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Measuring Implementation Strategy Fidelity in HealthyHearts NYC: A Complex Intervention Using Practice Facilitation in Primary Care

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Abstract

Few studies have assessed the fidelity of practice facilitation (PF) as an implementation strategy, and none have used an a priori definition or conceptual framework of fidelity to guide fidelity assessment. The authors adapted the Conceptual Framework for Implementation Fidelity to guide fidelity assessment in HealthyHearts NYC, an intervention that used PF to improve adoption of cardiovascular disease evidence-based guidelines in primary care practices. Data from a web-based tracking system of 257 practices measured fidelity using 4 categories: frequency, duration, content, and coverage. Almost all (94.2%) practices received at least the required 13 PF visits. Facilitators spent on average 26.3 hours at each site. Most practices (95.7%) completed all Task List items, and 71.2% were educated on all Chronic Care Model strategies. The majority (65.8%) received full coverage. This study provides a model that practice managers and implementers can use to evaluate fidelity of PF, and potentially other implementation strategies.

Keywords

practice facilitation, implementation strategy, fidelity

Practice facilitation (PF) has emerged as a potentially potent implementation strategy for supporting primary care practice improvements. The goal of facilitation in general is to "strengthen research utilization with the ultimate aims of improving health outcomes and organizational performance."[1] The authors' main study on the impact of PF on cardiovascular disease (CVD) outcomes found that the intervention led to improved smoking outcomes but no significant changes to aspirin, blood pressure, or cholesterol management.[2] Other studies on PF have resulted similarly in mixed findings, which may reflect variation in the implementation of the PF strategy.[3–8] Two systematic reviews found that, overall, interventions that used PF as their implementation strategy are associated with significant improvements in prevention and individual chronic disease care processes and outcomes compared to usual care alone, but there were inconsistencies across studies, particularly for chronic care. Findings from a recent study that focused on improving multiple concurrent measures of CVD care process did not find an effect for PF, possibly because of the complexity of the intervention as well as poor implementation fidelity.[5]

Mixed findings about the impact of PF across studies may reflect variation in implementation of the PF strategy.[9–13] In general, there is limited research assessing the fidelity of implementation strategies such as PF; most implementation research assessing fidelity focuses on fidelity of the evidence-informed interventions and not on the fidelity of the implementation strategies.[14] Furthermore, assessment of fidelity of implementation strategies has been largely atheoretical and ill defined. A scoping review of 72 studies that used implementation strategies found that although 71% of them reported on fidelity of implementation strategies, not one included definitions or conceptual frameworks for assessing fidelity.[14] The authors identified 4 articles on PF published after the scoping review that included some assessment of fidelity of PF as an implementation strategy, but none defined

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fidelity a priori nor used a conceptual framework to systematically guide assessment of fidelity.[7,8,15,16]

HealthyHearts NYC (HHNYC), one of 7 cooperatives funded through the EvidenceNOW initiative, was a stepped-wedge cluster-randomized controlled trial designed to evaluate the effectiveness of PF as an implementation strategy for improving adoption of the Million Hearts "ABCS" evidence-based guidelines for CVD prevention and treatment (ie, the intervention)—(*a*) appropriate aspirin use, (*b*) blood pressure control, (*c*) cholesterol management, and (*d*) tobacco use screening and counseling—in 257 small primary care practices.[17] The objective of this article is to assess the fidelity of PF in HHNYC, thus addressing the gap in systematic, conceptually driven evaluation of PF as an implementation strategy. This study is the first to use an a priori definition of fidelity and an established conceptual framework to guide the evaluation of fidelity of a PF implementation strategy to deliver a complex intervention.

Methods

HHNYC is a partnership between the New York University School of Medicine and the Primary Care Information Project (PCIP), a bureau of the NYC Department of Health and Mental Hygiene.[17] The study was approved by the institutional review boards of both institutions (Approval Number i14-02042).

