Annals Journal Club:

Annals Journal Club: Acanthosis Nigricans and Diabetes Risk Factors
Ann Fam Med 2007 5: iii.

Editorials:

Kurt C. Stange
In This Issue: New Concepts for Diabetes and Chronic Disease Management

Original Research:

Michael L. Parchman, Jacqueline A. Pugh, Raquel L. Romero, and Krista W. Bowers
Competing Demands or Clinical Inertia: The Case of Elevated Glycosylated Hemoglobin
Ann Fam Med 2007 5: 196-201.
Alberta S. Kong, Robert L. Williams, Melissa Smith, Andrew L. Sussman, Betty Skipper, Andrew C. Hsi, Robert L. Rhyne On behalf of RIOS Net Clinicians
Acanthosis Nigricans and Diabetes Risk Factors: Prevalence in Young Persons Seen in Southwestern US Primary Care Practices

Jesse C. Crosson, Pamela A. Ohman-Strickland, Karissa A. Hahn, Barbara DiCicco-Bloom, Eric Shaw, A. John Orzano, and Benjamin F. Crabtree
Electronic Medical Records and Diabetes Quality of Care: Results From a Sample of Family Medicine Practices
Bruce Barrett, Brian Harahan, David Brown, Zhengjun Zhang, and Roger Brown
Sufficiently Important Difference for Common Cold: Severity Reduction
Beth Barnet, Jiexin Liu, Margo DeVoe, Kari Alperovitz-Bichell, and Anne K. Duggan
Home Visiting for Adolescent Mothers: Effects on Parenting, Maternal Life Course, and Primary Care Linkage

**Different Paths to High-Quality Care: Three Archetypes of Top-Performing Practice Sites**

William M. Tierney, Caitlin C. Oppenheimer, Brenda L. Hudson, Jennifer Benz, Amy Finn, John M. Hickner, David Lanier, and Daniel S. Gaylin

**A National Survey of Primary Care Practice-Based Research Networks**

**Theory:**

Leif I. Solberg

**Improving Medical Practice: A Conceptual Framework**

**Reflections:**

John P. Geyman

**Disease Management: Panacea, Another False Hope, or Something in Between?**

Ian Douglas Couper

**The Impotence of Being Important – Reflections on Leadership**

Hassan Soubhi

**Toward an Ecosystemic Approach to Chronic Care Design and Practice in Primary Care**

**On TRACK:**

Kurt C. Stange

**On TRACK: Primary Care Opportunities for Filling Unmet Need**

**Thank You, TRACK Participants**

**Family Medicine Updates:**

From the Society of Teachers of Family Medicine, North American Primary Care Research Group, and Association of Departments of Family Medicine

**Academic Family Medicine’s Response to CTSA**
From the American Academy of Family Physicians

**Academy Builds Coalitions for Health System Reform**

From the American Board of Family Medicine

**ABFM’s In-Training Examination**

From the Association of Family Medicine Residency Directors

**P^[4] = Innovation**
Acanthosis Nigricans and Diabetes Risk Factors

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The Annals of Family Medicine encourages readers to develop the learning community of those seeking to improve health care and health through enhanced primary care. You can participate by conducting a RADICAL journal club, and sharing the results of your discussions in the Annals online discussion for the featured articles. RADICAL is an acronym for Read, Ask, Discuss, Inquire, Collaborate, Act, and Learn. The word radical also indicates the need to engage diverse participants in thinking critically about important issues affecting primary care, and then acting on those discussions.1

HOW IT WORKS

In each issue, the Annals selects an article or articles and provides discussion tips and questions. We encourage you to take a RADICAL approach to these materials, and to post a summary of your conversation in our online discussion. (Open the article online and click on “TRACK Comments: Submit a response.”) You can find discussion questions and more information online at: http://www.AnnFamMed.org/misc/AJC.shtml.

CURRENT SELECTION

Article for Discussion

Discussion Tips
This article presents opportunities for many levels of learning about diabetes, diagnostic testing, and practice-based network (PBRN) research. (See the article by Tierney et al in this issue of Annals for an overview of US PBRNs). You can examine Supplemental Figure 1 online to see what acanthosis nigricans looks like.

Discussion Questions
• What are the research questions and why are they important? What already is known about acanthosis nigricans and diabetes risk factors?
• What are the limitations of the cross-sectional study design for answering the different study questions?
• To what degree are the findings affected by:
  1. How participants (practices, clinicians, patients) were selected?
  2. How critical variables were measured and/or defined?
  3. Missing data?
  4. Confounding (false attribution of causality because 2 variables discovered to be associated actually are associated with a third factor)?
  5. Chance?
• What are the main findings? How do they advance current knowledge?
• How do you interpret the “unanticipated finding”?
• How transportable are the findings to your setting and patients? How might the information be used to change practice?

References
EDITORIAL

In This Issue: New Concepts for Diabetes and Chronic Disease Management

Kurt C. Stange, MD, PhD, Editor

This issue of Annals brings into view new ways of understanding chronic illness care and efforts to improve the quality of care. It identifies a possible new diabetes risk factor that is easily visible on physical examination, rather than requiring an expensive or invasive test. Research in this issue shows that the electronic medical record is not a panacea for improving chronic illness care and discovers a novel typology of 3 ways that high-performing practices achieve high-quality care.

Four of these studies take place in practice-based research networks (PBRNs), and an additional study characterizes the increasing capacity of PBRNs. This research shows that amidst the growing recognition of the potential of PBRNs by outside investigators and by the National Institutes of Health Roadmap, there is a concomitant need to foster bottom-up participation by PBRN members to avoid unbalancing the partnerships that create the power of the PBRN to generate relevant, applicable new knowledge.

Four of these articles debunk popular theoretical frameworks for understanding disease management and practice improvement, and propose more robust alternatives. By helping us to think differently, these authors provide hope for getting out of the current rut of large resource investment for small improvements.

Other important research in this issue uses a novel method to discover that the treatment effect size people desire is greater than the actual effect of popular treatments for upper respiratory tract infections.

A clinical trial assesses the impact of an ingenious and intrepid intervention for adolescent mothers.

An essay illustrates that self-importance can get in the way of effective leadership.

TRANSITION OF EDITORIAL TEAM

The Annals is pleased to welcome Deborah Cohen, PhD, to the editorial team as an associate editor. Dr Cohen, an assistant professor in the Department of Family Medicine at Robert Wood Johnson Medical School, is a communication scientist with expertise in applying qualitative methods to understand communication in health care settings. She led the Robert Wood Johnson Foundation’s Qualitative Research Guidelines Project (http://www.qualres.org) and is principal investigator of the evaluation for the Prescription for Health project.

Also with this issue, Benjamin Crabtree steps down as associate editor. We extend our deep thanks to him for his vital role in establishing and developing the Annals. He has tirelessly worked with authors to improve their work and with the editorial team to set the direction for the Annals. Dr Crabtree will continue his internationally recognized work in qualitative research methods and understanding health care systems as complex organizations. With Dr Cohen’s expertise, the Annals will continue to be a home for strong qualitative and mixed methods research.

We encourage readers to participate in the Annals Journal Club and to share your insights by joining the Annals online discussion at http://www.AnnFamMed.org.

References


Competing Demands or Clinical Inertia: The Case of Elevated Glycosylated Hemoglobin

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ABSTRACT

PURPOSE This study aimed to examine the contribution of competing demands to changes in hypoglycemic medications and to return appointment intervals for patients with type 2 diabetes and an elevated glycosylated hemoglobin (A1c) level.

METHODS We observed 211 primary care encounters by adult patients with type 2 diabetes in 20 primary care clinics and documented changes in hypoglycemic medications. Competing demands were assessed from length of encounter, number of concerns patients raised, and number of topics brought up by the clinician. Days to the next scheduled appointment were obtained at patient checkout. Recent A1c values and dates were determined from the chart.

RESULTS Among patients with an A1c level greater than 7%, each additional patient concern was associated with a 49% (95% confidence interval, 35%-60%) reduction in the likelihood of a change in medication, independent of length of the encounter and most recent level of A1c. Among patients with an A1c level greater than 7% and no change in medication, for every additional minute of encounter length, the time to the next scheduled appointment decreased by 2.8 days (P = .001). Similarly, for each additional 1% increase in A1c level, the time to the next scheduled appointment decreased by 8.6 days (P = .001).

CONCLUSIONS The concept of clinical inertia is limited and does not fully characterize the complexity of primary care encounters. Competing demands is a principle for constructing models of primary care encounters that are more congruent with reality and should be considered in the design of interventions to improve chronic disease outcomes in primary care settings.


INTRODUCTION

Although tight glucose control can prevent or delay the onset of complications in patients with type 2 diabetes mellitus,1-3 optimal control is frequently not achieved.4-6 Recently, poor glucose control has been attributed to so-called clinical inertia on the part of physicians, defined as "recognition of the problem, but failure to act."7-12 Some have even proposed methods for a measure of clinical inertia as a quality of care indicator.11 The phenomenon of clinical inertia has been difficult to study because of the paucity of data on the content of the patient-physician encounter. All published studies of clinical inertia to date have used administrative or medical record data.

An alternative explanation for failure to intensify therapy despite poor glucose control is the presence of competing demands.14-18 Encounters are bounded by a time constraint within which multiple diagnoses, problems, and patient concerns compete with each other for a place on the agenda. Physicians and patients prioritize demands and only deal with the most pressing or symptomatic problem.19 Problems perceived to be less urgent, for example, intensifying medication therapy for poorly controlled glycosylated hemoglobin (A1c) levels, may not be addressed and may be deferred to future encounters. Competing demands have been shown to
interfere with depression care, mammography screening, and tobacco cessation counseling, and they limit the treatment of unrelated medical disorders. A primary determinant of intensification of therapy for an elevated A1c level may thus be the presence of competing demands during the encounter, not clinical inertia. If competing demands are present, we hypothesize that for patients with an elevated A1c level:

1. As the length of the encounter decreases, the likelihood of a change in hypoglycemic medication will decrease.

2. As the number of patient concerns increases within the bounds of the length of the encounter, the likelihood of a change in medication will decrease.

3. When there is no change in medications, the number of days to the next scheduled appointment will be inversely associated with the length of the current encounter and the most recent A1c level.

**METHODS**

**Study Design and Recruitment**

The Direct Observation of Diabetes Care Study was begun in 2002 with the primary aim of conducting an in-depth examination of the care delivered to patients with type 2 diabetes across a diversity of primary care settings. Details of the study design have been published elsewhere. The design was cross-sectional and observational: no interventions were performed, and participants received their usual care from their primary care physician. The study took place in 20 primary care clinics with 45 primary care physicians. None of the physicians were trainees. Clinics were recruited in a snowball fashion with an attempt to identify and recruit primary care settings wherein people with type 2 diabetes are most likely to seek care: solo practice physician clinics (11 clinics, 11 physicians), group practice settings (3 clinics, 10 physicians), community health centers (1 clinic, 1 physician), Veterans Affairs primary care clinics (2 clinics, 11 physicians), and city-county health clinics for uninsured patients (3 clinics, 12 physicians).

**Patients and Data Collection**

Within each clinic, consecutive patients seeking care with an established diagnosis of type 2 diabetes were recruited to participate in the study. None of the patients approached declined participation. A trained observer accompanied the first 8 to 10 consenting patients in each clinic to the examination room and directly observed the encounter. In the final sample, the range of patients per clinic was 8 to 10 and the range per physician was 1 to 10. The encounter was audio recorded, and a checklist of services performed was completed to record the length and content of each encounter. After each encounter, patients completed a survey form and their medical record was abstracted.

**Definition of Variables**

The observer noted and recorded any increase in dose or any addition or substitution of an oral hypoglycemic agent or insulin during the encounter. We defined these events as changes in medication. The length of the encounter was defined as the number of minutes the clinician was present in the examination room with the patient. The observer listened carefully to the exchange between the patient and physician, and recorded any symptom or complaint brought up by the patient and any topic brought up by the physician. A symptom or complaint was any type of physical or emotional distress expressed verbally by the patient. For example, in one encounter, the patient reported new-onset knee pain, and this was counted as 1 symptom or complaint. We called these collectively patient concerns. The most recent value of A1c in the medical record was used to evaluate glycemic control at the time of the encounter. Length of time between the observed encounter and the most recent A1c measurement was also noted out of concern that physicians may not act to intensify therapy if values are too distant in time. Because the trend in A1c value is often used in making clinical decisions about changes in medications, we created a variable to indicate whether the most recent A1c value was worse than the previous value.

