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Title: The cost-effectiveness of quality improvement projects: a conceptual framework, checklist and online tool for considering the costs and consequences of implementation-based quality improvement

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Abstract
In resource constrained systems, decision makers should be concerned with the efficiency of implementing improvement techniques and technologies. Accordingly, they should consider both the costs and effectiveness of implementation as well as the cost-effectiveness of the innovation to be implemented. An approach to doing this effectively is encapsulated in the ‘policy cost-effectiveness’ approach. This paper outlines some of the theoretical and practical challenges to assessing policy cost-effectiveness (the cost-effectiveness of implementation projects). A checklist and associated (freely available) online application are also presented to help services develop more cost-effective implementation strategies.
Introduction

“Implementation” – of guideline recommendations, research findings, or innovations - is a cornerstone of quality improvement efforts in mature healthcare systems [1]. Such efforts invariably involve changing clinical behaviour: asking professionals to do new things or stopping doing old things. Often the costs of these efforts and the economic impacts of implementation projects are played down or ignored [2].

In an era of rising healthcare costs and squeezed health budgets, policy makers are increasingly looking to get more quality from less resource. The UK, for example, has been asked to achieve efficiencies equating to 4% of the total NHS budget - something it has hitherto never managed - whilst improving (or at least maintaining) system quality. With amounts of guidance increasing, and a smaller pool of available resources to support implementation, it is inevitable that policy makers must prioritize how they spend finite money, time, and human resources. Exactly how this prioritization occurs is largely hidden. If efficiency is important to organizational policy makers, then implementation projects expected to result in greater net health benefits for lower net costs should be prioritized. In order to do this, policy makers need to consider the resources likely to be allocated to implementation projects alongside their likely consequent impacts on patients’ resource demands and health outcomes: an implementation project’s cost-effectiveness [3]. One conceptual framework that can help policy makers in this consideration is ‘policy cost-effectiveness’ (PCE) [4] (described in Box 1). PCE is theoretically founded around the axiomatically important economic concept of cost-effectiveness (and its commensurate desirability in resource constrained systems) [3-5]. As well as its theoretical foundation, PCE has been refined in, and explicated with reference to, differing empirical research contexts [4,7,8].

To be most useful for decision making, PCE should be considered in advance of implementation for estimating the likely cost-effectiveness of implementation projects [5-7]; reporting on the costs and cost-effectiveness of implementation projects to inform this application is comparatively rare [2]. Existing reports of the application of PCE often focus on the introduction of new technologies, and often in the context of randomised clinical trials, albeit of the pragmatic variety [2,7,8]. In this paper we outline some of the challenges in applying this important framework to the “messier” world of service quality improvement based around implementation.
Since 2009, the UK’s National Institute for Health Research (NIHR) CLAHRCs (Collaborations for Leadership in Applied Health Research and Care) have been a key part of the NIHR infrastructure [9]. Each CLAHRC is tasked with undertaking high quality applied health research, and ensuring that the results of that research and evidence-based innovations are widely and rapidly implemented. Our team has been working with healthcare organizations in one UK health economy, serving some 3.5 million people, to develop and deliver, evidence-based, theoretically-informed, locally-tailored research implementation projects [10]. Within our implementation projects we have attempted to apply the PCE framework. In this paper, we discuss the challenges involved in determining the costs and consequences of implementation-based quality improvement, and propose a checklist (and associated free web resource with example projects) for healthcare decision makers concerned with understanding the benefits and the costs of implementation to consider prior to embarking on projects.

[PLEASE INSERT BOX 1 HERE]

**Implementation Project Cost-Effectiveness**

Fundamentally, the cost-effectiveness of any implementation project is a function of the total value of resources allocated to achieving an additional quantity of health benefits. To calculate this, a policy maker needs to know i) the costs of the project, ii) the additional number of patients who will benefit as a result of the project, and iii) the per-patient cost-effectiveness of the innovation/finding/recommendation to be implemented. To be useful for prioritization PCE requires consideration before implementation projects start; doing so presents some significant challenges.

**Implementation Project Costs**

Accurate costings should include all the resources required for developing and delivering a project. In our experience, quality improvement designers often restrict estimates to, for example, the cost of hosting an educational event or the printing and distribution of information materials. Estimates of project labor - always a significant cost - need to include full salary costs (in the UK, these include national insurance and pension contributions). Implementation project costs often fail to include clinicians’ time away from clinical practice engaging with project specific activities; this needs accounting for and valuing. Fully costing
the quality improvement project involves valuing capital and non-capital overheads, travel, and other project related expenses.

