

ORIGINAL RESEARCH

Factors Related to Implementation and Reach of a Pragmatic Multisite Trial: The My Own Health Report (MOHR) Study

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Background: Contextual factors relevant to translating healthcare improvement interventions to different settings are rarely collected systematically. This study articulates a prospective method for assessing and describing contextual factors related to implementation and patient reach of a pragmatic trial in primary care.

Methods: In a qualitative case-series, contextual factors were assessed from the My Own Health Report (MOHR) study, focused on systematic health risk assessments and goal setting for unhealthy behaviors and behavioral health in nine primary care practices. Practice staff interviews and observations, guided by a context template were conducted prospectively at three time points. Patient reach was calculated as percentage of patients completing MOHR of those who were offered MOHR and themes describing contextual factors were summarized through an iterative, data immersion process.

These included practice members' motivations towards MOHR, practice staff capacity for implementation, practice information system capacity, external resources to support quality improvement, community linkages, and implementation strategy fit with patient populations.

Conclusions: Systematically assessing contextual factors prospectively throughout implementation of quality improvement initiatives helps translation to other health care settings. Knowledge of contextual factors is essential for scaling up of effective interventions. (J Am Board Fam Med 2017;30:337–349.)

Keywords: Delivery of Health Care, Health Resources, Patient Care Team, Primary Health Care, Quality Improvement

Understanding contextual factors relevant to primary care practice settings is critical for translating

findings from health care improvement interventions into practice change.^{1,2} Researchers are increasingly interested in examining and systematically documenting the specific contexts in which implementation occurs to better explain the mechanisms by which interventions improve outcomes in practice.^{2–7} Most clinical trials focus exclusively on internal validity^{8,9} over external validity, thus excluding the variability of contexts in which interventions are conducted.¹⁰ Knowledge of contextual factors is necessary, however, to understand both

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how and why findings fit into a particular setting and to generate the information needed to knowledgeably translate interventions to other settings and situations. Paying attention to contextual factors is especially important for pragmatic implementation trials that are intentionally designed for real-world health care settings.^{11–15}

Several models from the field of implementation science have posited the important influence of context on the successful translation of research and quality improvement findings into practice.^{16–20} In particular, Stange and Glasgow² identified domains of contextual factors representing multiple, diverse stakeholder perspectives by synthesizing information from 12 existing frameworks and described a method for collecting data on context. Fourteen research teams successfully applied this method retrospectively to diverse practice improvement projects.¹⁵ However, retrospective assessment of contextual findings can suffer from recall bias, especially for interventions implemented in busy, fast-paced clinical practices.

As a part of the protocol for the My Own Health Report (MOHR) study, a pragmatic trial focused on systematic implementation of a health behavior and mental health assessment tool and feedback system in 9 primary care practices, we adapted the method described by Stange and Glasgow² in order to prospectively assess contextual factors influencing intervention implementation and patient reach, calculated by dividing the number of patients who completed the MOHR assessment by the number of patients offered the MOHR. The aim of this study was to show how contextual factors can be assessed prospectively during a pragmatic trial and to delineate the contextual factors influencing the implementation and patient reach of this intervention.

Methods

The MOHR Pragmatic Trial

The MOHR study was a cluster-randomized pragmatic trial of an evidence-based, patient-centered health behavior and mental health assessment tool paired with a feedback system to promote patient counseling and goal-setting. Details about the intervention, the mixed methods evaluation, and main findings from this study are reported in detail elsewhere.^{21–25} Briefly, practices were provided with a web-based or Article health risk assessment

form, the MOHR, which assessed patients' diet, exercise, smoking, alcohol, drug use, stress, depression and anxiety, and sleep.²⁶ Practices were asked to implement MOHR in a way that was pragmatic and feasible for them. They chose whether they administered MOHR through Article or electronically (in person or online), and created their own workflow to share MOHR reports with clinicians and patients and to facilitate goal-setting discussions.

Practice Sample

Nine primary care practices from 6 states implemented the MOHR intervention. Practices were purposefully selected to enhance generalizability and represented the diversity of primary care practices in terms of type, ownership, location, electronic health record infrastructure, and patient panel demographics. Eight research teams that manage practice-based research networks or participated in the Cancer Prevention and Control Research Network used a convenience sampling approach to recruit these practices. Researchers from both networks used their extensive experience partnering with practices to identify suitable practices for this study. After recruitment, 1 practice withdrew early from the study and was replaced by the research team.