**Analysis**

We used descriptive statistics to examine the central tendency of the observed variables. A Student t test was used to evaluate differences in means. Random effects logistic regression models were used to adjust for the clustering of patients within clinics. We chose clinic as the level of analysis because of the sparse number of patients per physician and because in 12 of the 20 clinics, only 1 physician participated in the study. For the first 2 hypotheses, we included only patients with an A1c level greater than 7%. Change in medication (yes or no) was the dependent variable, and a Bournelli distribution was used because of the dichotomous nature of this variable. To test the third hypothesis, the number of days to the next scheduled appointment was the dependent variable. This model included only patients with both an A1c level greater than 7% and no change in medication. We did not enter any explanatory variables at the clinic level in either model. Descriptive and univariate statistics were performed with SPSS 13.0 (SPSS Inc, Chicago, Ill). All random effects models were performed using HLM 6.0 (Scientific Software International, Inc, Lincolnwood, Ill). Finally, there was a possibility that the interaction...
style of the physician during the encounter might influence the likelihood of a change in medication. For example, if some physicians tended to address $A_{1c}$ results and the need for a change in medication early during the encounter, they might have been less likely to elicit patient concerns. We evaluated this possibility in a separate analysis to determine whether these discussions occurred earlier in encounters with a medication change. Using the Davis Observation Codes, we examined the proportion of the encounter that occurred before the first of 2 behaviors appeared: (1) an “evaluation or feedback” code for when the physician tells the patient about results of recent test results, such as an $A_{1c}$ level, and (2) the “planning treatment” for when the physician and patient discussed a treatment plan, such as a change in medication. In addition, we used the Davis Observation Codes to compare the amount of time spent discussing diet, exercise, and medication adherence between patients with and without a change in medication.

This study was reviewed and approved by the institutional review board at the University of Texas Health Science Center, San Antonio, Tex.

RESULTS

A total of 211 patient encounters were observed across the 20 clinics. Of these, 177 patients had an $A_{1c}$ value recorded in their medical record before the encounter. Of the 18 patients without an $A_{1c}$ value, 8 were new patients and 1 received diabetes care from an outside specialist, resulting in 25 patients with missing $A_{1c}$ values. There were no differences in age, sex, race/ethnicity, or length of relationship with current primary care physician between those with and without an $A_{1c}$ value in the chart. None of the clinics had more than 2 patients with a missing value. For those with an $A_{1c}$ value, 35.6% had been obtained within the past 30 days before the encounter and 46.9% had been obtained within the last 60 days. All patients reported that the physician they saw was their usual primary care physician. The length of their current relationship (Table 2) with their usual physician was 54.9 months (SD, 56.4), approximately 6 years. Characteristics of all encounters observed are shown in Table 5.

Table 1. Characteristics of Patients and Encounters (N = 177)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean (SD) or %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>59.0 (13.3)</td>
</tr>
<tr>
<td>Female, %</td>
<td>51.3</td>
</tr>
<tr>
<td>Hispanic, %</td>
<td>59.2</td>
</tr>
<tr>
<td>Hemoglobin $A_{1c}$ level &gt;7.0%</td>
<td>55.4</td>
</tr>
<tr>
<td>&gt;8.0%</td>
<td>34.5</td>
</tr>
<tr>
<td>Length of encounter, minutes</td>
<td>17.0 (8.4)</td>
</tr>
<tr>
<td>Number of patient concerns</td>
<td>2.0 (1.9)</td>
</tr>
<tr>
<td>Encounters with a change in hypoglycemic medication, %</td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>26.7</td>
</tr>
<tr>
<td>With hemoglobin $A_{1c}$ level &gt;7%</td>
<td>35.6</td>
</tr>
<tr>
<td>With hemoglobin $A_{1c}$ level &gt;8%</td>
<td>42.9</td>
</tr>
<tr>
<td>With hemoglobin $A_{1c}$ level &gt;9%</td>
<td>46.4</td>
</tr>
<tr>
<td>Days to next scheduled appointment</td>
<td>60.9 (43.2)</td>
</tr>
</tbody>
</table>

Hemoglobin $A_{1c} = $ glycosylated hemoglobin.

For each additional patient concern, there was a proportion of the encounter spent discussing lifestyle changes or medication adherence between those with and without a change in medication. Patients with a change in medication were taking more medications on a long-term basis than those without a change. Having a most recent $A_{1c}$ level that was worse than the previous value was not associated with a change in medication (odds ratio = 1.09, 95% confidence interval, 0.59-2.03). Physicians were not more likely to order an $A_{1c}$ measurement if there was no change in medications, even if the last $A_{1c}$ level was more than 60 days ago (data not shown). Nor was there any evidence that physician practice style was associated with the likelihood of a change in medication: there were no significant differences between encounters with and without a change in medication in the proportion of encounter time until evaluation and feedback of test results or until discussion of planning treatment occurred (Table 2).

For each additional patient concern, there was a 49% reduction in the likelihood of a change in medication (Table 3). The results did not change if patient age, sex, or a variable indicating that the most recent $A_{1c}$ level was worse than the one before was included in the model. We performed a sensitivity analysis on the relationship between number of patient concerns and change in medication for this group. Once the number of patient concerns exceeded 4, none of the encounters had a change in medication. The analysis was repeated for patients with an $A_{1c}$ level of 8% or higher with similar results (Table 3). The figure displays the relationships between change in medication, length of encounter, and occurrence of any patient concern (yes or no).

For encounters with no change in medication, the
number of days to the next scheduled appointment was associated with the length of the encounter \((P = .001)\). For each additional 1 minute of encounter length, the number of days to the next appointment decreased by 2.8 days. In addition, for each additional 1% increase in \(A_1c\) value, the number of days to the next scheduled appointment decreased by 8.6 days \((P = .001)\). There was no relationship between length of encounter and number of days to the next scheduled appointment for encounters with a change in medication. Nor was there any difference in the number of days to the next appointment between encounters with and without a change in medication (data not shown).

**DISCUSSION**

The concept of clinical inertia does not adequately characterize the complexity of the primary care encounter. Instead, competing demands during the encounter, as observed by the number of patient concerns, is a more accurate description. As the number of patient concerns increased, the likelihood of a change in medication decreased, independent of the length of the encounter, the most recent \(A_1c\) level, the number of topics brought up by the clinician, the length of time since the last \(A_1c\) measurement, and the trend in \(A_1c\) levels. Detailed analysis of the content of the visit failed to support the possibility that physician interaction style explained the association between number of patient concerns and the likelihood of a change in medication.

As previously mentioned, soft reasons to avoid intensification of therapy are cited as an explanation for clinical inertia. For example, clinicians may substitute a discussion of self-care activities for therapy intensification. Our data fail to support this explanation: there was no difference in the amount of encounter time spent discussing self care between encounters with and without a change in medication for patients whose \(A_1c\) value was greater than 7%. It also does not appear that physicians are deferring a decision to change medications because the most recent \(A_1c\) value was obtained too long ago: the number of days since the last \(A_1c\) measurement was not a significant predictor of a change in medication.

Another explanation cited for clinical inertia is “…unawareness on the part of the clinician about the limitations of the care they provide.” Our findings also fail to support this explanation: when there was no change in medication, as length of encounter increased, days to next appointment decreased, suggesting that when the agenda of the encounter was

<table>
<thead>
<tr>
<th>Table 2. Changes in Medication by Patient and Encounter Characteristics if Hemoglobin (A_1c) Value Was Greater Than 7% (n = 98)</th>
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<tbody>
<tr>
<td>Characteristic</td>
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<tr>
<td>----------------</td>
</tr>
<tr>
<td>Patient characteristics</td>
</tr>
<tr>
<td>Age, years</td>
</tr>
<tr>
<td>Female, %</td>
</tr>
<tr>
<td>Hispanic, %</td>
</tr>
<tr>
<td>Number of comorbidities</td>
</tr>
<tr>
<td>Hemoglobin (A_1c), %</td>
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<tr>
<td>Previous hemoglobin (A_1c) level worse, %</td>
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<tr>
<td>Number of long-term medications</td>
</tr>
<tr>
<td>Encounter characteristics</td>
</tr>
<tr>
<td>Number of patient concerns</td>
</tr>
<tr>
<td>Number of topics discussed by physician</td>
</tr>
<tr>
<td>Length of encounter, minutes</td>
</tr>
<tr>
<td>Number of days since last measured hemoglobin (A_1c)</td>
</tr>
<tr>
<td>Percentage of encounter devoted to:</td>
</tr>
<tr>
<td>Discussing nutrition</td>
</tr>
<tr>
<td>Discussing exercise</td>
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<tr>
<td>Discussing medication compliance</td>
</tr>
<tr>
<td>Percentage of encounter time until:</td>
</tr>
<tr>
<td>Evaluation/feedback of test results</td>
</tr>
<tr>
<td>Discussion of planning treatment</td>
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</tbody>
</table>

Hemoglobin \(A_1c\) = glycosylated hemoglobin.

<table>
<thead>
<tr>
<th>Table 3. Predictors of Change in Medication If (A_1c &gt;7%) (n = 98) If (A_1c &gt;8%) (n = 61)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Predictor</td>
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<tr>
<td>----------------</td>
</tr>
<tr>
<td>Number of patient concerns</td>
</tr>
<tr>
<td>Number of clinician topics</td>
</tr>
<tr>
<td>Length of encounter in minutes</td>
</tr>
<tr>
<td>Most recent hemoglobin (A_1c) value</td>
</tr>
<tr>
<td>Number of long-term medications</td>
</tr>
<tr>
<td>Days since last hemoglobin (A_1c)</td>
</tr>
</tbody>
</table>

CI = confidence interval; hemoglobin \(A_1c\) = glycosylated hemoglobin.
full, clinicians were aware of the need to address the elevated A1c level and requested that the patient return sooner. In addition, when there was no change in medication, encounters with higher A1c values had shorter return times, again suggestive that clinicians were aware of the elevated A1c value but deferred action to the next encounter. This finding is consistent with those of a recent longitudinal study of intensification of therapy for poor glucose control: among patients with an A1c value exceeding 8%, therapy was intensified in 58.1% within 3 months and in 69.7% within 6 months.23

Some limitations exist in interpreting findings from this study. One is the potential for change in physician behavior because of the presence of an observer in the examination room during the encounter. If such a performance bias existed, it would most likely have resulted in a bias away from the null hypotheses in this study. That is, given that the purpose of the study as explained to physicians was to “…examine predictors of quality and outcomes of care for patients with type 2 diabetes,” physicians may have focused more on following current evidence-based guidelines with an observer in the room. On the other hand, prior studies of clinical inertia measured length of encounter. A second limitation is the lack of follow-up data. Although patients were scheduled to return sooner if there was no change in medication, we were unable to ascertain whether any action was taken in the subsequent encounter. As mentioned above, when follow-up encounters are analyzed in administrative data, approximately 70% of patients with elevated A1c levels do have a change in therapy within 6 months.24

Why should it matter whether we use the term clinical inertia or competing demands in describing primary care encounters? To understand why a change is or is not made in medication in the face of inadequate glucose control or any other observed phenomenon in a scientific manner, we develop an abstract representation, or a model, that helps us simplify reality so that we can understand what we observe.24 To construct a model, we use general principles that are rules for constructing models. One example of such a principle is that of natural selection. Different principles result in very different models. The empirical question that one must then answer is how well one model developed with one principle fits the intended aspects of the real world compared with a different model developed using a different principle. In this study, the principle of competing demands, when applied to a model of the clinical encounter, results in a better fit than a model constructed using the principle of clinical inertia. Studies conducted using a model based on the principle of clinical inertia thus are likely to provide misleading results, and interventions designed based on this principle are likely to be ineffective.

The principle of competing demands is also consistent with recent observations that primary health care delivery demonstrates properties of a complex adaptive system.25 These systems have nonlinear dynamic patterns over time, contrary to the notion that encounters are linear and mechanistic and follow the rules of Newtonian physics, such as demonstrating the property of inertia. Newtonian inertia states that objects at rest will remain at rest and those in motion will remain in motion until acted on by a force. Our findings suggest that primary care encounters are neither static nor linear, but instead are filled with multiple activities, suggesting movement. The problem with calculating a vector for movement (velocity plus direction) is that we do not know in which direction the agents in the system (physician and patient) are moving. It is therefore somewhat pejorative to assert that physicians are moving in the wrong direction when they are addressing problems other than a change in medication for glucose control as suggested by the clinical inertia model.

The comprehensiveness of the care provided by primary care clinicians to patients with one or more chronic illness is a strength of primary care but is also
a balancing act that requires prioritization and goal setting by both patient and physician during each encounter in a manner that takes into consideration patient resources, expectations, and willingness to intensify therapy.26-28 In contrast, much of the work published using the term clinical inertia has been from the limited perspective of diabetes specialists interested only in the quality of diabetes care without incorporating any evaluation of care for other concurrent problems. Development of models to advance our understanding of the delivery of primary care to patients with multiple chronic illnesses, including type 2 diabetes, should incorporate the principle of competing demands and complex adaptive system principles, rather than clinical inertia, as should interventions designed to improve outcomes for these patients in primary care settings.29

To read or post commentaries in response to this article, see it online at http://www.annfammed.org/cgi/content/full/5/3/196.

Key words: Diabetes mellitus, type 2; hemoglobin A, glycosylated; ambulatory care; primary care; health care delivery; health services research; quality of care; practice-based research networks; office visits

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These results were presented, in part, at the North American Primary Care Research Group Meeting, October 2005, Quebec City, Quebec.

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Disclaimer: The views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs.

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References

Acanthosis Nigricans and Diabetes Risk Factors: Prevalence in Young Persons Seen in Southwestern US Primary Care Practices

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ABSTRACT

PURPOSE Evidence shows acanthosis nigricans is often associated with hyperinsulinemia and may indicate increased risk of type 2 diabetes mellitus. The purpose of this study was to determine the association of acanthosis nigricans with type 2 diabetes risk factors and disease in young persons.