Accurately assessing these costs is not straightforward. Time sheets are sometimes used but to be useful these need to be detailed; these are often returned with large amounts of missing data, in addition to proving unpopular and unreliable [10]. The time to complete timesheets also imposes a cost. Retrospective estimates may be the only means of estimating labor costs on of an implementation project; recalling time allocated to specific projects is notoriously difficult, and the longer the project, the more prone to inaccuracies such estimates become. Unknown or missing overhead values for project contributors’ work mean proxies - of uncertain validity - may have to be used. Missing receipts for travel and other project-related expenses mean further assumed costs and risk of recall biases.

**Implementation Project Effects**

For an implementation activity to be cost-effective it needs to change behaviour. However evidence for estimating possible impact in advance may be absent or critically flawed. The gold standard of well-controlled implementation trials can provide information on how the treatment of targeted patients might progress over time both with and, crucially, without the implementation project. Such trials enable estimates of the additional number of patients who may receive the recommended treatment. Interpreting this evidence however requires critical appraisal skills and the ability to translate average effects to the specific setting and context of the project; skills that may be poorly developed in a service. Moreover, whilst implementation approaches can be efficacious [12], decision makers may view that trial results do not apply to their local context. Of course, this rejection of applicability can be mitigated somewhat by encouraging decision makers to base their estimates of potential project effects on the results of systematic reviews of implementation trials – and thus more than one context.

Often individual implementation trials do not look at, or are of too short duration to assess, the sustainability of any effect [13]. Without evidence of implementation trials’ sustained effects, a decision maker may have to rely on assumptions about this factor.

Assessing the number of patients whose treatment has been improved by an implementation project is made more difficult if clear measures of the treatment delivered to patients are not
available. Proxy process measures are not as informative. For example, when only referrals to a service can be measured, as opposed to information on whether and what treatment a patient actually received, assessing the true impact of an implementation project on patient outcomes is problematic.

**Treatment Economics**

The first consideration before widely implementing changes in treatments should be evidence of the expected net costs of treatment and health gains per patient [4]. These determine the cost-effectiveness of the treatment. Ideally the expected net treatment costs and health benefits per patient should be disaggregated. Breaking down this information is common in conventional cost-effectiveness analyses (in health technology assessment for example) but is often missing from quality improvement reports.

Assuming that a guideline recommendation or promoted technology is de facto cost-effective (because it managed to be included in a guideline for example) and therefore justifies the costs of a local implementation project may be misguided. Ultimately, guidelines are the product of expert opinion – albeit informed opinion. Evidence of the cost-effectiveness of a particular recommendation may support, but is not a requirement for, inclusion in a guideline. Implementing recommendations for which cost-effectiveness is sketchy, not adequately established, or accepted by stakeholders may be inappropriate [1,4]. Targeting recommendations with inadequate cost-effectiveness evidence means decision makers cannot assess the policy cost-effectiveness of potential, or indeed previous, implementation projects. Indeed, many guidelines lack clear information on the strength of recommendations and quality of evidence [15] and are thus prone to the sorts of logical fallacies described classically by Skrabnek and McCormick [16].

Where effects can only be measured using (proxy) process measures and only the costs of the implementation project can be measured, the only economic analysis that will be possible is a cost-consequence analysis. Cost-consequence analyses present information on costs and measures of impacts in a disaggregated manner, leaving the decision maker to decide on the value [17]. Economic evaluation of complex implementation projects is often difficult. Perhaps because of this, some commentators suggest that a cost-consequence analysis is often the only feasible option [18]. The major downside of cost-consequence analyses however is their lack of easy transferability to other settings.
Contextual and Practical Issues for Assessing the Cost-Effectiveness of Implementation Projects

Reference Class Forecasting

The true cost and impacts of any implementation project are only revealed after the project is finished. However, for policy cost-effectiveness to be useful to a health system, the expected costs of implementation must be considered beforehand. This can be achieved in part by considering the costs of similar implementation projects done elsewhere: reference class forecasting [19]. Reference class implementation cost forecasts require descriptions of context and methods, resources allocated and associated costs of implementation projects similar to the approach being considered. Even if reports of individual projects were more transparent, no such collection or database of reports currently exists. In this paper we highlight a freely available on-line resource that aims to combat this by collecting data on reference costs associated with others’ quality improvement efforts.

Theoretically-Informed, Locally-Tailored, Implementation Projects

Implementation based on local “institutional” knowledge and pragmatic “common sense” may cost less than formally diagnosing local barriers [12] and using appropriate theories of change [20]. However, implementation projects based on theories of behavioural change may not only be more effective in inducing behaviour change, but also aid learning if the implementation “fails” – as many do [21, 22]. Theory not only increases the probability of empirical effects, but also provides a better foundation for generalising from the trial to other contexts. Formally developing theoretically-informed, locally-tailored, implementation projects adds costs. In particular, if an implementation project needs expert or academic help to understand and apply such theories, the implementation costs may be considerably higher than if the expertise is foregone. In our experience, expecting administrators and clinicians to make use of theories of behaviour change in their raw unadulterated state, in the context of implementation projects, is unrealistic. Extra costs for “knowledge translation” must be considered and these costs may be substantial.