Conceptual Framework

The authors adapted the Conceptual Framework for Implementation Fidelity (CFIF)[11] to guide the evaluation of fidelity of PF. CFIF identifies adherence as the main component of *intervention* fidelity and assesses adherence using 4 subcategories: (1) Frequency: number of intervention-related interactions; (2) Duration: length of the program or length of each intervention interaction; (3) Content: the skills or knowledge an intervention seeks to deliver to its recipients; and (4) Coverage: the number of recipients who receive the intervention as intended. For the HHNYC study, the authors adapted the CFIF to measure fidelity not to the intervention but to the protocol of the PF implementation strategy. The adherence targets to the protocol of the PF strategy were determined prior to the study. The definition, measurements, and targets for each of the adherence subcategories are described in the following text.

On-site Practice Facilitation

HHNYC studied the use of PF to help primary care practices adopt ABCS evidence-based guidelines. The protocol for the PF implementation strategy consisted of facilitators delivering a minimum of 13 in-person, on-site visits to an assigned panel of practices within the 1-year intervention period. Facilitators conducted visits with either providers or lead support staff at the practices and used 2 tools developed by PCIP to guide each visit: (1) Task List and (2) Chronic Care Model (CCM) assessment form. The Task List and CCM assessment form are available in the Supplemental Appendices (available at http://links.lww.com/AJMQ/A35; http://links.lww.com/AJMQ/A36). Both are also included in the ABCS Toolkit for the Practice Facilitator, created by the NYC Department of Health and Mental Hygiene, at www.ahrq.gov/evidencenow/heart-health/overall/dashboard.html. The Task List consisted of standardized activities designed to facilitate adoption of the ABCS evidence-based guidelines. Tasks could be completed in any order, with the caveat that Introductory Tasks (eg, check accuracy of measures) needed to be accomplished first. The CCM assessment form included quality improvement (QI) strategies, often referred to as practice change strategies, that aligned with the CCM domains of practice transformation (eg, delivery system redesign, clinical information system, clinical decision support, self-management support).[18] Implementation of CCM domains has proven to be an effective method of practice transformation in primary care settings.[6] The protocol for the PF strategy was prescriptive in terms of number and approximate timing of on-site visits, completion of the Task List, and education and assistance implementing CCM strategies; however, it also allowed for facilitators to tailor the order and pace of implementing tasks, educating on CCM strategies, and degree of contact with practices outside of on-site visits.

Study Sample

Practice eligibility criteria included the following: (1) fewer than 10 full-time equivalent providers (ie, physician, nurse practitioner, physician assistant); (2) focus on adult primary care; (3) implementation of an electronic health record (EHR) for ≥1 year; (4) signed agreement with PCIP to participate in PCIP's Hub Population Health System, an EHR query architecture; (5) no immediate future plans to participate in a CVD-related QI initiative; and (6) no plans to change the EHR system in the next 18 months.[17,19] A total of 437 small independent practices in New York City in PCIP's practice network were screened for eligibility, 291 were randomized into one of 4 waves,[17] and 257 completed the intervention.

All 16 facilitators responsible for delivering the intervention were employed by PCIP and had a minimum of

6 months of prior work experiences (range 6 months to 18 years) conducting on-site PF in a health care setting. A majority had postsecondary education, and all completed PF training and targeted trainings on the ABCS evidence-based guidelines and the protocol for the PF strategy. PCIP provided extensive training, monitoring, and feedback to facilitators. Facilitators also received training on QI strategies, motivational interviewing techniques, and proper documentation. PCIP managers met with facilitators on a weekly basis, were responsible for approving data entered into Salesforce (monitoring), and provided comments/next steps/reflections (feedback). PCIP managers met with HHNYC researchers on a weekly basis to ensure the intervention was being delivered uniformly. HHNYC researchers worked in partnership with PCIP to provide additional training and retraining opportunities to ensure little variation.

Data Sources

PCIP provided the authors with data on practice characteristics, including patient-centered medical home (PCMH) status and EHR type. From December 1, 2015 (start of Wave 1), to August 31, 2017 (end of Wave 4), facilitators used a web-based system (Salesforce[20]) to document completion of the Task List and CCM assessment. Data documented in Salesforce by facilitators were used to measure the adherence subcategories.

Task List

The Task List encompassed 7 Introductory Tasks (non-ABCS specific) and 32 ABCS-specific tasks, totaling 39 tasks. The number of tasks varied across each ABCS domain, with aspirin containing 5 tasks, blood pressure control containing 12, cholesterol management containing 7, and smoking cessation containing 8. After each on-site visit, facilitators documented completed tasks in structured fields in Salesforce. Facilitators used the Task List to guide on-site visits and were expected to complete the 7 Introductory Tasks first (eg, explain project goals, review baseline dashboards). Facilitators were then free to complete the 32 ABCS-specific tasks in any order.