Data Collection

Data on contextual factors were collected using a step-wise approach recommended by Stange and Glasgow.² This included (1) identifying contextual factors using a "Context Matters" template^{2,15} (see the Appendix); (2) assessing context at the beginning, middle, and end of the study; and (3) evaluating how contextual factors affected key processes and outcomes through an immersion/crystallization analytic approach.²⁷

The Context Matters template is a tool developed by Stange and Glasgow² to systematically collect and report data on contextual factors relevant to change interventions. This template includes specific domains informed by an extensive review of theoretical models and frameworks,² and informs interview questions and clinic observations about topics such as payment systems, health information technology support, practice culture, and staffing (see the Appendix). Data collectors were experienced in qualitative data collection and were those who served as research

team liaisons with practice staff and leaders. Data collectors and research team members were trained in the use of the context template for data collection and reporting before baseline data collection.

Contextual data were prospectively collected between March and December 2013. Data collectors used the context template as a guide to conduct brief interviews with multiple stakeholders at each practice site, including clinic leaders, clinicians, and staff. They also conducted observations of clinic activities such as patient flow, practice workflow, and interactions among staff to supplement interview data. Field notes from interviews and observations were recorded by practice number on the context template. Data collectors were encouraged to collect and record direct quotes. They then forwarded the completed templates to members of the MOHR context workgroup²² for further data summary and subsequent thematic analysis. The MOHR context workgroup was multidisciplinary, with members representing primary care medicine, epidemiology, anthropology, and health behavior sciences.

For quality control, conference calls were held with research teams before and halfway through implementation to discuss each practice's approach to collecting qualitative data and to problem-solve challenges to completing the context template. Some variations in data collection methods were identified; for example, some sites completed interviews in person, whereas others completed them by phone. Two sites collected data for only 2 of the 3 time points, leading to some missing data at the midpoint and at the end of the implementation period.

Research teams also collected quantitative data on patient reach, defined as the number, proportion, and representativeness of eligible patients offered and completing the MOHR assessment.²⁸ Patient reach was calculated by dividing the number of patients who completed the MOHR assessment by the number of patients offered the MOHR.¹⁵

Data Analysis

The context template served as raw data that were uploaded into Atlas.ti (version 7.0; Scientific Software Development GmbH, Berlin, Germany) for coding and analysis. The coding scheme was chosen a priori based on the model developed by

Stange and Glasgow.² At least 2 workgroup members independently coded each practice's context template. Any coding discrepancies were resolved through discussion among the multidisciplinary team. Data were compared across geographic locations (urban, semiurban, rural), networks (practice-based research network vs federally qualified health center, and MOHR administration types (Article-based, online and faxed to office, online and printed at office). Passages of coded text were coalesced to form higher-level themes through a multistage, iterative data immersion process. Excerpts of field notes provided in the Results section of this article were selected to represent these higher-level themes. The study was approved by institutional review boards at the Virginia Commonwealth University (no. HM12746), University of California, Los Angeles (no. 12-0017900), and 5 other participating institutions.

Results

MOHR practices varied with respect to size, ownership, health system affiliation, geographic location, and patient sociodemographics (Table 1). This variation was intentional to enhance generalizability of the findings.

Contextual factors influencing MOHR implementation and patient reach included factors both internal and external to the practice. Below, we describe in more detail how these factors influenced MOHR implementation and patient reach, and Table 2 provides representative quotations and field notes exemplifying the identified factors.

Factors Internal to the Practice

Internal factors included practice staff members' motivation to use MOHR, practice staff's capacity to take on additional responsibilities to facilitate MOHR administration, and practices' information system capacity.