Assessing Compliance with Desired Behaviour

Even where evidence exists of a gap between local practice and desired behaviors (often this is not the case and the trigger for implementation is a vague sense of, “we are not doing that,
and should be”), assessing compliance with specific guideline recommendations can be hampered by omissions or variation in coding patients’ health conditions and the healthcare delivered.

Vagueness in guideline recommendations can also contribute to variations in practice. For example, in the UK NICE guidelines for treating women with mild or moderate post-natal depression (PND) recommend, as a first step, that physicians “consider” any of several strategies including guided self-help, computerized CBT, exercise, non-directive counselling delivered at home, or brief CBT or interpersonal therapy [23]. Where guideline recommendations are vague it may be difficult to use techniques such as clinical audit to see if guidelines, “are being followed” if there is uncertainty about what “followed” means in any measurable sense. Proxy measures of compliance may be used (in the case of PND, referrals for psychological therapies amongst women identified with depressive symptoms in a post-natal timeframe); but proxies may not measure what is really of interest. When practice depends heavily on clinical judgment and is more complicated than, “do X when confronted with condition Y”, audits of patient records may lead to misperceptions of the degree of compliance. There may be good reasons why physicians choose not to use a specific recommended treatment for particular patients (e.g. patient preferences, unavailability or unsuitability of a treatment for a particular patient), which may not be apparent to a computerized audit, or even a human auditor, and may contribute to the erroneous conclusion that a guideline recommendation is being ignored.

**Treatment Rivalry**

In economics, ‘rivalry’ describes the situation where one person’s use of a resource restricts another’s ability to use the same resource (at least at the same time). For an implementation project to successfully increase the numbers of patients receiving recommended care, the targeted health jurisdiction must be able to meet increased demand for the innovation. Where the recommended behaviour is prescribing a commonly available medication, there may be little to prevent all targeted patients from receiving the recommended treatment: one patient’s treatment with the recommended medication would generally not inhibit another patient’s treatment. However, implementation projects targeting behaviours that are potentially rival are more challenging. For example, if the clinicians capable of accepting referrals for a particular therapy are operating at capacity, their treatment of one patient is rival to their treatment of another patient, and it will not be possible to increase the total number of
patients receiving the therapy by encouraging referrals without increasing numbers of staff (and thus costs). So, the increased use of a particular therapy may benefit one group of patients at the expense of others. Little, if any, net population health benefit may result in this case. If rival considerations are not addressed, analyses of implementation efforts may be misleading. Where a treatment is being delivered at capacity, an implementation project to increase demand for that service cannot be cost-effective if there is no concurrent increase in the supply of treatment capacity to meet the increase in demand for that treatment.

**Duplication**

The production and dissemination of guidelines themselves constitutes constant, background, “passive” implementation activity. Decision makers judging whether to pursue more “active” implementation projects should consider whether others are planning or delivering implementation projects for the same behaviours. The size and complexity of healthcare organizations mean that it is not always possible to know about competing implementation projects. However, discovery of competing implementation projects should lead to cessation of projects that are solely duplicating efforts. The “sunk costs” of a duplicative project do not justify its continuation – doing so is inefficient. If competing implementation projects are delivered regardless, then unpacking whether eventual impact is due to either one separately or both is almost impossible; the benefit of learning about which implementation approaches are effective, how, and why is denied.

**A Checklist and Online Resource (PCEERT) for Considering the Value of Implementation-Based Quality Improvement**

Implementation occurs for myriad reasons other than expected cost-effectiveness. For those decision makers considering quality improvement based around the implementation of a guideline, innovation or research findings on the grounds of cost-effectiveness, we suggest the following as criteria:

- A clear and empirically demonstrable need for implementation-based quality improvement. Such needs might include unwarranted (inefficient) variation between services, clinicians or patient outcomes; distance from the status quo to a desired state (as, for example, revealed by clinical audit results) – demonstrable sub optimality. Innovation “fatigue” [24] is a documented threat to improvement in the UK NHS,
arising in part because of services responding to perceived needs for change rather than empirically defensible requirements.

- Satisfactory evidence, relevant to the patient population and implementation context/setting, of the innovation’s cost-effectiveness. Population estimates of costs and effects require conversion to per-patient figures for estimating PCE.
- Capacity to increase provision of the recommended treatment to the targeted patient group without significantly impinging on treatments to other patient groups
- A positive likely impact on the additional number of patients benefiting from the recommended innovation as a result of the implementation project. If the change is to happen over time (as is almost inevitable), then the possibility that the degree and sustainability of any change will alter should be explored and modelled appropriately.
- Clearly identified and valued resources to be allocated to the implementation project.
- The absence of competing implementation projects targeting the same healthcare messages.