METHODS We conducted a cross-sectional study in the Research in Outpatient Settings Network, a practice-based research network in southwestern US communities. Participating clinicians (N = 96) collected data on children and young adults aged 7 to 39 years seen during a 2-week sampling period. The main outcomes were the prevalence of acanthosis nigricans, type 2 diabetes risk factors (ethnicity, family history of type 2 diabetes, hypertension, overweight/obesity), type 2 diabetes, and the relationships among these.

RESULTS Among 1,133 patients sampled, risk factors for type 2 diabetes were common: 69% had a family history of the disease; 3% of children (aged 7 to 19 years) and 12% of adults had hypertension; 43% of children and 73% of adults were overweight or obese; and 80% were members of ethnic minorities. Acanthosis nigricans was found in 17% of children and 21% of adults. Among children and adults alike, the more type 2 diabetes risk factors that were present, the higher the prevalence of acanthosis nigricans (P < .001). The prevalence ratio for type 2 diabetes in patients with acanthosis nigricans was 1.97 (95% confidence interval, 1.18-3.27; P = .01) after controlling for age, body mass index, and the number of type 2 diabetes risk factors. Clinicians reported that the identification of acanthosis nigricans frequently led to discussions about lifestyle modification for decreasing the risk of type 2 diabetes.

CONCLUSIONS Patients with acanthosis nigricans are likely to have multiple risk factors for type 2 diabetes. Acanthosis nigricans may be an independent risk factor for this disease. Detection of acanthosis nigricans may help clinicians more rapidly identify high-risk individuals for diabetes counseling.


INTRODUCTION

Type 2 diabetes mellitus has reached epidemic proportions in the United States, affecting 20.8 million people, or 7% of the population. In 2002, this disease cost the nation $132 billion dollars, or 10% of the annual health care budget. Risk factors associated with type 2 diabetes are older age, obesity, family history of the disease, hypertension, dyslipidemia, physical inactivity, and belonging to certain racial/ethnic groups. The greater the number of risk factors a person has, the greater the chance of developing the disease. Lifestyle interventions can prevent or delay disease onset by as much as 58%, making identification of high-risk patients a priority in primary care.

In primary care practices, where competing demands exist within the
Acanthosis nigricans is a dermatologic condition associated in some cases with hyperinsulinemia. Children with this condition are 1.6 times to 4.2 times as likely as those without it to have hyperinsulinemia. Acanthosis nigricans is characterized by thickening and darkening of the upper layers of the skin, resulting in a velvety appearance (see Supplemental Figure, available online-only at http://www.annfammed.org/cgi/content/full/5/3/202/DC1).

Typical areas of involvement include the posterior neck, the axilla, the elbows, and the knees; the neck is involved 93% to 99% of the time. The association of acanthosis nigricans with hyperinsulinemia has led to speculation of a possible further association with type 2 diabetes. The natural history of acanthosis nigricans with respect to type 2 diabetes has not been determined, but evidence suggests the former may be a risk factor for the latter. A readily apparent, rapidly identifiable physical examination marker identifying patients at increased risk for type 2 diabetes could stimulate discussions of lifestyle modifications in the primary care setting.

We conducted this study to clarify further the relationship of acanthosis nigricans to type 2 diabetes mellitus and its risk factors in patients aged 7 to 39 years. These associations are important because the use of this dermatologic condition in identifying patients at increased risk for diabetes can potentially help direct clinical prevention strategies. The research questions addressed in this study were (1) What is the relationship of acanthosis nigricans to type 2 diabetes risk factors? and (2) Is acanthosis nigricans an independent risk factor for type 2 diabetes?

METHODS

Study Design and Setting

We used a cross-sectional study design to describe the prevalence of acanthosis nigricans and other risk factors for type 2 diabetes mellitus in persons aged 7 to 39 years seen in primary care practices in New Mexico. The study was conducted in a practice-based research network, the Research in Outpatient Settings Network (RIOS Net). At the time of the study, RIOS Net comprised 176 clinicians (57% family physicians, 23% pediatricians, 9% internists, 5.5% nurse-practitioners, and 5.5% physician’s assistants) practicing in 30 community health centers, 10 Indian Health Service clinics, 11 academic sites, and 5 private practices. Network members serve predominantly low-income, culturally diverse communities. RIOS Net clinicians were recruited into the study through listserv notices, direct contact, and network meetings. Recruitment was designed to produce a sample of clinicians who were geographically and organizationally representative of the overall network membership.

Sample

Practice staff provided patients a study information sheet while the patients were waiting to be seen. In the examination room, participating clinicians asked all patients aged 7 to 39 years if they would participate. Consecutive 2-week data collection periods were distributed throughout the overall sampling period, from October 2002 to June 2004, to accommodate for seasonal variations in patient visits.

Patients were enrolled only once during the sampling period. Other than age, there were no exclusion criteria. Pregnant women were later excluded from analysis because their weight did not accurately reflect their baseline body mass index (BMI). The protocol was approved by 4 human subjects review boards with jurisdiction over participating RIOS Net practices. We calculated a sample size sufficient to produce an acanthosis nigricans prevalence estimate of 0.5 (which produces a maximum sample size) with 95% confidence interval widths of 0.05. The required sample size was 371 for children aged 7 to 19 years and for adults aged 20 to 39 years.

Data Collection

Data were collected by primary care clinicians at the time of encounter, using either a paper data collection instrument or a personal digital assistant (PDA). Patient demographics, family history of type 2 diabetes in first- or second-degree relatives, personal history of type 2 diabetes, hypertension, or hyperlipidemia by clinician diagnosis; measured height and weight on that day; and presence or absence of acanthosis nigricans on the neck were recorded. Data were collected by the clinician from information available in the chart and by interview of the patient at the time of the visit. Overweight was defined as having a BMI in the 85th to 94th percentile range for children and having a BMI of 25 to 29 kg/m² for adults; obesity was defined as having a BMI in the 95th percentile or greater for children and having a BMI of 30 kg/m² or greater for adults.

Participating clinicians completed Web-based training on acanthosis nigricans before data collection. A
similar training course was validated on a sample of 13 clinicians using an examination that consisted of 20 photographs of patients who had this condition or other dermatoses. The overall sensitivity and specificity in diagnosing acanthosis nigricans after training were 96% (75/78) and 94% (171/182), respectively.

Before data collection, participating clinicians were personally contacted by RIOS Net staff who provided them with study instruments and protocols, instructed them on the research protocol and use of PDAs for data collection, and helped set up computer systems needed to download data from PDAs. In addition, PDAs were programmed to reject out-of-range responses.

The study protocol was piloted in 3 primary care practices. To validate recorded data, the charts of 10 participating clinicians were subsequently reviewed to determine whether diagnoses conformed to published diagnostic criteria. Of 152 charts sampled, 98.7% of participating clinicians were subsequently reviewed to practices. To validate recorded data, the charts of 10 National Committee diagnostic criteria,19 and 94.7% of hypertension diagnoses conformed to the Joint National Committee diagnostic criteria,19 and 94.7% of diagnoses of hyperlipidemia conformed to the National Cholesterol Education Program diagnostic criteria.20

Statistical Analysis

Frequencies, confidence intervals, and summary statistics were calculated for all variables. We evaluated bivariate relationships of acanthosis nigricans to variables related to type 2 diabetes (age, sex, ethnicity, family history of type 2 diabetes, personal history of type 2 diabetes, hypertension, or hyperlipidemia; and BMI). Differences in prevalence of multiple diabetes risk factors in bivariate analyses are displayed in Table 2. For those who knew their health history, 69% had a family history of type 2 diabetes. American Indians had the highest prevalence of family history (78%), followed by Hispanics (69%). Some 73% of adults aged 20 to 39 years and 43% of children aged 7 to 19 years were overweight or obese. In all racial/ethnic groups except the non-Hispanic white group, the prevalence of overweight or obesity exceeded 50%. Adults and males had a higher prevalence of hypertension and hyperlipidemia; however, more than half of the population had an unknown lipid status. Acanthosis nigricans was seen in 17% of children and 21% of adults. Its prevalence by racial/ethnic group ranged from 3% in non-Hispanic whites to 19% in Hispanics and 28% in American Indians.

Patient demographics associated with diabetes risk factors in bivariate analyses are displayed in Table 2. For those who knew their health history, 69% had a family history of type 2 diabetes. American Indians had the highest prevalence of family history (78%), followed by Hispanics (69%). Some 73% of adults aged 20 to 39 years and 43% of children aged 7 to 19 years were overweight or obese. In all racial/ethnic groups except the non-Hispanic white group, the prevalence of overweight or obesity exceeded 50%. Adults and males had a higher prevalence of hypertension and hyperlipidemia; however, more than half of the population had an unknown lipid status. Acanthosis nigricans was seen in 17% of children and 21% of adults. Its prevalence by racial/ethnic group ranged from 3% in non-Hispanic whites to 19% in Hispanics and 28% in American Indians.

Table 1. Characteristics of the Study Sample (N = 1,133)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>% (No.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td></td>
</tr>
<tr>
<td>7-11</td>
<td>15.8 (179)</td>
</tr>
<tr>
<td>12-19</td>
<td>26.8 (304)</td>
</tr>
<tr>
<td>20-29</td>
<td>26.4 (299)</td>
</tr>
<tr>
<td>30-39</td>
<td>31.0 (351)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>61.6 (698)</td>
</tr>
<tr>
<td>Male</td>
<td>38.4 (435)</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
</tr>
<tr>
<td>American Indian</td>
<td>35.7 (405)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>30.6 (347)</td>
</tr>
<tr>
<td>White, non-Hispanic</td>
<td>16.9 (192)</td>
</tr>
<tr>
<td>Other*</td>
<td>13.7 (155)</td>
</tr>
<tr>
<td>Missing data</td>
<td>3.0 (34)</td>
</tr>
</tbody>
</table>

* Other race/ethnicity included Asian, black, Pacific Islander, or mixed. Five of the 155 patients were not Hispanic or Latino and reported “other race.”
Acanthosis Nigricans and Diabetes Risk Factors

Children and adults with a family history of type 2 diabetes had more than twice the prevalence of acanthosis nigricans compared with those without such family history (Table 3). The prevalence of acanthosis nigricans increased as BMI increased and was higher in those with hypertension. Only 13 (3%) of normal-weight patients had acanthosis nigricans. Hyperlipidemia was not included in the analysis presented in Table 3 because of a low screening rate among the sampled population.

Among children and adults with more than 1 type 2 diabetes risk factor (family history of type 2 diabetes, overweight, hypertension, and minority race/ethnicity, defined as race/ethnicity other than white, non-Hispanic), the prevalence rate of acanthosis nigricans increased successively with each additional risk factor (Figure 1). The positive likelihood ratio of having acanthosis nigricans in patients with more than 2 risk factors for type 2 diabetes was 8.3 between ages 7 and 19 years and 4.2 between ages 20 and 39 years. Two patients with none of the examined diabetes risk factors had acanthosis nigricans.

Table 2. Prevalence of Type 2 Diabetes Mellitus Risk Factors and Acanthosis Nigricans by Demographic Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Prevalence*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Family History of Type 2 Diabetes Mellitus</td>
</tr>
<tr>
<td>Total</td>
<td>69.2 (761/1,100)</td>
</tr>
<tr>
<td>Age, years</td>
<td></td>
</tr>
<tr>
<td>7-11</td>
<td>67.4 (118/175)</td>
</tr>
<tr>
<td>12-19</td>
<td>67.2 (195/290)</td>
</tr>
<tr>
<td>20-29</td>
<td>71.8 (211/294)</td>
</tr>
<tr>
<td>30-39</td>
<td>69.5 (237/341)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>71.8 (491/684)</td>
</tr>
<tr>
<td>Male</td>
<td>64.9 (270/416)</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
</tr>
<tr>
<td>American Indian</td>
<td>77.6 (305/393)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>68.8 (234/340)</td>
</tr>
<tr>
<td>White, non-Hispanic</td>
<td>54.9 (100/182)</td>
</tr>
<tr>
<td>Other</td>
<td>60.9 (92/151)</td>
</tr>
</tbody>
</table>

Note: total numbers of patients for each variable are given in Table 1.

* Cell entries show percentages with risk factor present followed by (number positive/number for whom information was available).
† P < .001 for χ² comparing all categories for indicated variable.
‡ P < .05 for χ² comparing all categories for indicated variable.
§ P < .01 for χ² comparing all categories for indicated variable.

Table 3. Prevalence of Acanthosis Nigricans by Type 2 Diabetes Mellitus Risk Factor

<table>
<thead>
<tr>
<th>Type 2 Diabetes Risk Factor</th>
<th>Aged 7-19 Years</th>
<th>Aged 20-39 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>% (95% CI)</td>
</tr>
<tr>
<td>Family history of type 2 diabetes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>313</td>
<td>21.4 (17.0-26.4)*</td>
</tr>
<tr>
<td>No/unknown</td>
<td>170</td>
<td>8.8 (5.0-14.1)</td>
</tr>
<tr>
<td>BMI category†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>274</td>
<td>2.6 (1.0-5.2)*</td>
</tr>
<tr>
<td>Overweight, not obese</td>
<td>80</td>
<td>11.2 (5.3-20.3)</td>
</tr>
<tr>
<td>Obese</td>
<td>129</td>
<td>51.2 (42.2-60.1)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>16</td>
<td>68.8 (41.3-89.0)*</td>
</tr>
<tr>
<td>No/unknown</td>
<td>467</td>
<td>15.2 (12.1-18.8)</td>
</tr>
</tbody>
</table>

BMI = body mass index; CI = confidence interval.