Practice Members' Motivations

Practice leaders and staff members were motivated to adopt the MOHR tool because it would enable them to systematically identify patients with unhealthy behaviors and mental health concerns. In particular, patient and provider reports generated by the MOHR tool helped streamline the goal-setting process by easily identifying patients' risk factors and highlighting the behaviors patients

Table 1. Descriptive Characteristics of the My Own Health Report Primary Care Practices (March-December 2013)

	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7	Site 8	Site 9
State	VA	VA	VA	CA	VT	NC	CA	TX	TX
Location*	Suburban	Rural	Urban	Rural	Rural	Rural	Urban	Rural	Urban
Practice ownership	Private	Federally qualified health center	Health system	Federally qualified health center	Health system	Federally qualified health center	Federally qualified health center	Federally qualified health center	Federally qualified health center
Patients seen each year (n)	1,500	2,500	4,770	3,500	9,500	12,800	2,180	4,800	2,518
Patient ethnicity/race (%)									
Latino	20	1	1	3	1	2	75	48	67
Black	10	49	17	1	5	60	25	23	13
Insurance type (%)									
Medicare	9	12	26	13	13	49	5	2	3
Medicaid	0	1	42	3	1	10	45	15	22
None	1	49	17	1	5	10	50	38	69
Implementation strategy [†]	Mail	Paper	Mail/Phone	Mail	Mail	Web	Web	Web	Web
Patient reach [‡] (%)	33.7	43.9	2.6/64.2 [§]	31.7	45.6	94.4	69.9	76.1	56.8

*Location was self-reported by practices as urban, rural, or suburban.

[†]“Mail”: staff mailed patients an invitation to complete the My Own Health Report (MOHR) online; “paper”: patients completed the MOHR on paper in the office; “phone”: staff called patients and completed the MOHR over the phone; “web”: staff assisted patients completing the MOHR online while in the office.

[‡]Patient reach is defined as the number of patients who filled out the MOHR assessment divided by the number of patients offered the MOHR.

[§]During study weeks 4–16, site 3 mailed MOHR invitations to patients. During study weeks 14–19, site 3 phoned patients to complete the MOHR.

Table 2. Contextual Factors Related to Implementation and Patient Reach* of the My Own Health Report Health Risk Assessment

Contextual Factor	How Factor Influenced Implementation and Reach	Illustrative Quote(s)
Factors internal to a practice		
Practice members' motivations	Practice leaders perceived added value of the MOHR in identifying at-risk patients	"The MOHR fits right in to what we are trying to do. Nowadays, we are all about prevention and getting our patients to take better care of themselves. I like how it asks about eating fast food." (site 3, time point 1)
	Patient and provider reports helped identify problem behaviors and streamlined goal-setting process	"She [the clinic's director of initiatives] is hoping to tie the MOHR project into the clinic's patient-centered medical home initiative goals that address providing patients with support in self-management, self-efficacy, and behavior change by providing self-management tools." (site 8, time point 1)
	MOHR could help with reporting requirements to external agencies	"MOHR also addresses the [patient-centered medical home] initiative goals related to documenting self-management plans and goals and counseling patients to adopt healthy behaviors." (site 8, time point 1)
	Added time burden on clinicians and staff and disrupted workflow	The CEO, COO, and site supervisor described the resistance that they were getting from providers and MAs to actually administer the MOHR survey. The MAs were under too much time pressure to field the survey (taking about 15–20 min). (site 9, time point 2)
	Created redundancy with existing health risk assessment questions	While the director of initiatives is the project's biggest champion, she expresses concern about the length of time and duplication of the questions in other assessments. (site 8, time point 2)
Practice staff capacity	Practice staff took on additional responsibilities to help patients complete MOHR, further adding to time burden and disruptions in workflow	Throughout the course of the study, more practice leaders assisted with coordination and became hands-on with the project. For instance, the clinic practice manager and the manager of the nurse operators were heavily involved with tracking MOHR completions and monitoring the process. By the end of the study, E-mail and phone communication between the clinic staff, the calling center manager, and study coordinator occurred multiple times throughout the week. (site 3, time point 3) The MAs were under too much time pressure to field the survey (taking about 15–20 min), and the provider was actually instructing the MAs to stop fielding the survey if they were falling too far behind schedule. (site 9, time point 2)