The empirical cost-effectiveness of a quality improvement project can only be assessed after the fact. However, using this checklist prior to embarking on implementation-based quality improvement projects may result in a more cost-effective healthcare system by reducing the likelihood of pursuing implementation projects that have little chance of being cost-effective.

We have produced a web-based tool (registration is free and immediate) to help decision makers collect and consider the information necessary for thinking about implementation-based quality improvement project using PCE [https://hsciweb.york.ac.uk/pceert/]. The Policy Cost-Effectiveness Evaluation and Reporting Tool (PCEERT) provides two “worked up/walk through” exemplar projects demonstrating the application of the principles and the information required in the checklist.

The first, which considers changing prescribing behaviour to implement Ivabradine (a drug used in the symptomatic management of stable angina pectoris), is an example of a “classic” PCE study in which effects can be measured with reference to Quality of Life and cost-effectiveness analysis with reference to the impact on £ per QALY.

The second focuses on promoting the use of aspiration rather than x-ray for confirming nasogastric feeding tube placement. This example considers reducing the use of the more
costly x-ray confirmation procedure (rather than QALYs or some other patient outcome). In this example, the implementation project would be considered “cost-effective” if the savings from avoided x-ray confirmations exceeded the cost of developing and delivering the implementation project. That is, the implementation project could be considered "cost-effective" if the Net Policy Cost was negative. Such improvement projects are a common feature in health services attempting to reduce costs.

**Conclusion**

Being presented with guideline recommendations, vociferously promoted innovations, and new health technologies should not de facto lead to the conclusion that implementing the recommendation is necessarily a cost-effective decision for a specific healthcare context. The costs of implementation may be high enough, and the impacts on patient outcomes low enough, that implementation in a given context is just not “cost-effective”.

Despite the challenges, we think healthcare decision makers should explicitly consider the impact an implementation project might have on clinical outcomes and whether the costs of an implementation project are justifiable. Where more than one project is justifiable, policy makers should prioritize those that are likely to be most cost-effective.

The practical challenge of assessing policy cost-effectiveness (outside tightly controlled clinical trials) may explain why the framework has not been more widely applied since its introduction over a decade ago. Many of these challenges are currently met using "guestimation" (for example of implementation reference costs), which is clearly suboptimal for high-quality decision making. As implementation science continues to grow, greater efforts should be made to capture and document the full costs (as well as the benefits) of implementation projects in a form useful for decision makers delivering implementation projects. Guidelines specifically tailored to assessing the full costs of developing and delivering implementation projects should be developed to aid this process.

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9. [http://www.nihr.ac.uk/infrastructure/Pages/CLAHRCs.aspx](http://www.nihr.ac.uk/infrastructure/Pages/CLAHRCs.aspx)


BOX 1: Policy Cost-Effectiveness (adapted from Mason et al. [4,7])

The cost-effectiveness of an implementation-based quality improvement project (for example, increasing the use of a (new) recommended treatment) can be summarized in the policy cost-effectiveness (PCE) statistic. The PCE statistic considers the patient-level net costs and health benefits (i.e. cost-effectiveness) associated with the treatment, as well as the costs of delivering a project and the scale of the project’s impact on the treatment of patients. The costs of the implementation project can be considered as contributing to a loading factor that diminishes the apparent cost-effectiveness of a treatment for patients benefiting from the implementation project. Where health benefits are non-negative, projects with lower PCE statistics would be considered more cost-effective. As Mason et al. [7] highlight, reapplication of implementation methods requires separate cost estimates and the appropriate discounting of future health benefits and costs.

\[
\text{Net Treatment Cost} = \# \text{ Additional Patients Treated with New Treatment} \times \Delta \text{ New Treatment Cost per Patient}
\]

\[
\text{Net Policy Cost} = \text{Implementation Project Cost} + \text{Net Treatment Cost}
\]

\[
\text{Net Policy Health Benefit} = \# \text{ Additional Patients Treated with New Treatment} \times \Delta \text{ New Treatment Health Benefit per Patient}
\]

\[
\text{Policy Cost-Effectiveness} = \frac{\text{Net Policy Cost}}{\text{Net Policy Health Benefit}}
\]

Where the health benefit of the (new) recommended treatment is equal to the comparator treatment, the Net Policy Health Benefit will be zero. In this case, proceeding with an implementation based quality improvement project would be judged worthwhile if the Net Policy Cost was less than zero, reflecting expected net treatment savings overwhelming the costs of the implementation project.