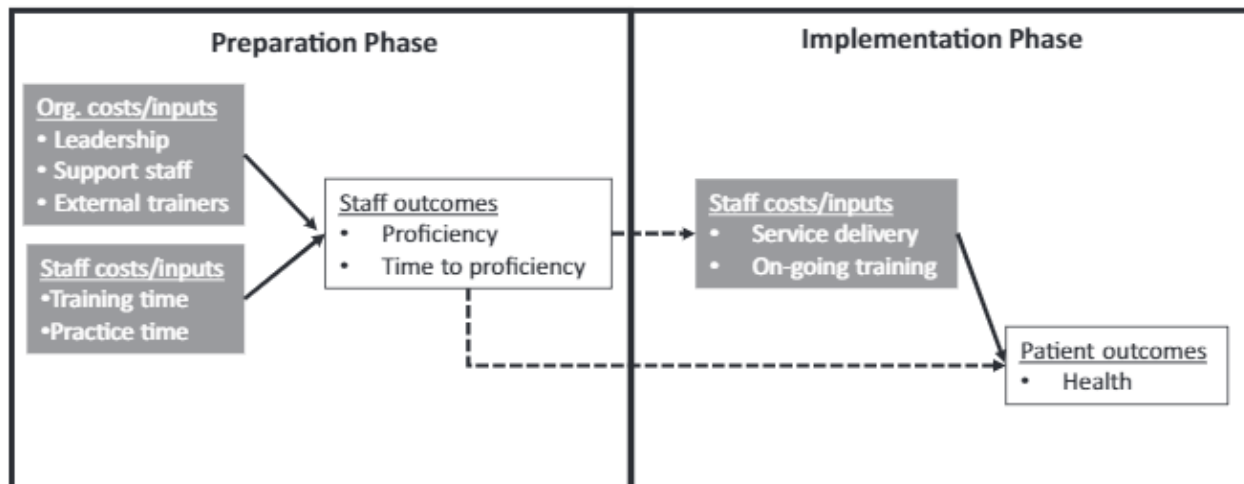
## Implications for Practice

Incorporating the relevant implementation stages, perspectives, outcomes, and measures of value are fundamental not only to economic evaluations but also to fully assessing implementation success. Thus, we contend that all implementation researchers, not just economists, need logic models that lay out for each implementation phase the relevant inputs (i.e., costs), the relevant outputs (i.e., outcomes), and the affected level (e.g., organization, staff, patient) to inform their decisions on the appropriate margin. This is especially important for complex, multifaceted strategies attempting to address a variety of outcomes. A good example of the disconnect is shown in Dopp and colleagues (2019), where they highlight that both the implementation and service delivery costs need to be included when assessing implementation strategies, but they do not disentangle the phases of implementation, the specific outcomes of interest, or the relationship between the phases. We argue that carefully laying out a conceptual input–output model of costs and outcomes is critical in accurately estimating the economic impacts of implementation strategies, which in turn is essential to understanding the success or failure of the implementation strategy. Figure 1 presents an example of what we envision this could look like for the organizational- and staff-level outcomes in hypothetical Example 1, and Figure 2 presents an example of the staff- and patient-level outcomes for hypothetical Example 2.



**Figure 1.** Input–output model for organizational- (org.) and staff-level outcomes in hypothetical Example 1. The cost inputs are the dark gray boxes, and the outcomes are the white boxes. Solid lines represent direct cost inputs, and dashed represent fixed, or sunk, cost inputs. In this figure, the preparation phase costs directly affect the implementation phase staff outcome of the number (#) of consultations even though the costs cross phases. The preparation phase costs are fixed costs for the relevant organization outcomes, noted by the dashed line connecting the staff outcomes to the organization outcomes. The implementation phase staff costs may not be relevant to the implementation phase staff outcomes but are a direct cost input to the

organizational outcomes. The inclusion of the preparation phase costs for the organizational outcomes may be appropriate for a return on investment (ROI) analysis but may not be included for a budget impact analysis focused on whether to continue delivering services. Org. = organizational.



**Figure 2.** Input–output model for staff- and patient-level outcomes in hypothetical Example 2. The cost inputs are the dark gray boxes, and the outcomes are the white boxes. Solid lines represent direct cost inputs, and dashed represent fixed, or sunk, cost inputs. In this figure, the preparation phase costs directly affect the preparation phase staff outcomes. The preparation phase costs are fixed costs for the implementation phase patient outcomes and also influence the implementation phase staff costs. The implementation phase staff costs are a direct cost input to the patient outcomes. In this scenario, a cost-effectiveness analysis of patient outcomes at the patient level may be challenging, given the importance of the costs in the preparation. We suggested an alternative approach that aggregates costs across both phases and patient outcomes at the staff level. Org. = organizational.

In closing, we wish to emphasize that perspective is fundamental to addressing both questions for implementation and those for economic evaluation. Who is paying for implementation strategies, and what objective do they want to achieve? More important, how much are payers willing to pay for implementation strategies? Researchers should not forget that continued implementation of evidence-based practices in real-world settings hinges upon persuading funders not only that implementation strategies increase organizational uptake and quality of service delivery but also that the investment in these strategies efficiently addresses the problem (of service volumes or quality or both). To date, there is not strong evidence that the deployment of implementation strategies in primary care settings efficiently improves downstream clinical and patient outcomes, and this should be a high priority for the field.

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