CCM Assessment Form

The CCM assessment form in Salesforce contained 27 structured fields for facilitators to document practice change strategies and an unstructured, open-text field in which facilitators could write an open-ended visit summary. Using the structured fields, facilitators documented practice change strategies during each on-site visit via a 5-point scale based on PCIP's existing assessment tool: 1 = Not Yet Educated; 2 = Educated/Not Using/Refused; 3 = Educated/Not Using/Deferred; 4 = Educated/PDSA (Plan-Do-Study-Act); 5 = Educated/Using. All forms were reviewed monthly by PCIP managers.

Measures of Adherence

Frequency

Defined as the number of interactions for intervention delivery,[11] the authors measured frequency using the minimum number of on-site visits specified in the protocol for the PF strategy—13 on-site visits during the 1-year intervention period. The target for frequency was 100% of practices receiving at least 13 on-site visits.

Duration

Duration is defined as the length of each interaction for intervention delivery.[11] Facilitators documented their duration on site (excluding travel time) in Salesforce, but there was no required or expected amount of time. Therefore, there was no predetermined target of duration fidelity, so descriptive statistics are provided for this subcategory.

Content

To measure content fidelity, or the "skills or knowledge an implementation seeks to deliver to its recipients,"[11] the authors used the Task List and CCM assessments documented by facilitators to develop 2 measures of adherence to content corresponding to each tool. For the CCM assessment form, the practice change strategies (already described) were recoded from a 5-point scale to a 0 to 1 scale. As the role of the facilitator is to educate practices on skills and processes, the "education" portion of the CCM assessment is essential to content fidelity and delivery of the intervention as intended. The value of 1 was assigned to responses that demonstrated education of strategies (Educated/Not Using/Refused, Educated/Not Using/Deferred, Educated/PDSA, and Educated/Using). All Not Yet Educated responses were recoded as 0. Content fidelity was assessed as (1) the percentage of practices documented as completing all 39 tasks on the Task List; and (2) the percentage of practices that facilitators documented as any category of Educated for all 27 CCM strategies. The target for content was 100% of practices completing all Task List items and education on all CCM strategies.

Coverage

Defined as the number of participants who received the implementation strategy as intended, coverage represents a combination of the other 3 subcategories

and is thus the most stringent.[11] The authors defined complete adherence in coverage as receiving a minimum of 13 on-site visits, completion of all 39 tasks, and documented education of all 27 CCM strategies. The Duration subcategory was excluded because it lacked a predetermined measure of fidelity. Because the coverage subcategory was so stringent, the target was 75% of all practices achieving complete coverage.

Practice Characteristics

Several practice characteristics were included in exploratory analyses: PCMH status; type of EHR (eClinicalWorks vs MDLand), which served as a proxy for length of involvement with PCIP and its QI efforts as only practices recently involved with PCIP could have MDLand; and medically underserved area (MUA) status as a proxy for variability in serving patients with greater social, financial, and medical needs. PCIP provided data on PCMH status and EHR vendor from their records, and data on MUA were obtained from the US Health Resources and Services Administration website.[21] The authors also investigated whether there was significant variability among facilitators in terms of completing visits.

Analysis

Descriptive statistics were used to assess fidelity in each of the subcategories. Independent groups *t* tests and χ^2 analyses were used to compare practices that did and did not achieve fidelity with respect to the PF implementation strategy. All quantitative analyses were completed using R 3.5.1 statistical programming software (R Foundation for Statistical Computing, Vienna, Austria).[22]

Results

Fidelity of PF Implementation Strategy

Unless indicated otherwise, analyses included all 257 practices that completed the intervention.

Frequency

Almost all (94.2%, 242) practices received at least 13 visits, with 51.0% (131) receiving exactly 13 visits and 43.2% (111) receiving 14 to 18 visits (Table 1). Only 5.8% (15) of the total sample received fewer than 13 visits, with no site receiving fewer than 10 visits.

Table 1. Frequency of Completed Assessments.