Continued

Table 2. Continued

Contextual Factor	How Factor Influenced Implementation and Reach	Illustrative Quote(s)
Practice information system capacity	Research staff assisted with implementation when practice staff lacked capacity	The graduate assistant and student worker (research staff) assist the staff with MOHR completions 3 half-days a week. Although the research team has agreed to help with patient recruitment, the clinic staff prefer to approach the patient first and obtain verbal consent. The research staff then enter the exam room while the patient is reading/signing the consent form, provides the patient with any additional information needed, and assists with completing the MOHR assessment. (site 8, time point 3)
Factors external to a practice	Delays in printing or faxing patient and provider reports hindered goal-setting discussions	Physician enthusiasm and use of summaries have been mixed. Because of the modest frequency of missing physician summaries, certain physicians have diminished enthusiasm and participation. There is a clear feeling that they do not want paper summaries and want the activities integrated into EHR. There is also a concern that without a more clearly available pathway for initiating practice support, use will remain inadequate. (site 3, midpoint)
Linkages with the larger health system	Changes in existing health information technology infrastructure hindered consistent implementation and reach	“The practice does have an online patient portal, but it is underutilized at the moment . . .”; this trend may support the ease of adoption for the online patient portal. (site 9, time point 1)
Linkages with the larger health system	Access to information technology and human resources of health systems that practices were affiliated with fostered implementation and reach	Site 4 (health system) has done considerable work to make it easy for us to get, review, and use the health reports. This work included activities related to getting patients to initially complete the MOHR assessment (eg, mailing them invitations) and conducting the research study (eg, mailing and coordinating the Patient Experience Survey). Site 4 (health system) has a very sophisticated research workshop with extensive experience that made this process smooth and easy for the practice. (site 4, time point 1) Sharing details and challenges with MOHR completion at the program meeting for a weight-loss project led to the suggestion to engage the health care system’s nurse operators with the project. The nurse operators are comfortable with conducting surveys and asking patients sensitive health questions. To date, the operators’ experience and capacity for making calls has proven beneficial to the project. (site 3, time point 2)

Continued

Table 2. Continued

Contextual Factor	How Factor Influenced Implementation and Reach	Illustrative Quote(s)
	Competing demands from other initiatives on health system resources could pose a barrier to implementation	“There was developing concern that a large, emerging, cross-system primary care initiative would put the project [MOHR] at risk. Because of increasing demands of [the] office manager the responsibility for organizing and distributing physician feedback, changed to a line staff member which improved efficiency, and decreased overall amount of time.” (site 5, time point 2)
Linkages with community resources	Lack of community resources to refer patients for additional counseling influenced goal setting	The practice is located in a rural community and it is difficult to reach the practice without a long drive. The community does not have many resources for health behavior change. (site 4, time point 1) There were a significant number of mental health issues and not a very robust referral system to outside resources (one counselor at the delayed site who saw 1 patient per week, but the position was unfilled for about a month during the study period). (site 9, endpoint)
	Lack of a systematic referral process for more intensive counseling reduced clinician enthusiasm for MOHR	Nurse operators did not feel prepared when a patient responded positively to having suicidal thoughts and/having a desire to harm himself. Once the team received this comment, a study co-investigator and the medical director outlined a protocol for instant transfer to the health care system’s Connect hotline. Before transfer, the patient was provided the crisis line’s toll-free number and instructed to seek medical attention. The clinic also received notation from the manager of the nurse operators for patient follow-up. (site 3, time point 3)
Fit of implementation strategy with patients	Some patient subgroups (eg, older patients, those with low literacy) required more resources to administer the MOHR	The MAs will be administering the MOHR to patients since there was a concern that the level of literacy among patients is too low for self-reported measures. (site 9, time point 1) It is easier for most patients to do the paper version (particularly elderly patients). (site 6, time point 2)

*Patient reach is defined as the number, proportion, and representativeness of eligible patients offered and completing the My Own Health Report (MOHR) assessment.²⁸ Patient reach was calculated by dividing the number of patients who completed the MOHR assessment by the number of patients offered MOHR.¹⁵
EHR, electronic health record; MA, medical assistant.

were ready to work on. In addition to facilitating goal setting, some practice leaders perceived that implementing MOHR could be helpful in meeting reporting requirements to external agencies, patient-centered medical home certification, or criteria for meaningful use of the electronic medical record (EMR). Such motivations for adopting MOHR

greatly facilitated startup of the intervention in practices.

However, enthusiasm waned over time, even among practices that were initially motivated and that perceived MOHR to be useful to clinicians and patients. This is because MOHR added a significant time burden to visits, which resulted in imple-

mentation challenges. In addition, in 2 practices, some of the health assessment questions were already part of existing patient intake forms, and practice members were concerned from the outset that implementing MOHR created an element of redundancy and would add more time to patient visits that were already running over schedule.