* P < .001 for comparison of prevalence of acanthosis nigricans between those with and without the risk factor.
† For children, normal is defined as less than 85th percentile; overweight but not obese is defined as 85th to less than 95th percentile; and obese is defined as 95th percentile or higher. For adults, normal is defined as 25 kg/m²; overweight but not obese is defined as 25 to 30 kg/m²; and obese is defined as ≥30 kg/m².

Type 2 Diabetes

The overall prevalence of type 2 diabetes in this sample was 6.2%; the prevalence increased as age increased. Ethnic minorities had a higher prevalence than nonminorities (7.3% vs 1.0%, P < .001), and American Indians had the highest prevalence (9.6%). Patients with a family history of type 2 diabetes had almost
4 times the prevalence of the disease, and those with hypertension had close to 10 times the prevalence, compared with those without the respective risk factor. The prevalence was 12% in obese individuals, 3.4% in overweight individuals, and 2.5% in normal-weight individuals. Type 2 diabetes was present in 15% of patients with acanthosis nigricans but only 4% of those without it (P < .001).

Acanthosis Nigricans and Type 2 Diabetes

Patients with diagnosed type 2 diabetes had a higher prevalence of acanthosis nigricans compared with patients without that diagnosis (47% vs 17%, P < .001). Only 5 (1%) of the children had a diagnosis of type 2 diabetes; 3 of the 5 had acanthosis nigricans (P = .04). Of 650 adults, 65 (10%) had type 2 diabetes; 46% of those had acanthosis nigricans, compared with 18% of their nondiabetic counterparts (P < .001).

Acanthosis nigricans was independently associated with type 2 diabetes after controlling for age, BMI, and the number of other examined diabetes risk factors (Table 4). Patients with acanthosis nigricans were 1.97 times as likely as those without it to have type 2 diabetes (P = .01). Patients who were older, obese, and had more than 1 risk factor were also more likely to have the disease.

An Unanticipated Finding

We received reports from a number of participating clinicians that the identification of acanthosis nigricans led to discussions about lifestyle modification that would not have otherwise occurred. Awareness of acanthosis nigricans and its possible association with type 2 diabetes reportedly changed their practice behaviors or changed patient receptivity to discussion about risk reduction for diabetes. Because this outcome was unanticipated, our design did not allow us to systematically study this behavioral phenomenon; however, we report it here as a result of potential importance.

DISCUSSION

We found acanthosis nigricans to be associated with having multiple risk factors for type 2 diabetes mellitus in patients aged 7 to 39 years. As the number of these risk factors increased, so did the prevalence of acanthosis nigricans in both children and adults. The positive likelihood ratio of having this dermatologic condition in patients with more than 2 risk factors for type 2 diabetes was 8.3 for ages 7 to 19 years and 4.2 for ages 20 to 39 years.

Most studies have found acanthosis nigricans to be associated with insulin resistance or hyperinsulinemia, major factors in the pathophysiology of type 2 diabetes, in a substantial proportion of patients.8,9,11,14,22,23 Although our study did not measure insulin levels, we found that acanthosis nigricans was independently associated with diagnosed type 2 diabetes. Patients with this dermatologic condition were 1.97 times more likely than those without it to have type 2 diabetes. Patients with 2 risk factors for type 2 diabetes had a prevalence ratio of 3.4 in children and 4.2 in adults. Types 2 diabetes was present in 15% of patients with acanthosis nigricans but only 4% of those without it (P < .001).

<table>
<thead>
<tr>
<th>Table 4. Type 2 Diabetes Mellitus Prevalence Ratios for Factors Related to Type 2 Diabetes Mellitus, by Log-binomial Regression Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factor</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>Age, years</td>
</tr>
<tr>
<td>7-19</td>
</tr>
<tr>
<td>20-39</td>
</tr>
<tr>
<td>Acanthosis nigricans</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>BMI category</td>
</tr>
<tr>
<td>Normal or overweight</td>
</tr>
<tr>
<td>Obese</td>
</tr>
<tr>
<td>Number of risk factors*</td>
</tr>
<tr>
<td>0-1</td>
</tr>
<tr>
<td>2-3</td>
</tr>
</tbody>
</table>

CI = confidence interval; BMI = body mass index.

* Risk factors included family history of type 2 diabetes mellitus, hypertension, and minority ethnicity.

Figure 1. Prevalence of acanthosis nigricans by number of diabetes risk factors.

Note: Risk factors included family history of type 2 diabetes mellitus, overweight/obesity, hypertension, and minority ethnicity.
likely to have type 2 diabetes compared with their counterparts without it, after controlling for age, BMI, and the number of type 2 diabetes risk factors (hypertension, ethnicity, and family history of the disease). The strength of this association may be understated in these data because we included only patients who had already received the diagnosis of type 2 diabetes.

Clinical detection of acanthosis nigricans may help identify individuals at high risk for type 2 diabetes mellitus because, as noted, acanthosis nigricans is associated with hyperinsulinemia in a proportion of those with this skin condition. Our study supports its association with type 2 diabetes risk factors and disease.

Although obesity and family history are well-known risk factors for type 2 diabetes, they do not lead to screening for the disease at rates approaching their prevalence in primary care. Drobac et al found that screening laboratory tests were ordered for only 38% of children who met screening criteria of the American Diabetes Association for type 2 diabetes. They found that a family history of the disease was frequently not recognized. In addition, in that study of 997 children, BMI was calculated for only 92 children and BMI percentiles were plotted for only 10 children. Similarly, Dorsey et al found that BMI was recorded by clinicians in only 0.5% (3/600) of medical records and that rates of undiagnosed and untreated overweight among children were 79.5% and 83.1%, respectively. Cook et al examined 32,930 ambulatory visits from the 1997 to 2000 National Ambulatory Medical Care Survey and the National Hospital Ambulatory Medical Care Survey, and found that obesity was diagnosed at only 0.78% of all visits and 0.93% of well-child visits. These studies show that well-known risk factors for type 2 diabetes mellitus do not lead to recommended actions to detect the disease.

Although Drobac et al found limited screening for type 2 diabetes in the presence of traditional risk factors for the disease, they also found that 93% of patients with acanthosis nigricans were screened. The report from our clinicians that the detection of acanthosis nigricans stimulated discussions of diabetes prevention suggests that the presence of this condition may somehow change the dynamic of the primary care encounter. Further research is needed to confirm this observation and to determine how the presence of acanthosis nigricans influences clinician decisions to take time to discuss type 2 diabetes risk reduction (eg, by changing patient receptivity to discussions of lifestyle modification).

A recent publication identified factors influencing clinicians’ decisions to include obesity prevention counseling in the brief primary care encounter and may help to explain the clinician response to traditional diabetes risk factors. Clinicians’ decisions about time allocation and decisions to engage in preventive counseling were based on multiple stable and situational factors, including the lack of motivation in their patients. In the face of competing demands within the brief encounter, the observable nature of acanthosis nigricans may influence patient motivation.

**Limitations**

Some limitations to this study should be noted. First, health history was self-reported. Obtaining family history by self-report is standard clinical practice, however, so our method reflects the usual clinical approach. Second, the study design was cross-sectional and therefore limits our ability to determine the natural history of acanthosis nigricans with respect to type 2 diabetes. Third, because our design did not include blood sampling for diabetes, we were not able to identify those who had undiagnosed disease, thereby possibly underestimating its true prevalence among both those with and those without acanthosis nigricans. Fourth, because our protocol did not require that blood samples be drawn to establish the diagnosis of hyperlipidemia, and more than one half of the study population had unknown lipid status, the prevalence of known hyperlipidemia may be underestimated because those with an unknown lipid status were categorized as not having hyperlipidemia. Because of the missing data on lipid status, we did not include hyperlipidemia in our analysis of the relationships between type 2 diabetes risk factors and acanthosis nigricans. Finally, because of the nature of southwestern US communities represented in RIOS Net, Hispanic and American Indian persons were overrepresented in our sample. Acanthosis nigricans is less common in non-Hispanic whites, and the relationships we observed between acanthosis nigricans and type 2 diabetes risk factors and disease may not be generalizable to this group. Further studies are needed to confirm our findings in other populations.

In conclusion, acanthosis nigricans can be used to rapidly identify those patients with multiple risk factors for type 2 diabetes mellitus. Because lifestyle changes have been proven to reduce the incidence of type 2 diabetes in high-risk adults, acanthosis nigricans may provide primary care clinicians with an efficient method for identifying patients who would most benefit from lifestyle modification interventions. Detection of acanthosis nigricans may also enhance patient and clinician receptivity to discussing risk reduction for type 2 diabetes. Studies are needed to investigate the natural history of acanthosis nigricans, its relationship to the development of type 2 diabetes, and how its presence influences screening and counseling for this disease.
To read or post commentaries in response to this article, see it online at http://www.annfammed.org/cgi/content/full/5/3/202.

Key words: Acanthosis nigricans; diabetes mellitus; practice-based research network; primary care; screening; risk factors; risk reduction

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References


Electronic Medical Records and Diabetes Quality of Care: Results From a Sample of Family Medicine Practices

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ABSTRACT

PURPOSE Care of patients with diabetes requires management of complex clinical information, which may be improved by the use of an electronic medical record (EMR); however, the actual relationship between EMR usage and diabetes care quality in primary care settings is not well understood. We assessed the relationship between EMR usage and diabetes care quality in a sample of family medicine practices.

METHODS We conducted cross-sectional analyses of baseline data from 50 practices participating in a practice improvement study. Between April 2003 and December 2004 chart auditors reviewed a random sample of medical records from patients with diabetes in each practice for adherence to guidelines for diabetes processes of care, treatment, and achievement of intermediate outcomes. Practice leaders provided medical record system information. We conducted multivariate analyses of the relationship between EMR usage and diabetes care adjusting for potential practice- and patient-level confounders and practice-level clustering.

RESULTS Diabetes care quality in all practices showed room for improvement; however, after adjustment, patient care in the 37 practices not using an EMR was more likely to meet guidelines for process (odds ratio [OR], 2.25; 95% confidence interval [CI], 1.42-3.57) treatment (OR, 1.67; 95% CI, 1.07-2.60), and intermediate outcomes (OR, 2.68; 95% CI, 1.49-4.82) than in the 13 practices using an EMR.

CONCLUSIONS The use of an EMR in primary care practices is insufficient for insuring high-quality diabetes care. Efforts to expand EMR use should focus not only on improving technology but also on developing methods for implementing and integrating this technology into practice reality.


INTRODUCTION

Use of an electronic medical record (EMR) in ambulatory care settings has been widely recommended as a method for reducing errors, improving the quality of health care, and reducing costs.1-10 One area where EMRs are expected to improve quality is in the management of care for patients with chronic illnesses, such as diabetes. For example, by facilitating the management of complex clinical information, EMRs have been shown to improve the coordination of tasks among members of the health care team,8 to lead to lower rates of missing clinical information,11 and to support evidence-based clinical decision making.12-15 Several recent systematic reviews of EMRs and clinical decision support systems have shown that systems developed in-house over many years lead health care institutions to improve adherence to clinical guidelines.16-18 There is little evidence, however, on whether commercially developed multifunctional health information technology systems, such as EMRs, improve patient care in the primary care settings, where most chronic illness care is delivered.18,19
Much of the current evidence addressing EMR effectiveness in primary care settings is derived from a few intervention studies and from case study reports. Some studies have documented improved diabetes-related patient outcomes after EMR adoption, whereas others have shown improvements in the processes of diabetes care but not in patient outcomes. In a previous case study we found that, with everyday use of an EMR in a primary care practice, clinical decision support functions may be disabled, resulting in EMR uses which differ substantially from those in institutions reporting efficacy of this technology. Another comparative case study found that EMR implementation can have a temporarily negative impact on the quality of diabetes care and care outcomes. In this case, the EMR practice failed to exceed outcomes of a similar non-EMR practice 4 years after implementation. To date, no studies have examined the effect of EMR use across a large number of primary care settings. Such studies are needed to assess the impact of widespread EMR implementation on quality of care in primary care settings.

We examined the relationship between EMR usage and diabetes care quality across a variety of primary care settings by analyzing baseline data collected in 50 family medicine practices participating in an organizational change intervention.

**METHODS**

**Setting**

We analyzed data from family medicine practices in New Jersey and Pennsylvania participating in the Using Learning Teams for Reflective Adaptation (ULTRA) study. This study was designed to improve adherence to multiple chronic disease guidelines through a quality improvement process of organizational reflection and adaptation. The intervention in the study is described in detail elsewhere. A convenience sample of 60 family medicine practices was recruited for the ULTRA study. Practices represented a range of ownership and practice arrangements, including private community-based practices, university-owned practices, health-system-owned practices, solo practitioners, and single-specialty and multispecialty group practices. Five practices withdrew from the study, and 1 practice did not provide information about their medical record system, leaving 54 practices for analysis. Four of the remaining practices had implemented an EMR within the past year. Because the earliest stages of implementation can be disruptive to practice systems, we took a conservative approach and excluded the recent-adopter practices from the analyses. Notably, these 4 practices had diabetes care quality similar to those practices without an EMR, and including recent-adopter practices in either the EMR or non-EMR groups did not substantively change our results.