Total number of completed assessments	Number of practices	%
10	3	1.2
11	5	1.9
12	7	2.7
13	131	50.9
14	76	29.6
15	21	8.2
16	10	3.9
17	3	1.2
18	1	0.4
Total	257	100

Duration

Over the course of the 1-year intervention period, facilitators spent on average 26.3 hours at each site conducting on-site facilitation. The minimum number of hours spent on-site was 9.5 hours, and the maximum was 51.5 hours. Visits averaged 2.0 hours, ranging from 0.5 to 7.5 hours.

Content

For the Task List, the vast majority of practices (95.7%, 246) completed all 39 Introductory and ABCS-specific tasks with very little variability across items in terms of completion rates. Among practices that did not complete the entire Task List, the average number of completed tasks was 37, indicating that these 11 practices had about 2 uncompleted tasks on average remaining by the end of the intervention period. All Introductory Tasks and 17 of the 31 ABCS-specific tasks had 100% completion across all practices. Completion rates for 13 of the remaining 14 tasks were >99%. The only task with a <99% completion rate was completed in 98.8% of the practices.

For the CCM assessment form, facilitators documented Educated for every CCM strategy in 71.2% (183) of practices. Among the 74 practices that did not complete all 27 CCM strategies, the average number of strategies completed was 24.5, indicating that these practices had, on average, 2.5 uncompleted strategies remaining. Facilitators demonstrated 100% compliance in educating practices on 3 specific CCM components: lab order and review (100%); smoking status documentation (100%); and vital sign documentation (100%). Compliance was 95% or greater for all but 2 strategies: (1) voice/text messaging (84.8%) and (2) clinical huddles (94.2%).

Coverage

In order to achieve fidelity in the coverage subcategory, all practices must have (1) received a minimum of 13 on-site visits, (2) completed all 39 Task List items, and (3) received education on all 27 CCM strategies at any

point during the 1-year intervention period. Facilitators achieved full coverage in the majority of HHNYC practices (65.8%; 169 practices).

Comparison of Practices That Did and Did Not Achieve Complete Fidelity

Practices that completed all Task List items did not differ from those that did not complete all tasks for PCMH status, type of EHR, and MUA. Similarly, practices that were and were not educated on all CCM elements did not differ on these 3 practice characteristics.

There also were no statistically significant relationships between completing 13 or more visits and completing all Task List items or education on all CCM strategies. Practices educated on all CCM strategies experienced greater overall duration in encounters with the facilitators than those that did not receive education on all (27 hours vs 25 hours, respectively; $P = .04$), but there was no statistically significant difference in duration for practices completing all Task List items compared to those that did not. Practices that completed all Task List items were more likely to have received education on all CCM strategies, but the difference was not statistically significant ($P = .05$). Finally, the mean number of visits per site by facilitators fell into a narrow range (11.8-14.2) while the intraclass correlation (ICC) for visits was low (ICC = .17), suggesting that most of the variation in number of visits to sites was within rather than between PFs.

Discussion

This study is the first to apply an a priori definition of fidelity and a conceptual framework (CFIF) to systematically assess fidelity of PF as an implementation strategy. CFIF guided a systematic evaluation of the fidelity of PF as an implementation strategy by prospectively defining the core measures and benchmarks (adapting CFIF's 4 subcategories from measuring an "intervention" to measuring the "implementation strategy"), and further collaborating with partners at PCIP to ensure the data capture system could track fidelity of the PF strategy. Prior studies that included some assessment of PF fidelity also assessed frequency as the numbers of facilitation visits and/or phone calls,[7,8,15] but only one specified a target number.[7] One study documented the numbers of unique representatives and clinicians from the practices that met with facilitators,[15] another described the types of activities undertaken by the facilitators,[8] and 2 other studies described qualitative methods to assess other aspects of PF as an implementation strategy.[7,16] None compared the content that facilitators implemented to what was planned or expected, which is a dimension of fidelity central to duplicating effective PF models. Furthermore, none of these studies employed a conceptual framework to guide the systematic assessment of fidelity.