Practice Staff Capacity

We observed that existing staff modified their roles or took on additional duties to implement MOHR. For instance, among practices that administered MOHR in the office, the medical assistants took on additional responsibilities in assisting patients who needed help completing it. In practices where patients completed the MOHR online at home, practice staff adapted their roles to locate the completed physician reports and include them in the goal-setting discussion. When practices members did not have internal capacity to take on additional responsibilities to implement MOHR, research teams assisted with implementation. This was often the case among federally qualified health center practices that had large patient volumes and a higher proportion of underserved patients.

Practice Information System Capacity

Practice information systems capacity was related to MOHR implementation. Delays in printing or receiving faxes of the MOHR reports disrupted clinical workflow. This resulted in fewer visits that included goal setting because patient and/or provider reports were not available at the time of the visit. In addition, several practices experienced challenges with their existing technology infrastructure, such as changing EMR systems and low use of patient portals, which hindered MOHR implementation.

External Factors Influencing MOHR Implementation

Availability of external resources to support quality improvement emerged as an important contextual factor relevant to MOHR implementation, in particular, support from larger health care systems, practice linkages with community resources, and fit of the implementation strategy with patient populations.

Linkages with a Larger Health Care System

Practices organized within larger health care systems had additional support for implementation

that they could leverage and use. This included information technology support as well as help from research or health system staff members to implement quality improvement initiatives. Significant support from 1 practice's affiliated health care system's nurse operators helped increase patient reach of the MOHR intervention. Practices that had such support often were able to leverage internal and external resources to facilitate implementation and even make midcourse changes to implementation when necessary, as described here. At baseline, 1 practice decided to test a comprehensive implementation approach that included (1) mailing MOHR invitations to patients' homes, (2) inviting patients to complete MOHR before their appointment, or (3) inviting patients to complete MOHR over the phone. In the first few weeks, however, they learned that these approaches were unable to reach a large proportion of their target population. Therefore, they modified their approach midstream by seeking help from their health care system to have additional staff administer the MOHR. This resulted in a substantial increase in the proportion of patients reached over subsequent weeks. On the other hand, when a practice belonged to a larger network of clinics, they could compete for staff time and clinic resources, thereby hindering implementation.

Linkages with Community Resources

Another contextual factor that posed a barrier to goal setting was practices' lack of established linkages with community resources to refer patients who needed additional counseling for unhealthy behaviors or mental health issues. Further, the lack of a systematic referral process for more intensive counseling also contributed to inconsistent use of the MOHR tool.

Fit of Practice Implementation Strategy with Patients

Practices' patient panel characteristics (age, predominant language spoken, and health literacy) were an important contextual factor that influenced practices' decisions on how MOHR would be administered to patients. Practices that served large panels of low-income and non-English-speaking patients administered the MOHR in the office, rather than at home via the web, because they perceived that most of their patients would not have consistent Internet access or access to computers at home. Even when administered in the

office, patients of these practices needed significant help from practice members or research staff to complete the MOHR on laptop computers or tablets. Another concern that affected the mode of administration was the ability of older patients to navigate a web-based tool.

Interaction Between Contextual Factors

The contextual factors described above often interacted, exacerbating the challenges to successful implementation of the MOHR. To illustrate, practice information capacity limitations, along with sustained lack of support for the new quality improvement initiative and demotivated staff, specifically presented challenges to MOHR implementation for practice 6:

The MOHR report often does not get to them [physicians] in time for their visit with the patient so the information is not utilized; when it is scanned into the EMR, it is not easily located and they do not have [the] motivation to search for it at the next visit (they also do not know who has filled it out and who hasn't). (site 6, time point 2)

The "physician champion" did not really turn out to be a champion of the project because he said the reports did not get into their medical record in a timely manner and there was no time within the patient visits to address additional issues. As with the other providers, the lead physician and nursing director were not very impressed with the MOHR and did not feel that it added value to their patient care. (site 6, time point 3)

This example highlights how interaction of several contextual factors resulted in breakdowns in the process of MOHR reports reaching clinicians and patients during the visit and a lack of integration of MOHR into existing clinic workflow for this practice.