**Data Collection**

Physician-owners or office managers at participating practices completed a practice information form that asked about various organizational characteristics, including practice type, ownership structure, number of clinicians and other staff, number of years in business, estimates of insurance payer mix, whether they used an EMR, the presence of a registry of patients with diabetes, the regular use of clinician reminder systems, and whether they had adopted a new medical records system within the past 12 months.

For each practice chart auditors retrospectively assessed 20 patient charts randomly selected from a list of all adult patients coded (for insurance purposes) as having been treated for diabetes (ICD-9 diagnosis code 250.x) within the last year. In the 3 non-EMR practices with fewer than 20 patients coded for diabetes, auditors assessed the charts of all diabetes patients. Chart auditors reviewed any paper records available in all practices; in practices with an EMR, they also reviewed the electronic records. Auditors assessed these records in 2003 and 2004, looking at the previous 12-month period to determine diabetes care quality. All chart auditors were formally trained as licensed practical nurses or medical assistants and had experience working in patient care settings. A project physician trained the chart auditors in standard chart review techniques. Using a chart abstraction form developed by clinician researchers on the ULTRA project, auditors abstracted approximately 300 items from each chart.

This study was reviewed and approved by the Institutional Review Board at the University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School. Because this study was a retrospective review of patient records, and no identifiers were recorded, informed consent from individual patients was waived by the Institutional Review Board.

**Measurement**

We assessed diabetes care quality by measuring adherence to guidelines for processes of care, treatment, and achievement of intermediate outcomes for patients with diabetes. A team of family physicians and health services researchers selected the guidelines from the clinical practice guidelines of the American Diabetes Association. Processes of care guidelines were based on their relationship to intermediate outcomes associated with cardiovascular disease risk. To avoid an overly conservative adjustment of significance levels as a result of multiple testing, we created dichotomous
composite scores for adherence in each of the 3 areas (Table 1). For process of care, the care of individual patients was scored 1 if 3 or more of the 5 criteria were met and 0 if fewer than 3 criteria were met. Patients whose care met all of the treatment guidelines were given a score of 1, with all others scoring 0. For the intermediate outcomes variable, we used 2 acceptable limits: (1) patients were given a score of 1 for partial achievement of intermediate outcomes targets if 2 of 3 laboratory values were at or below the target value, and (2) patients were given a score of 1 for complete achievement of outcomes targets if all 3 laboratory values were at or below the target value. We examine these 2 outcomes adherence criteria in separate analyses.

Statistical Analysis
To explore differences between the EMR and non-EMR practices, we used Fisher exact tests for categorical variables (eg, ownership, practice type), and analysis of variance for continuous variables (eg, number of clinicians). When exploring differences between patient level variables, we used hierarchical linear models to account for clustering of patients within practices. With binary variables such as sex, a logit link was used, whereas with continuous variables such as age, a standard identity link was used.

Because our dependent variables were all binary, we used hierarchical logistic regression to examine the log-odds of adherence as a function of EMR use while controlling for practice- and patient-level confounders (eg, practice ownership, staff/clinician ratios, patient age and sex). We used generalized estimating equations, applying the GENMOD procedure within SAS, for estimation.29 The odds ratios associated with each covariate were estimated, and standard errors were adjusted for correlation between patients with diabetes within a practice using a working correlation matrix with an exchangeable structure.30-32

RESULTS
Of the 50 practices, 13 (26%) had used an EMR for 1 year or more. Whereas larger practices were disproportionately represented among EMR-using practices, this pattern was not statistically significant. Although one commonly mentioned benefit of an EMR is the disease registry, only 9 (18%) practices (3 EMR and 6 non-EMR) reported that they used a registry to track the care of patients with diabetes, and this difference was not statistically significant. Furthermore, there were no significant differences between the 2 groups of practices in their use of various electronic or paper reminder systems, such as flow sheets, reminders to clinicians, patient recall systems, or internal chart auditing designed to improve practice adherence to clinical guidelines. Patients in practices that did not use an EMR were somewhat older than those in the practices that reported using an EMR (Table 2). EMR and non-EMR practices did not differ significantly on any of the other patient-level or organizational-level variables. Across both groups, older patients were somewhat more likely to receive the selected treatments and to meet the targets, and male patients were more likely than female patients to meet all 3 treatment targets.

The 50 practices had between 7 and 21 charts of diabetic patients per practice audited, for a total of 927 patients. Across all 50 practices the care of 49.9% of patients met our criterion for processes of care, 46.2% met the criterion for treatment, and 40.3% met the criterion for achievement of 2 of the 3 intermediate outcomes targets. 8.7% met our criterion of simultaneous achievement of all 3 outcomes. Table 3 displays the mean practice-level rates of guideline adherence for EMR and non-EMR practices. In all cases, the mean rates for non-EMR practices were higher. Hierarchical logistic regression analyses showed that, after controlling for potential practice- and patient-level confounders and for the clustering of patients within practices, patients with diabetes in practices that did not have an EMR were significantly more likely to have received care that met the guidelines for processes of care, treatment, and intermediate outcomes (Table 4). For intermediate outcomes outcomes, the odds of patients in non-

<table>
<thead>
<tr>
<th>Table 1. Components of Guideline Adherence Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Processes of Care Any 3 of 5</td>
</tr>
<tr>
<td>-----------------------------</td>
</tr>
<tr>
<td>HgA1c: assessed within last 6 months</td>
</tr>
<tr>
<td>Urine microalbumin assessed within last 12 months</td>
</tr>
<tr>
<td>Smoking status assessed within last 6 months</td>
</tr>
</tbody>
</table>

HgA1c = glycosylated hemoglobin, percentage of total hemoglobin; LDL = low-density lipoprotein cholesterol.
* For outcome measures the most recent recorded value was used.
EMR using practices meeting all 3 targets was 2.68 times the odds of patients in EMR-using practices.

**DISCUSSION**

Diabetes care in the family medicine practices assessed here, regardless of whether they reported using an EMR, showed marked room for improvement, especially with regard to achievement of target values for intermediate outcomes. Contrary to the assumptions underlying suggestions from professional organizations, other researchers, and federal policy makers, we found that EMR usage was associated with poorer adherence to the diabetes quality of care measures examined here. Because we have data for the presence or absence of an EMR only, rather than on specific features of each EMR, our explanation for the quality differences between the 2 groups is somewhat speculative. Because commercially developed EMR systems vary by manufacturer in the features and levels of technological support available to users, our findings are likely to represent an accurate picture of the systemwide health effects of EMR implementation on quality of diabetes care in primary care practices.33 Thus the study findings from our sample may be more representative of the overall effects of EMR implementation than the findings of previous studies evaluating the impact of particular EMR systems or features.

The main limitations of this study derive from the cross-sectional nature of the observations and that data were collected as a baseline for a practice improvement trial rather than to evaluate EMR effects on diabetes care quality. Specifically, our sample may not be representative; in fact, we found that in comparison with national data, a relatively high proportion of the practices participating in this study reported using an EMR.34-37 Our findings are similar to the National Ambulatory Medical Care Survey data in that we found proportionately fewer solo practitioners reporting EMR use.36 Moreover, our overall findings of quality of diabetes care are similar to those from a recent study of a nationally representative sample of patients, which documented a low proportion of recommended care provided to patients with chronic illnesses, such as diabetes.38

<table>
<thead>
<tr>
<th>Variable</th>
<th>EMR Practices (n = 13)</th>
<th>Non-EMR Practices (n = 37)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td></td>
</tr>
<tr>
<td>Processes of care (3 of 5 guidelines met)</td>
<td>35.0 (19.5)</td>
<td>53.8 (22.1)</td>
</tr>
<tr>
<td>Treatment (all guidelines met)</td>
<td>35.3 (16.9)</td>
<td>48.6 (15.7)</td>
</tr>
<tr>
<td>Outcome targets (2 of 3 guidelines met)</td>
<td>29.0 (11.7)</td>
<td>43.7 (15.4)</td>
</tr>
<tr>
<td>Outcome targets (all guidelines met)</td>
<td>3.9 (3.8)</td>
<td>10.7 (9.0)</td>
</tr>
</tbody>
</table>

EMR = electronic medical record.
particular difficulties providing lists of patients, which would potentially bias our results. Even so, excluding these practices from our analyses did not lead to substantially different results.

Finally, this study faces the same limitations of any study that relies on chart audit in that the thoroughness of chart documentation may vary considerably among clinicians, across practice sites, or even between paper and electronic records. Despite these limitations, the guidelines examined here include items likely to be included in most medical records (ie, physical examinations, laboratory testing orders, and laboratory testing results), and a recent study found that in terms of intermediate outcomes, such as those assessed here, electronic and paper charts do not differ in the information that they include.23

Primary care practices are under increasing pressure to computerize their patient records and, as the recent United Kingdom experience has shown, documentation requirements of pay-for-performance programs are likely to increase this pressure.40 Furthermore, the Medicare Management Performance Demonstration of the Centers for Medicare and Medicaid Services, set to begin payments to participating practices in summer 2007, includes a bonus for reporting data using a certified EMR.41 Although pay-for-performance systems also include incentives for increased quality of care and have been successful in the United Kingdom,42 practice leaders may react to these reporting pressures by implementing EMR systems without paying sufficient attention to the effects on the overall system of care delivery within their practices.25 As has been found with computerized physician order entry and other technologically based safety procedures, implementation of health information technologies without sufficient attention to workflow redesign can create new quality problems and adversely affect patient health.43-46 Our findings suggest that these sorts of unintended consequences may already be affecting the quality of diabetes care in our sample of US family medicine practices.

The findings presented here suggest that national policy makers and primary care practice owners should pay renewed attention to maintaining and improving quality in primary care settings during and after EMR implementation. EMR vendors should be encouraged to address existing recommendations to develop products that provide more than a means to enhance billing for clinician services. They should include, or make more easily usable, features that can support improved health care quality (such as developing a chronic illness registry capable of identifying patients for whom treatment intensification would be warranted or offering real-time clinical guidelines support).47,48 More research on best uses of EMR technology and a high level of support for EMR implementation will be required if the federal goal of an electronic health record for every American by 2014 is to be met while preserving and enhancing the quality of care delivered. Policy makers should demand that evidence-based quality benchmarks be met as part of this support to ensure that EMR technology is used to enhance the quality of care. Finally, practice leaders

### Table 4. Practice and Patient Characteristics Associated With Diabetes Care Quality

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Adjusted Odds Ratio</th>
<th>P Value</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Processes of care</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No EMR/EMR</td>
<td>2.25</td>
<td>&lt;.001</td>
<td>1.42-3.57</td>
</tr>
<tr>
<td>Solo practice/other</td>
<td>0.38</td>
<td>.02</td>
<td>0.17-0.87</td>
</tr>
<tr>
<td>Physician owned/other</td>
<td>1.03</td>
<td>.90</td>
<td>0.65-1.62</td>
</tr>
<tr>
<td>Staff/clinician ratio</td>
<td>1.03</td>
<td>.66</td>
<td>0.91-1.17</td>
</tr>
<tr>
<td>Patient sex, male/female</td>
<td>1.21</td>
<td>.22</td>
<td>0.89-1.62</td>
</tr>
<tr>
<td>Patient age in 10-year increments</td>
<td>1.02</td>
<td>.68</td>
<td>0.92-1.13</td>
</tr>
<tr>
<td><strong>Treatment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No EMR/EMR</td>
<td>1.67</td>
<td>.02</td>
<td>1.07-2.60</td>
</tr>
<tr>
<td>Solo practice/other</td>
<td>0.63</td>
<td>.04</td>
<td>0.41-0.98</td>
</tr>
<tr>
<td>Physician owned/other</td>
<td>1.03</td>
<td>.89</td>
<td>0.70-1.50</td>
</tr>
<tr>
<td>Staff/clinician ratio</td>
<td>1.01</td>
<td>.86</td>
<td>0.89-1.16</td>
</tr>
<tr>
<td>Patient sex, male/female</td>
<td>1.06</td>
<td>.74</td>
<td>0.77-1.45</td>
</tr>
<tr>
<td>Patient age in 10-year increments</td>
<td>1.27</td>
<td>&lt;.001</td>
<td>1.14-1.41</td>
</tr>
<tr>
<td><strong>Outcomes 2 of 3</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No EMR/EMR</td>
<td>1.67</td>
<td>&lt;.001</td>
<td>1.25-2.24</td>
</tr>
<tr>
<td>Solo practice/other</td>
<td>0.61</td>
<td>.11</td>
<td>0.33-1.12</td>
</tr>
<tr>
<td>Physician owned/other</td>
<td>1.44</td>
<td>.02</td>
<td>1.05-1.96</td>
</tr>
<tr>
<td>Staff/clinician ratio</td>
<td>1.08</td>
<td>.08</td>
<td>0.96-1.18</td>
</tr>
<tr>
<td>Patient sex, male/female</td>
<td>1.36</td>
<td>.02</td>
<td>1.07-1.72</td>
</tr>
<tr>
<td>Patient age in 10-year increments</td>
<td>1.11</td>
<td>.03</td>
<td>1.01-1.22</td>
</tr>
<tr>
<td><strong>Outcome all</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No EMR/EMR</td>
<td>2.68</td>
<td>.001</td>
<td>1.49-4.82</td>
</tr>
<tr>
<td>Solo practice/other</td>
<td>0.93</td>
<td>.85</td>
<td>0.54-1.94</td>
</tr>
<tr>
<td>Physician owned/other</td>
<td>1.43</td>
<td>.30</td>
<td>0.73-2.78</td>
</tr>
<tr>
<td>Staff/clinician ratio</td>
<td>0.96</td>
<td>.50</td>
<td>0.86-1.08</td>
</tr>
<tr>
<td>Patient sex, male/female</td>
<td>1.40</td>
<td>.17</td>
<td>0.87-2.25</td>
</tr>
<tr>
<td>Patient age in 10-year increments</td>
<td>1.19</td>
<td>.04</td>
<td>1.01-1.42</td>
</tr>
</tbody>
</table>

CI = confidence interval; EMR = electronic medical record.