Overall, the authors found that fidelity was high across the 4 domains of the conceptual framework as compared to a priori benchmarks. Virtually all practices met the frequency criteria of at least 13 visits, and facilitators completed all Task List items in the vast majority of practices. Compared to the Task List items, facilitators educated fewer practices, but still a large majority, on all CCM strategies. Combining all 3 considerations into the coverage measure, this analysis indicated that a substantial majority of practices received the PF implementation strategy as intended. Facilitators delivered a large-scale, complex intervention within urban, small primary care practices with high fidelity.

Other investigators have posited a number of factors that may moderate degree of fidelity, including complexity, quality of delivery, and participant responsiveness.[5,11,12,23] The authors' experience with HHNYC suggests that these potential moderators contributed to the fidelity of PF as the implementation strategy. In terms of complexity as a moderator, the intervention itself (ie, adoption of the Million Hearts ABCS evidence-based guidelines) was very complex, and yet the implementation strategy (ie, protocol for the PF strategy) enjoyed high content fidelity overall. There were, however, differences across the 2 main areas assessed as part of content fidelity. The greater success in covering all the Task List items as compared to education on all CCM strategies may be related to the relatively greater complexity of educating practices about the CCM strategies and how to implement them compared to completing Task List items, which were generally more specific and narrower. Moreover, Task List items often could be completed by the facilitators themselves; for example, facilitators could check that the clinical decision support alert was working for aspirin.

Quality of delivery of PF, operationalized as the training and supervision of facilitators, also may have contributed to the high degree of fidelity of the PF strategy in implementing a complex intervention. The level of supervision provided by PCIP helped ensure high quality in the delivery of PF but may be too costly for some health systems or organizations to replicate, particularly ones that

support small practices (eg, Independent Practice Associations). Given the potential impact of PF, additional research is needed to analyze cost-benefit ratios and the association between levels of fidelity and outcomes.

Finally, the considerable degree of participant (ie, primary care practices) responsiveness in this study likely contributed to the high fidelity achieved by facilitators. In a separate qualitative study, the authors found that providers enrolled in HHNYC viewed facilitators as an important resource, particularly in terms of optimizing the practice's use of the EHR for QI and creating awareness of quality gaps.[24]

More studies are needed to examine differences between practices with different rates of implementation strategy fidelity, to inform strategies for optimizing the impact of PF for chronic disease prevention and management in primary care. Although overall fidelity was high in the present study, some variation existed, especially in terms of education on CCM strategies, but the authors were unable to identify drivers of these differences. One might hypothesize that practices that did not achieve 100% fidelity "ran out of time," but practices that completed all CCM strategies had no more visits on average than practices that did not, and only an average of 2 more hours of overall contact with facilitators. Alternatively, practices that were more advanced at the start required fewer visits to complete all tasks. The authors also did not find that practices with lower PF fidelity were less experienced with PCIP or PCMH than practices with greater fidelity, and they were no more likely to serve in MUAs. Taken together, these findings suggest there were unidentified barriers that impeded completion of the CCM strategies in a minority of practices, which merit further study.

Limitations

PF fidelity results from this sample may not be generalizable to all small independent practices. The small independent practices involved in HHNYC were involved with PCIP prior to the intervention; the practices thus had a history of working on QI initiatives with PCIP and benefitted from additional resources and support beyond practice facilitation. Results also may not generalize to larger practices or those with different ownership arrangements. Another limitation is that the information on fidelity comes from facilitators' own documentation. Although facilitators received rigorous training and managers regularly monitored documentation, it is possible that facilitators were motivated to overreport their efforts or, alternatively, were less than vigilant in reporting. It is not possible to ascertain the degree or nature of bias in the documentation of intervention elements.

Conclusions

Facilitators implemented the HHNYC intervention with high fidelity to the protocol of the implementation strategy, adhering to targets for documentation and content delivery. To the authors' knowledge, this is the first assessment of PF as an implementation strategy that utilized a priori definitions of fidelity and a conceptual framework to guide assessment of fidelity. It is critical for program implementers and evaluators to understand and accurately assess the fidelity of implementation strategies to effectively implement long-lasting practice changes and provide data necessary for scaling interventions that use PF as an implementation strategy. This study provides a model for evaluating fidelity of PF, and potentially other implementation strategies.

Authors' Note

The data sets generated and/or analyzed during the current study are not publicly available but are available from the corresponding author on reasonable request.

Declaration of Conflicting Interests

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Trial Registration

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