Discussion

Prospectively assessing contextual factors in a pragmatic trial conducted in primary care revealed factors both within and external to the practice environment as influencing implementation and patient reach. Quality improvement intervention studies rarely collect systematic data on contextual factors. Even rarer are intervention studies that collect con-

textual data at multiple points over time. This is especially problematic because numerous rapid quality improvement cycles are needed to implement an improvement initiative, and contextual factors facilitating or hindering these improvement cycles are often lost if not assessed in real time.²⁹ This prospective approach in the MOHR study identified key contextual factors, including practice members' motivations toward using the intervention, practice capacity, quality improvement support available to practices, linkages to community resources, and patient panel characteristics.

The MOHR study was designed and implemented as a pragmatic trial,²² such that practices could and did tailor MOHR implementation to suit their local setting. Despite this flexibility, additional contextual factors hindered implementation, including practices' capacity to take on a new quality improvement initiative, practice members' motivation to change, and resources available to the practice in order to support change. Other primary care change initiatives also identified these factors as particularly salient because they require significant changes to practice workflow and are potentially disruptive to practice functioning, suggesting that these may be important to consider for most practice change initiatives.^{15,16,30,31}

In addition to these general contextual factors, our prospective method helped identify variations across practices in goal setting for unhealthy behaviors, even though the study's main findings demonstrated an increase in goal setting among intervention compared with control practices.²⁵ Technology challenges in accessing patient and clinician MOHR reports at the point of care, coupled with the additional time needed to complete MOHR, hindered goal setting. Practices' limited external linkages with community resources for behavioral health counseling (for example smoking cessation and physical activity counseling) challenged implementation, as clinicians perceived no benefit in setting goals with patients if there was no place to send them for additional counseling. Paying attention to context throughout the study helped explain observed variations in implementation and, more importantly, helped identify conditions under which goal setting was more likely to be successfully implemented. Our findings could enable other practices seeking to implement an electronic health risk assessment tool to identify, in advance, "real-world" trade-offs to integrating it in

their workflow. And, as our findings suggest, these trade-offs may change over time as implementation proceeds within the practice.

These findings should be interpreted in light of the study's strengths and limitations. While participating practices were very diverse, they were volunteer practices from research networks and thus are unlikely to be representative of all primary care practices. None of the participating practices sustained MOHR after the study's completion,²³ so our observations of implementation were restricted in time. Nevertheless, our study shed light on reasons for the lack of sustainability. For instance, the significant additional time and staff resources needed to administer MOHR made it impossible for practices with large volumes of underinsured and uninsured patients to integrate it into their daily workflow. Thus, MOHR was discontinued once the study ended. Even in the practice-based research network practices, additional, unreimbursed time for goal setting made it difficult to sustain MOHR after the end of the study.

The study's methods, involving case studies, may have further limited generalizability. Nonetheless, randomized controlled trials offer only average measures of effectiveness and are context-specific, whereas a series of case studies in different contexts could provide valuable information about how an intervention operates, as with the findings from this study.¹⁵ Another, more subtle limitation of the study concerned the context of the study itself. The MOHR study was developed, funded, and led by a national study team based at the National Institutes of Health, with an academic coordinating center that changed during the course of the project. Other than the impact of national reimbursement and reporting requirements, however, respondents did not report any effects of the study aegis, leadership, or even the research staff itself (except as staff "extenders" to administer the MOHR) on implementation.

Notwithstanding these limitations, the study has some significant strengths, most notably the prospective collection of data over multiple assessment times and the diversity of clinics. Context is increasingly recognized as important, but few primary care implementation studies explicitly collect and report on contextual factors, and fewer still do so prospectively throughout implementation.^{2,15} Paying attention to contextual factors throughout the course of this study helped identify key factors

resulting in implementation challenges that would not have otherwise been recognized.

The methodology used in this study can be helpful to both researchers and practicing clinicians. We recommend the use of the Context Matters template to systematically and prospectively capture data on contextual factors at multiple levels (practice, community, and state). This method will enable researchers to identify factors that may influence implementation differentially by practice context. Reporting on contextual factors using this method may also help practices assess whether identified factors are relevant to them when implementing MOHR or a similar health risk assessment (HRA). Our study findings suggest that enhanced capacity to make quality improvement changes in a practice where practice members are motivated and that has resources to make and sustain changes is critically important for the successful implementation of most quality improvement interventions. Specifically, for practices wishing to implement MOHR, we recommend that they pay attention to their information technology capacities to effectively administer MOHR via patient portals or using web-enabled tablets in the office, and to modify their workflows to account for the additional visit time needed for the important task of goal setting.