Note: These odds ratios are obtained from a single regression model for each outcome such that the odds ratios are adjusted for all other covariates in the table.
should encourage a culture of improvement and quality within their practices and work to develop methods to improve diabetes care before implementation of an EMR. Simply having an EMR does not guarantee higher quality care.

To read or post commentaries in response to this article, see it online at http://www.annfammed.org/cgi/content/full/5/3/209.

Key words: Medical record system/computerized; diabetes mellitus; quality of health care; primary health care; electronic medical records

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References


Sufficiently Important Difference for Common Cold: Severity Reduction

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ABSTRACT

PURPOSE We undertook a study to estimate the sufficiently important difference (SID) for the common cold. The SID is the smallest benefit that an intervention would require to justify costs and risks.

METHODS Benefit-harm tradeoff interviews (in-person and telephone) assessed SID in terms of overall severity reduction using evidence-based simple-language scenarios for 4 common cold treatments: vitamin C, the herbal medicine echinacea, zinc lozenges, and the unlicensed antiviral pleconaril.

RESULTS Response patterns to the 4 scenarios in the telephone and in-person samples were not statistically distinguishable and were merged for most analyses. The scenario based on vitamin C led to a mean SID of 25% (95% confidence interval [CI] 0.23-0.27). For the echinacea-based scenario, mean SID was 32% (95% CI, 0.30-0.34). For the zinc-based scenario, mean SID was 47% (95% CI, 0.43-0.51). The scenario based on preliminary antiviral trials provided a mean SID of 57% (95% CI, 0.53-0.61). Multivariate analyses suggested that (1) between-scenario differences were substantive and reproducible in the 2 samples, (2) presence or severity of illness did not predict SID, and (3) SID was not influenced by age, sex, tobacco use, ethnicity, income, or education. Despite consistencies supporting the model and methods, response patterns were diverse, with wide spreads of individual SID values within and among treatment scenarios.

CONCLUSIONS Depending on treatment specifics, people want an on-average 25% to 57% reduction in overall illness severity to justify costs and risks of popular cold treatments. Randomized trial evidence does not support benefits this large. This model and these methods should be further developed for use in other disease entities.


INTRODUCTION

It is generally agreed that randomized controlled trials (RCTs) provide the least biased evidence regarding the effects of interventions on health-related outcomes, and hence are important for medical decision making and public policy. These principles apply to treatments aimed at reducing symptom burden, screening tests designed to detect disease, or preventive therapies aimed at avoiding diseases altogether.

Randomized trials are powered to detect specific effect sizes. The larger the number of participants, the smaller the effect size that can be detected. A trial that is too small may miss an effect size that might be important, whereas a larger trial might demonstrate an effect that is too small to be clinically significant. Following this rationale, many experts now agree that trials should be powered to detect a minimal important difference.1-3 This conceptual entity was first defined in 1989 to be "the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troubling side effects and excessive cost, a change in the patient’s management."16 Although an important addition to the theory and practice of evidence-
Based medicine, minimal important difference is limited in that it does not account for negatively valued consequences of medical interventions (harms), such as costs, side effects, and risks of adverse effects.

In 2005 we defined "sufficiently important difference" (SID) as "the smallest amount of patient-valued benefit that an intervention would require in order to justify associated costs, risks, and other harms." We consider SID to be very similar to the "smallest worthwhile effect" concept described elsewhere. The advantage of SID is that it extends the notion of minimal important difference, has an operational definition, and can be estimated using benefit-harm tradeoff methods. Using reduction of illness duration in the common cold as the desired benefit (outcome), we previously showed how benefit-harm tradeoffs could serve as a method of SID estimation. In this article, we report on a second sample of respondents and assess SID as overall severity reduction benefit.

METHODS

Using community advertisement, we interviewed respondents with acute respiratory tract infection, presumed viral (common cold). This study was carried out alongside other common cold research projects using shared study promotion and screening methods, one of which was an RCT testing echinacea, placebo, and doctor-patient interaction. Another project was aimed at assessing validity of the Wisconsin Upper Respiratory Symptom Survey (WURSS), an illness-specific quality-of-life questionnaire instrument. For the WURSS validation study, participants were enrolled within 48 hours of their first cold symptom, then monitored with daily questionnaires until the illness had resolved. To provide data for the current SID study, participants in the WURSS validation study were asked benefit-harm tradeoff questions at enrollment (intake, within 48 hours of first cold symptom) and again at exit, after the illness had resolved. These participants make up the prospective, in-person group of the SID study. The same benefit-harm tradeoff questions were administered to a second group of participants interviewed by telephone. Participants responding by telephone also had self-described colds but were interviewed only once and had extended inclusion criteria allowing symptoms for up to 7 days.

To be eligible for either arm of this study, prospective adult participants had to answer "yes" to the question, "Do you think that you have a cold or are coming down with a cold?" They also had to report at least 1 of 4 cold symptoms (sneezing, runny nose, nasal obstruction, or sore throat), and to have a total Jackson score of at least 2 points. Jackson scores are simple sums of severity ratings (1 = mild, 2 = moderate, 3 = severe) for 8 symptoms: those noted above plus cough, headache, chilliness, and malaise. For prospective participants with eye or nose itching, sneezing, or history of allergy, the interviewer, as well as the participant, had to be convinced that the participant's symptoms indicated a cold, not an allergic illness. Interviewers were also given permission to exclude potential participants whom they suspected were dishonest when reporting symptoms or whom they believed would not be competent to follow study protocol. These instances occurred rarely. Interviewers questioned prospective participants by telephone and then again in person using semistructured interview techniques aimed at stimulating recall to enhance accuracy of symptom reporting. All interviewers were trained and supervised by the senior author (B.B.), a family physician and anthropologist who had substantial experience with interview methods and patients with acute respiratory tract infection. The protocol was approved by the Institutional Review Board of the University of Wisconsin School of Medicine and Public Health.

Interviews began with the following statement:

We are trying to understand what people think about when making decisions about treating their colds. Specifically, we're interested in how much benefit you would want to expect in exchange for the costs and possible side effects of a given treatment. Benefit can come in the form of reduced severity and/or decreased duration of illness. I would like to describe 4 different cold treatments, then have you tell me whether or not you would want to take these medicines, and why or why not.

Next, the participant was presented with 1 of the following scenarios:

A 10-cent vitamin pill must be taken 3 times daily for the first 3 days of your cold. There are no significant risks or side effects to this treatment. It is unlikely that the length of your cold would be reduced significantly. Severity of symptoms might be reduced by as much as 30%.

A 20-cent lozenge must be dissolved in the mouth every 2 to 3 hours while awake for the first 3 days of your cold. Side effects may include bad taste, and, very occasionally, nausea. It is possible that the length of the cold could be reduced slightly. Severity of symptoms might be reduced by as much as 30%.

A 50-cent dropperful of an herbal extract must be taken 3 times each day for the first 3 days of your cold. Side effects are limited to bad taste. It is possible that the length of the cold could be reduced slightly. Severity of symptoms might be reduced by as much as 30%.

A $2 prescription-only pill must be taken 3 times daily for the first 3 days of the cold. Side effects are unknown. Preliminary data suggests an average 24-hour reduction in

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the length of your cold. Severity of symptoms might be reduced by as much as 30%.

The scenarios were presented in varied order, so that each scenario had an approximately equal chance of being considered first, second, third, or last. After each scenario was presented, participants were asked, “Would you take this treatment?” and then, “Why?” or “Why not?” Brief notes were taken regarding the answers to these qualitative questions. Next, participants who had answered “yes” to the original question were asked: “Would you take this [treatment] if it were able to reduce severity by 20%?” If the answer was still “yes,” the hypothetical severity reduction was lowered to “10%,” then if still “yes,” it was lowered to “5%,” and, finally, “any?” If the original answer was “no,” severity reduction benefit was increased to “40%,” then if still “no,” it was increased to “50%,” then “75%.” Severity reduction SID was defined as the smallest severity reduction that justified the treatment scenario for that participant.

The scenarios represent our interpretation of best evidence available when the study began. Although potential severity reduction benefits were varied beyond what many experts would consider reasonable (ie, a 75% overall severity reduction is unlikely), the initial scenarios were designed to be realistic. Toward this end, we reviewed trial reports and systematic reviews16-19 and aimed for a brief scenario that was both easy to understand and evidence-based.

After benefit-harm trade-off interviews were completed, we gathered descriptive data, including age, sex, tobacco use, ethnicity, income, and educational achievement. Responses were scored on paper forms by the interviewer for telephone interviews, and directly on paper by the participant for the in-person interviews. Data were entered twice, then cross-checked, with discrepancies resolved by comparison with paper sheets. Statistical analysis began with tabular and graphical inspection, followed by assessment of missing data and outliers. We then proceeded to correlation matrices, analysis of variance, and multivariate regression models. We assessed potential relationships of demographic variables (age, sex, smoking, ethnicity, education, income) and Jackson severity scores with the primary SID severity reduction outcome variable. Whereas data representing SID were ordinal in nature, the underlying SID domain was considered to be continuous. We did not assume that SID distributions would be normal and used nonparametric as well as parametric methods in our analysis strategy. Multivariate models were developed using PROC MIXED in SAS 9.1.3 (SAS Institute, Cary, NC, 2001). These models assessed within-person effects assuming a compound symmetry variance matrix.

RESULTS

From May 6, 2003, when the study began until August 22, 2005, when data collection ended, 983 people contacted our research team, and 253 enrolled in 1 of the 2 groups reported here. Of the 730 not enrolled in this study, 217 joined another study, 201 did not meet inclusion criteria, 128 declined to participate, and 43 were simply calling for information. Some 141 could not be categorized meaningfully. Of those excluded, 55 were thought to have allergy or an illness other than a cold, 35 had symptoms for more than 7 days, 25 were younger than 18 years, 19 were considered unreliable after the screening interview, and 67 were excluded for a variety of other reasons. (Our screening protocol allowed people to be excluded for more than one reason.)

Of the 253 participants enrolled in this study, 162 completed a single benefit-harm trade-off interview by telephone. The remaining 91 were enrolled in person within 48 hours of first cold symptom, were followed up with daily reports until their cold had resolved, and then were interviewed again in person using the same questions they were asked at intake. Thus, the database for this report includes data from 162 telephone and 182 in-person interviews, representing SID values for the 253 participants.

Table 1 shows that our sampled population was reasonably diverse in terms of income and education, but mostly female (67.8%) and mostly white (68.4%). Jackson scores were similar for telephone interviews (mean 9.6, SD 3.7) and the intake interviews (mean 9.7, SD 3.6). Demographic measures were collected for all prospective participants, but for only 117 of 162 participants responding by telephone because of interviewer error during the first few weeks of the study. To calculate indicators of central tendency and variability for the SID variable, “any” and “never” responses were conservatively assigned values of 5% and 88%, respectively.

As in our previous study,16 the scenario based on vitamin C received the most favorable ratings, with a mean severity benefit SID of 24.6% (95% CI, 0.23-0.27). Of the 253 participants, 77 (30%) said they would take the vitamin regardless of any severity benefit, and 8 (3%) said they would not even if global severity reduction was 75% or greater (Table 2). The scenario based on the herbal medicine echinacea yielded the next most favorable responses, with a mean SID of 31.9% (95% CI, 0.30-0.34). Among the 253 participants, 39 (15%) said they would take the herbal medicine regardless of severity benefit, and 18 (7%) said they would not regardless of benefit. The scenario based on zinc lozenge led to a mean SID of 46.9% (95% CI, 0.43-0.51), with 12 (5%) saying they would
take the lozenge regardless of severity benefit, and 37 (15%) refusing. Finally, the antiviral scenario had a mean SID for severity benefit value of 57.2% (95% CI, 0.53-0.61), with 12 (5%) saying they would take an antiviral treatment regardless of benefit, and 94 (37%) rejecting such treatment. The range of treatment-specific responses is illustrated in Figure 1.

Extending the analysis a step further, we calculated a value to represent SID for cold treatments in general. Averaging across all 4 scenarios, the general mean severity benefit SID was calculated to be 40.3% (95% CI, 39.3-41.4). To reflect values of those who were sick, and to represent participants equally, only intake and telephone interview data were averaged when computing these values.

Scatter plots, correlation matrices, and simple linear regressions were used to look for potential relationships between SID and the covariates of age, sex, ethnicity, education, household income, Jackson severity score, and nature of interview (telephone, intake, exit). Next, multivariate regression equations were constructed to account for potential covariate influence on SID values. Very little in the way of statistically significant associations were found. Considering multiple comparisons, those associations that were found could be due to chance (Table 3). In both bivariate and full multivariate models, sex was significantly associated with SID for lozenges (coefficient = 0.09; \( P < .05 \)), but not for other treatments. Higher education was significantly associated with lower SID for vitamins in bivariate analysis (fixed-effect F score = 2.98; \( P < .05 \)) and in the multivariate model (fixed-effect F score = 2.57; \( P < .05 \)), but there was no clear dose-response relationship. Education was not significant in other estimates of SID. No other association reached statistical significance.

### DISCUSSION

This study represents the second phase of benefit-harm trade-off interviews aimed at assessing sufficiently important difference (SID) for common cold. In the first study, reduction in duration of illness was the primary benefit domain under investigation. In the present study, overall severity reduction was assessed. The 2 studies yielded very similar results. In both studies, the 4 treatment scenarios followed the same order of preference, with the vitamin requiring the least benefit to justify treatment, then an herbal medicine, then lozenge, and finally a prescription pill. In both studies, neither demographic indicators (age, sex, ethnicity, education, income) nor severity of illness at time of interview appeared to influence SID value judgments. The 2 studies yielded very similar results. In both studies, the 4 treatment scenarios followed the same order of preference, with the vitamin requiring the least benefit to justify treatment, then an herbal medicine, then lozenge, and finally a prescription pill. In both studies, neither demographic indicators (age, sex, ethnicity, education, income) nor severity of illness at time of interview appeared to influence SID value judgments.

In both studies, heterogeneity characterized both between-person and between-scenario distributions. For example, although many participants would accept a treatment for small benefit (10% or less), many others required larger benefits (50% or greater). Similar between-person differences were seen in the first study, with many saying they would take treatments for small duration reductions (12 hours or less for a 6-day cold), but many others indicating the need for larger benefits (36 hours or more). Despite this heterogeneity, specific treatment scenarios yielded distinctive response
distributions. In the current study, for example, mean severity-reduction SID for the prescription antiviral drug scenario (57%) was more than twice that resulting from the vitamin C scenario (25%). This between-scenario difference was even more pronounced in the first study, where the mean SID reduction in length of a 6-day cold was 83 hours (57%) for the prescription pill scenario, but just 26 hours (18%) for the vitamin.10 Qualitative responses in the 2 studies were also similar and helped make sense of response patterns. Participant responses suggested that between-scenario differences were partially due to negatively valued costs and risks. For the prescription pill scenario, responses were influenced by the implication that potential side effects were not well known. Additionally, the need to see a physician was reported as a barrier by some participants. Regarding the lozenge scenario, several participant responses suggested that the use of the word “nausea” negatively influenced responses. Overall, we interpret these findings to support the SID concept and the benefit-harm trade-off method. Effect size in and of itself is not sufficient to justify treatment. Instead, expected benefits should be interpreted within the specific context of associated costs and risks.

Another consistent finding, and one more pronounced in the first study, was the trimodal nature of the SID data distribution. Some people will take a treatment regardless of the benefit under consideration. Some will not, even when hypothetical benefits are large. The majority, however, require a certain amount of benefit to justify costs and risks, which makes sense and fits with both clinical experience and psychological theory. People are (somewhat) rational, and make choices based on perceived likelihood and magnitude of both positively and negatively valued outcomes, but since different people value health-related domains differently, there is diversity in SID magnitudes across populations.

When benefits and harms are made explicit and portrayed in simple language, population distributions of SID are characteristic, reproducible, and largely unaffected by age, sex, ethnicity, income, education, and severity of illness at time of interview. By including 2 sets of participants (in-person and telephone) with varying degrees of illness severity, we were able to show that SID value judgments are influenced by positive and negative aspects of treatments, but not by demographic characteristics, and, in this study, not by severity of illness at time of interview. We must caution that this finding may not generalize to other illness conditions. Indeed, we suspect that preference patterns may be more stable for common cold than for other disease entities, as most people have experienced numerous colds and thus have had a chance to solidify their expectations, values, and preferences regarding cold treatments.

It is relatively clear that existing cold treatments do not provide the SID desired by our participants. Although space does not permit a review of available evidence,20-22 the existence of any benefit is controver-

### Table 2. Sufficiently Important Difference (SID) Severity Benefit by Interview Method and Treatment Scenario Type

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intake</th>
<th>Exit</th>
<th>Telephone</th>
<th>Intake + Telephone</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of interviews</td>
<td>91</td>
<td>91</td>
<td>162</td>
<td>253</td>
</tr>
<tr>
<td>Jackson score, mean (SD)</td>
<td>9.7 (3.6)</td>
<td>1.5 (2.6)</td>
<td>9.6 (3.7)</td>
<td>9.6 (3.7)</td>
</tr>
<tr>
<td>Unadjusted mean SID</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall (SD)</td>
<td>0.40 (0.20)</td>
<td>0.41 (0.16)</td>
<td>0.40 (0.17)</td>
<td>0.40 (0.18)</td>
</tr>
<tr>
<td>95% CI</td>
<td>0.38-0.44</td>
<td>0.36-0.44</td>
<td>0.37-0.43</td>
<td>0.38-0.42</td>
</tr>
<tr>
<td>Accepting, regardless of severity benefit, % (SD)</td>
<td>15.9 (0.37)</td>
<td>17.6 (0.38)</td>
<td>15.3 (0.36)</td>
<td>15.5 (0.36)</td>
</tr>
<tr>
<td>Refusing, regardless of severity benefit, % (SD)</td>
<td>12.6 (0.33)</td>
<td>15.4 (0.36)</td>
<td>14.5 (0.35)</td>
<td>13.8 (0.35)</td>
</tr>
<tr>
<td>Unadjusted mean SID</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sick groups, No. (SD)</td>
<td>0.25 (0.22)</td>
<td>0.32 (0.24)</td>
<td>0.47 (0.26)</td>
<td>0.57 (0.30)</td>
</tr>
<tr>
<td>95% CI</td>
<td>0.23-0.27</td>
<td>0.30-0.34</td>
<td>0.43-0.51</td>
<td>0.53-0.61</td>
</tr>
<tr>
<td>Accepting, regardless of severity benefit, % (SD)</td>
<td>30.4 (46.1)</td>
<td>15.4 (36.2)</td>
<td>4.7 (21.3)</td>
<td>4.7 (21.3)</td>
</tr>
<tr>
<td>Refusing, regardless of severity benefit, % (SD)</td>
<td>3.1 (17.5)</td>
<td>7.1 (25.8)</td>
<td>14.6 (35.4)</td>
<td>37.2 (48.4)</td>
</tr>
<tr>
<td>Group and Jackson score, adjusted SID</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sick groups (SD)</td>
<td>0.23 (0.22)</td>
<td>0.31 (0.38)</td>
<td>0.49 (0.45)</td>
<td>0.63 (0.50)</td>
</tr>
<tr>
<td>95% CI</td>
<td>0.19-0.27</td>
<td>0.27-0.35</td>
<td>0.43-0.55</td>
<td>0.56-0.69</td>
</tr>
</tbody>
</table>

CI = confidence interval.

Note: data distributions tended to skew to the negative (6 of 8 had mean values of ≤50%).

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220 COMMON COLD SEVERITY REDUCTION
COMMON COLD SEVERITY REDUCTION

sial for most, if not all, cold treatments. Even the more optimistic interpretations of existing evidence fall short of supporting overall severity reductions in the 25% to 57% range indicated as necessary by our participants. This conclusion, however, may be trivial compared with the implications should similar results be found for other medical treatments, where effects sizes are usually quite modest. For example, best evidence suggests that a person with mild or moderate depression might expect a 1- or 2-point reduction on the Hamilton Depression Rating Scale, where 20 points is considered indicative of depression.23-25 For Alzheimer-type dementia, where 100 points may be expected on the Alzheimer Disease Assessment Scale cognitive function subscale, a 1- to 3-point improvement may be attributable to cholinesterase inhibitors.26-28 For both classes of medication, monetary costs are substantial and side effects are common. If patients (or their families or caregivers) were provided simple descriptions of likely benefits and harms, how many would choose these treatments? Of the millions currently taking these medicines, how many have been provided an accurate description of expected benefits, costs, and risk of harm?

In our opinion, there have been too few investigations into health values in general and into the nature of clinical significance in particular, which is unfortunate, as medical decision making, as well as trial design and interpretation, is inextricably linked to these conceptual entities. The introduction and development of minimal important difference were milestones, as benefits reaching the minimal important difference threshold must not only be of statistical significance but must also be recognized and valued by patients. The concept of a SID raises the bar another notch, as effect size meeting a SID must also be sufficient to justify costs and risks. Finally, we would like to note that the benefit-harm trade-off methods portrayed here and previously5,10 are only one method of estimating SID. Others will surely be invented, as SID (smallest worthwhile effect) serves as both the effect size for which trials should be powered and as the benchmark by which they should be judged.

Table 3. Potential Explanatory Factors of Sufficiently Important Difference (SID) by Treatment Scenario

<table>
<thead>
<tr>
<th>Factor</th>
<th>Vitamin</th>
<th>Herbal</th>
<th>Lozenge</th>
<th>Antiviral</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>β (SD)</td>
<td>P Value</td>
<td>β (SD)</td>
<td>P Value</td>
</tr>
<tr>
<td>Intercept</td>
<td>0.27 (0.13)</td>
<td>.032</td>
<td>0.49 (0.13)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Female</td>
<td>-0.05 (0.03)</td>
<td>.198</td>
<td>0.04 (0.04)</td>
<td>.292</td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cigarettes, &gt;5/d</td>
<td>0.00 (0.05)</td>
<td>.925</td>
<td>-0.01 (0.05)</td>
<td>.813</td>
</tr>
<tr>
<td>Cigarettes, &lt;5/d</td>
<td>-0.02 (0.05)</td>
<td>.758</td>
<td>-0.10 (0.06)</td>
<td>.092</td>
</tr>
<tr>
<td>Past</td>
<td>-0.03 (0.06)</td>
<td>.634</td>
<td>0.02 (0.06)</td>
<td>.814</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>-0.08 (0.08)</td>
<td>.318</td>
<td>-0.10 (0.08)</td>
<td>.244</td>
</tr>
<tr>
<td>African American</td>
<td>-0.08 (0.09)</td>
<td>.365</td>
<td>-0.04 (0.09)</td>
<td>.704</td>
</tr>
<tr>
<td>Hispanic</td>
<td>-0.03 (0.13)</td>
<td>.803</td>
<td>-0.16 (0.14)</td>
<td>.238</td>
</tr>
<tr>
<td>Asian</td>
<td>-0.14 (0.17)</td>
<td>.415</td>
<td>-0.10 (0.18)</td>
<td>.569</td>
</tr>
<tr>
<td>Education level</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;High school degree</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High school degree</td>
<td>-0.22 (0.08)</td>
<td>.007</td>
<td>-0.08 (0.09)</td>
<td>.348</td>
</tr>
<tr>
<td>Some college</td>
<td>-0.15 (0.08)</td>
<td>.071</td>
<td>-0.07 (0.09)</td>
<td>.417</td>
</tr>
<tr>
<td>College degree</td>
<td>-0.21 (0.06)</td>
<td>.018</td>
<td>-0.13 (0.09)</td>
<td>.175</td>
</tr>
<tr>
<td>≥Graduate school</td>
<td>-0.15 (0.09)</td>
<td>.121</td>
<td>-0.10 (0.10)</td>
<td>.301</td>
</tr>
<tr>
<td>Annual income</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;$15,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$15,000-$25,000</td>
<td>0.10 (0.10)</td>
<td>.339</td>
<td>-0.07 (0.11)</td>
<td>.521</td>
</tr>
<tr>
<td>$25,000-$50,000</td>
<td>0.14 (0.10)</td>
<td>.160</td>
<td>-0.03 (0.10)</td>
<td>.772</td>
</tr>
<tr>
<td>$50,000-$75,000</td>
<td>0.12 (0.10)</td>
<td>.198</td>
<td>-0.11 (0.10)</td>
<td>.274</td>
</tr>
<tr>
<td>$75,000-$100,000</td>
<td>0.08 (0.10)</td>
<td>.440</td>
<td>-0.14 (0.11)</td>
<td>.204</td>
</tr>
<tr>
<td>≥$100,000</td>
<td>0.13 (0.10)</td>
<td>.191</td>
<td>-0.15 (0.10)</td>
<td>.158</td>
</tr>
<tr>
<td>Jackson score</td>
<td>0.00 (0.00)</td>
<td>.679</td>
<td>0.00 (0.00)</td>
<td>.779</td>
</tr>
</tbody>
</table>

Note: Results of multivariate regression analysis of associations of SID with covariates (potential explanatory factors).
COMMON COLD SEVERITY REDUCTION

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**Key words:** Clinical significance; common cold; effect size; important difference; outcomes; quality of life; questionnaires; respiratory tract infections; evidence-based medicine; health policy research; quantitative methods; randomized clinical trial

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**References**


Home Visiting for Adolescent Mothers: Effects on Parenting, Maternal Life Course, and Primary Care Linkage

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ABSTRACT

PURPOSE Adolescent mothers are at risk for rapidly becoming pregnant again and for depression, school dropout, and poor parenting. We evaluated the impact of a community-based home-visiting program on these outcomes and on linking the adolescents with primary care.