Conclusion

Understanding practice contexts can be used to successfully implement HRAs as a part of the Medicare annual wellness visit and as part of routine care. Involvement of diverse stakeholders in gathering and interpreting data on relevant contextual factors over time can advance the understanding of what happened with a particular intervention and why, and can allow others to make reasonable judgments about how an intervention or its implementation might need to be modified in order to be effectively executed in different settings and circumstances.

To see this article online, please go to: <http://jabfm.org/content/30/3/337.full>.

References

1. Kaplan HC, Provost LP, Froehle CM, Margolis PA. The Model for Understanding Success in Quality (MUSIQ): building a theory of context in healthcare quality improvement. *BMJ Qual Saf* 2012;21:13–20.
2. Stange KC, Glasgow RE. Considering and reporting important contextual factors in research on the

- patient-centered medical home. Rockville, MD: Agency for Healthcare Research and Quality; 2013.
- Badger F, Plumridge G, Hewison A, Shaw KL, Thomas K, Clifford C. An evaluation of the impact of the Gold Standards Framework on collaboration in end-of-life care in nursing homes. A qualitative and quantitative evaluation. *Int J Nurs Stud* 2012;49:586–95.
 - Chaney EF, Rubenstein LV, Liu CF, et al. Implementing collaborative care for depression treatment in primary care: a cluster randomized evaluation of a quality improvement practice redesign. *Implement Sci* 2011;6:121.
 - Macq J, Solis A, Martinez G, Martiny P. Tackling tuberculosis patients' internalized social stigma through patient centred care: an intervention study in rural Nicaragua. *BMC Public Health* 2008;8:154.
 - Shaw RJ, Kaufman MA, Bosworth HB, et al. Organizational factors associated with readiness to implement and translate a primary care based telemedicine behavioral program to improve blood pressure control: the HTN-IMPROVE study. *Implement Sci* 2013;8:106.
 - Van Herck P, De Smedt D, Annemans L, Remmen R, Rosenthal MB, Sermeus W. Systematic review: effects, design choices, and context of pay-for-performance in health care. *BMC Health Serv Res* 2010;10:247.
 - Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *J Clin Epidemiol* 2010;63:e1–37.
 - Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. *Ann Intern Med* 2010;152:726–32.
 - Green LW, Glasgow RE. Evaluating the relevance, generalization, and applicability of research: issues in external validation and translation methodology. *Eval Health Prof* 2006;29:126–53.
 - Dobrow MJ, Goel V, Lemieux-Charles L, Black NA. The impact of context on evidence utilization: a framework for expert groups developing health policy recommendations. *Soc Sci Med* 2006;63:1811–24.
 - May CR, Mair FS, Dowrick CF, Finch TL. Process evaluation for complex interventions in primary care: understanding trials using the normalization process model. *BMC Fam Pract* 2007;8:1–9.
 - McDonald KM, Schultz EM, Chang C. Evaluating the state of quality-improvement science through evidence synthesis: insights from the closing the quality gap series. *Perm J* 2013;17:52–61.
 - Rojas Smith L, Ashok M, Dy SM, Wines RC, Teixeira-Poit S. Contextual frameworks for research on the implementation of complex system interventions. Rockville, MD: Agency for Healthcare Research and Quality; 2014.
 - Tomoaia-Cotisel A, Scammon DL, Waitzman NJ, et al. Context matters: the experience of 14 research teams in systematically reporting contextual factors important for practice change. *Ann Fam Med* 2013;11(Suppl 1):S115–23.
 - Kaplan HC, Brady PW, Dritz MC, et al. The influence of context on quality improvement success in health care: a systematic review of the literature. *Milbank Q* 2010;88:500–59.
 - Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* 2009;4:50.
 - Kitson A, Harvey G, McCormack B. Enabling the implementation of evidence based practice: a conceptual framework. *Qual Health Care* 1998;7:149–58.
 - Bergstrom A, Skeen S, Duc DM, et al. Health system context and implementation of evidence-based practices-development and validation of the Context Assessment for Community Health (COACH) tool for low- and middle-income settings. *Implement Sci* 2015;10:120.
 - Harvey G, Kitson A. PARIHS revisited: from heuristic to integrated framework for the successful implementation of knowledge into practice. *Implement Sci* 2016;11:33.
 - Glasgow RE, Kessler RS, Ory MG, Roby D, Gorin SS, Krist A. Conducting rapid, relevant research: lessons learned from the My Own Health Report project. *Am J Prev Med* 2014;47:212–9.
 - Krist AH, Glenn BA, Glasgow RE, et al. Designing a valid randomized pragmatic primary care implementation trial: the my own health report (MOHR) project. *Implement Sci* 2013;8:73.
 - Krist AH, Phillips SM, Sabo RT, et al. Adoption, reach, implementation, and maintenance of a behavioral and mental health assessment in primary care. *Ann Fam Med* 2014;12:525–33.
 - Phillips SM, Glasgow RE, Bello G, et al. Frequency and prioritization of patient health risks from a structured health risk assessment. *Ann Fam Med* 2014;12:505–13.
 - Krist AH, Glasgow RE, Heurtin-Roberts S, et al; MOHR Study Group. The impact of behavioral and mental health risk assessments on goal setting in primary care. *Transl Behav Med* 2016;6:212–9.
 - National Cancer Institute. MyOwnHealthReport. 2016. Available from: <http://myownhealthreport.org/>. Accessed January 11, 2017.
 - Borkan J. Immersion/crystallization. In: Crabtree BF, Miller WL, editors. *Doing qualitative research*. Thousand Oaks, CA: Sage Publications; 1999. pp. 179–94.

28. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health* 1999;89:1322–7.
29. Balasubramanian BA, Cohen DJ, Davis MM, et al. Learning evaluation: blending quality improvement and implementation research methods to study healthcare innovations. *Implement Sci* 2015; 10:31.
30. Nutting PA, Crabtree BF, Stewart EE, et al. Effect of facilitation on practice outcomes in the National Demonstration Project model of the patient-centered medical home. *Ann Fam Med* 2010;8(Suppl 1):S33–44; S92.
31. Shaw EK, Chase SM, Howard J, Nutting PA, Crabtree BF. More black box to explore: how quality improvement collaboratives shape practice change. *J Am Board Fam Med* 2012;25:149–57.

Appendix

MOHR Context Matters Template

MOHR Context Matters Worksheet

Research Site: _____

Clinic Code: _____

Date Completed: _____

Early or Delayed Intervention Site: _____

Instructions: Contextual factors affect all real world research projects, but seldom are identified or reported. The idea of this form is to provide a way to consider and report the contextual factors that are important for each participating network. Please identify **one person on your team who best knows each clinic** to complete this worksheet and return it to Suzanne Heurtin-Roberts, sheurtin@mail.nih.gov, prior to beginning the fieldwork, in the middle of the project, and at the end. The person completing the form should get input from stakeholders with different points of view, e.g. other project team members, staff members with different roles at participating practices, any relevant health care system people (e.g. IT staff). This input can come from informal observations or interactions, and also could include group discussions. A half hour to complete the form is reasonable. The form completer may wish to keep brief notes of important contextual factors that become apparent along the way, and especially of any important local events, major changes in staff, policies, priorities, etc. . We anticipate that the forms done at the middle and end of the project will be richer since you and your colleagues will have had a chance to consider important contextual factors that make themselves apparent during the course of your work. We should be able to co-author a paper together based on this work.

****Remember to de-identify all clinic information. There should be NO personal health information or other identifying information about clinic partners.

Contextual Factors Relevant for Understanding & Transporting Findings from (Name of clinical site)

(Factors to consider in identifying the ones important in *your* setting: Relevant theory or participant mental models, national, state and local public policy, community norms and resources, health care system organization, payment systems, IT support, practice culture and staffing, different patient populations and subgroups, available information, relevant historical factors or recent events, the culture and motivations surrounding monitoring and evaluation, relationship between the research team and participating practices; changes in these factors over time.)

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Notes:

The following factors changed in important ways over the course of the study:

The following people/groups provided input on the relevant contextual factors and to consider how they might have affected the internal and external validity of the study (list names and/or relationship to the project)

Interpretive notes on key events and on how these contextual factors affected what happened during the study (internal validity) and what others should know to transport/re-invent the findings in their contexts (external validity)