METHODS Pregnant adolescents aged 12 to 18 years, predominantly with low incomes and of African American race, were recruited from urban prenatal care sites and randomly assigned to home visiting or usual care. Trained home visitors, recruited from local communities, were paired with each adolescent and provided services through the child’s second birthday. They delivered a parenting curriculum, encouraged contraceptive use, connected the teen with primary care, and promoted school continuation. Research assistants collected data via structured interviews at baseline and at 1 and 2 years of follow-up using validated instruments to measure parenting (Adult-Adolescent Parenting Inventory) and depression (Center for Epidemiologic Studies Depression). School status and repeat pregnancy were self-reported. We measured program impact over time with intention-to-treat analyses using generalized estimating equations (GEE).

RESULTS Of 122 eligible pregnant adolescents, 84 consented, completed baseline assessments, and were randomized to a home-visited group (n = 44) or a control group (n = 40). Eighty-three percent completed year 1 or year 2 follow-up assessments, or both. With GEE, controlling for baseline differences, follow-up parenting scores for home-visited teens were 5.5 points higher than those for control teens (95% confidence interval, 0.5-10.4 points; P = .03) and their adjusted odds of school continuation were 3.5 times greater (95% confidence interval, 1.1-11.8; P < .05). The program did not have any impact on repeat pregnancy, depression, or linkage with primary care.

CONCLUSIONS This community-based home-visiting program improved adolescent mothers’ parenting attitudes and school continuation, but it did not reduce their odds of repeat pregnancy or depression or achieve coordination with primary care. Coordinated care may require explicit mechanisms to promote communication between the community program and primary care.


INTRODUCTION

Adolescent mothers experience rapid repeat pregnancy in the short term,¹ depression,² and school dropout,³,⁴ as well as a reduced probability of future economic independence.⁵ Compared with their adult counterparts, teenage mothers may interact with their children less positively and have unrealistic expectations of child behavior that increase the risk of abuse and neglect.⁶,⁷ Adolescent mothers and children growing up in disadvantaged communities afflicted by drugs, violence, and inadequate supports may be particularly vulnerable.⁸
Family physicians provide most of the adolescent medical care in the United States, but the typical office may find it challenging to address the multifaceted needs of pregnant and parenting teenagers. Primary care clinicians may be better positioned to address these issues if they work in concert with community-based programs.

Home visiting is a community-based strategy for delivering services that aims to improve outcomes for high-risk families through education and support. It can function as a mechanism for integrating health and other services. For adolescents who are hard to engage, at high risk, and living under adverse conditions, home visiting may be particularly beneficial.

Studies of home visiting have raised questions about its practical importance and cost-effectiveness. A recent meta-analysis of 60 programs found wide variation in the effect sizes for outcomes, many of which were quite small. These variations in impact may be due to differences in the target population studied, program goals, design and implementation, outcomes measured, and variables that are difficult to quantify, such as the “fit” between staff and program participants.

Although teenagers might be a group for whom home visiting may be effective, whether and to what extent these programs succeed in coordination with primary care have not been well studied. Such linkages may play a role in outcomes that are influenced by primary care, such as depression and repeat pregnancy.

In 2000, we received funding to implement a community-based home-visiting program for pregnant and parenting teenagers. We evaluated the program experimentally to determine its impact on parenting attitudes and beliefs, repeat pregnancy, maternal depression, and school continuation. We also examined the program’s success in linking adolescents with primary care. We hypothesized that having a usual source of care would be associated with reduced rates of repeat pregnancy and maternal depression.

### METHODS

#### Participant Population

Between February 2001 and January 2003, pregnant adolescents aged 12 to 18 years whose pregnancies were of least 24 weeks’ gestation were recruited from 3 urban, university-affiliated prenatal care sites in Baltimore, Md. Two sites were family medicine sites, and 1 was an obstetrician-gynecologist site. Adolescents attending these clinics were predominantly African American and economically disadvantaged. This study was approved by the Institutional Review Board of the University of Maryland School of Medicine.

#### Design

Program staff identified eligible adolescents from computer scheduling databases and approached them during a prenatal care visit and explained to them the program and study. After informed consent was obtained from adolescents and their parents or guardians, adolescents completed baseline structured interviews administered by research staff and were randomly assigned to a home-visited group or a usual care control group.

#### Home-Visiting Program

In the home-visited group, adolescent mothers received home visitation, mentoring, and case management from 1 of 3 African American women who were recruited from communities served by the program. Home visitors were required to have a high school degree and experience related to health care, child development, or social work. They were selected for their empathetic qualities, ability to relate to teens and families, communication skills, and knowledge of the community.

Home visitation started in the third trimester and was planned to occur biweekly for the first year of the child’s life and then monthly until the child’s second birthday. Each home visitor was assigned a caseload of up to 15 adolescents visited biweekly and up to 10 adolescents visited monthly. They received 2 days of initial training in the use of the curriculum, followed by ongoing training in depression, contraception, substance use, and domestic violence.

We defined a home visit as an in-person contact between the home visitor and adolescent. Two thirds of contacts occurred in adolescents’ homes, whereas the remainder occurred elsewhere in the community, often because of safety concerns related to drug trafficking in the home.

Home visitors were to deliver a parenting curriculum and an adolescent curriculum. The curricula were grounded in social cognitive theory and were developed by a child development psychologist and an anthropologist specifically for urban, African American adolescent mothers. The parenting curriculum sessions aimed to improve teens’ understanding of child development, teach and model good parenting attitudes and skills, and promote appropriate health care use. If the adolescent mother gave consent, the home visitor attempted to engage the baby’s father along with the mother in parenting sessions. The adolescent curriculum sessions provided skills-based, interactive instruction on safer sexual practices, prevention of repeat pregnancy, goal setting geared toward school completion, and training geared toward improving communication and negotiation with partners.
Additionally, home visitors sought to identify depression, partner violence, and school dropout. Adolescents were asked about psychosocial stressors and distress. Their mental health was discussed in biweekly multidisciplinary staff meetings. If depression was identified as a potential concern, the teen was referred to the program’s social worker for further evaluation and counseling, and to primary care and mental health services. Home visitors conducted ongoing assessment of the teen’s school status and actively worked to promote school continuation or reengagement (eg, meeting with school officials, parents).

Finally, home visitors sought to connect adolescents with primary care for management of their contraceptive needs. Adolescents selected their primary care site, which was often different from their prenatal site, based on insurance requirements, location, and preference.

Home visitors completed standardized forms to measure how actual service delivery conformed to program standards (eg, completion of curriculum sessions, linkages).

**Baseline and Follow-up Data Collection**

Research staff blinded to the adolescents’ group assignment conducted structured baseline interviews. The evaluation was separate from program activities; thus, individual-level data collected from research interviews (eg, standardized depression assessments) were not shared with program staff.

Outcome data were collected when the child turned 1 and 2 years old. We used instruments with established psychometric properties to measure parenting attitudes and beliefs, and depression. Contraceptive behaviors, sexual relationships, repeat pregnancies, school status, and relationship with the baby’s father were measured at each follow-up assessment. At the year 2 follow-up interview, we asked adolescents whether they had a “regular personal doctor.” Those responding “yes” were considered to be linked to primary care.

**Measures**

Parenting attitudes and beliefs were measured with Bavolek’s Adult-Adolescent Parenting Inventory (AAPI), which was designed to identify negative parenting attitudes and child-rearing practices associated with a high risk of adverse outcomes for the child. To assess condom and contraceptive use, adolescents were asked how often during the past 12 months they used condoms. Response choices were “never,” “sometimes,” “most times,” and “always.” They were also presented with a list of possible contraceptive methods and asked whether they had used the method. We grouped condom use into “always” vs “not always” and contraceptives into hormonal types (eg, medroxyprogesterone acetate) vs nonhormonal types (eg, spermicide). Repeat pregnancy and birth were assessed by self-report.

Depressive symptoms were measured using the Center for Epidemiologic Studies Depression (CES-D) scale, which contains 20 questions asking about symptoms experienced in the past week. Adolescents having a score of 21 points or higher were defined as having moderate to severe depressive symptoms. For school status, we used the adolescents’ self-reports of whether they were in school, were not in school, or had graduated by the year 2 follow-up interview, and whether they returned to school if, at baseline, they had dropped out.

We assessed maternal demographics and covariates that have been shown to be associated with parenting outcomes, repeat pregnancy, and depression. These variables included history of sexual abuse, exposure to domestic violence, and substance use.

**Analyses**

We used the intention-to-treat approach to analyze the effectiveness of the program. Regardless of the adolescents’ level of program participation (including no home visits and early dropout), we measured outcomes according to their originally assigned group. This method helps maintain the benefits of randomization and minimizes bias when participant attrition is related to outcomes of interest.

We used the χ² Fisher exact test and Student t test to test for differences between the home-visited and control groups in baseline and follow-up measures. We controlled for baseline differences in the follow-up analyses. We checked for differential attrition both within and between the groups. There was no difference between groups in attrition, but we did observe greater loss to follow-up among adolescents reporting greater domestic violence (P < .05) and a trend toward greater attrition for those who were depressed at baseline (P = .09). We controlled for these associations in analyses.

Generalized estimating equations (GEE) were used to examine the impact of the home-visiting program on changes in adolescent mothers’ parenting attitudes and beliefs, contraceptive behaviors, repeat pregnancy, depressive symptoms, school continuation, and linkage to primary care, adjusting for baseline differences. We used GEE because it produces a summary estimate of the group effect averaged over the year 1 and year 2 follow-up assessments, taking into account the correlation of the repeated measurements. We examined using random effects modeling to adjust for within-person and home visitor–level correlations, but the findings were unchanged.

Studies of home visiting demonstrate that participants often have high rates of attrition and receive fewer services than specified by the program’s protocol.
Consequently, we assessed adolescents' total number of completed curriculum sessions and then determined whether they had a high level of exposure (≥75% of planned sessions) vs a low level of exposure (<75% of planned sessions). We repeated the GEE analyses comparing parenting scores of home-visited vs control adolescents, including exposure level in the model and controlling for significant baseline differences.

Finally, we examined whether program participants were more likely to report having a regular personal doctor and whether this variable was associated with contraceptive, repeat pregnancy, and depression outcomes.

We defined statistical significance as $P < .05$ and a statistical trend as $.05 < P < .10$. Our sample size of 40 per group yielded a power of 0.80 to test for an effect size of 0.40 for continuous outcomes. Missing values accounted for less than 6% of all tested independent variables. Descriptive statistics and GEE models were computed with Stata 8.0 (Stata Corp, College Station, Tex).

## RESULTS

We identified 122 eligible pregnant adolescents (Figure 1). Of these, 32 (26%) declined to give informed consent and another 6 (5%) did not complete a baseline assessment. Eighty-four teens were randomized to receive home visits ($n = 44$) and usual care as a control ($n = 40$). Among those randomized, follow-up assessments were completed at 1 year by 62 teens (74%) and at 2 years by 63 teens (75%). Seventy (83%) completed either assessment, and 56 (67%) completed both assessments.

### Figure 1. Participant flow through the study.

<table>
<thead>
<tr>
<th>Eligible pregnant adolescents ($n = 122$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not interested</td>
</tr>
<tr>
<td>Involved in another program</td>
</tr>
<tr>
<td>Guardian refusal</td>
</tr>
<tr>
<td>Schedule/time conflict</td>
</tr>
<tr>
<td>Granting consent ($n = 90$)</td>
</tr>
<tr>
<td>Lost ($n = 6$)</td>
</tr>
<tr>
<td>Refusal</td>
</tr>
<tr>
<td>Unable to contact</td>
</tr>
<tr>
<td>Ineligible</td>
</tr>
<tr>
<td>Baseline complete ($n = 84$)</td>
</tr>
<tr>
<td>Home visit ($n = 44$)</td>
</tr>
<tr>
<td>Control ($n = 40$)</td>
</tr>
<tr>
<td>1-year follow-up complete ($n = 36$)</td>
</tr>
<tr>
<td>1-year follow-up complete ($n = 26$)</td>
</tr>
<tr>
<td>2-year follow-up complete ($n = 31$)</td>
</tr>
<tr>
<td>2-year follow-up complete ($n = 32$)</td>
</tr>
</tbody>
</table>

Note: Some participants in the home visit and control groups who did not complete a year 1 follow-up did complete a year 2 follow-up.
Baseline Characteristics
The home-visited and control groups were comparable on most measures at baseline, except that AAPI parenting scores were significantly higher in the home-visited group (Table 1). The population was predominantly African American, had low socioeconomic status, and experienced challenges and stressors including sexual abuse (10%), physical fighting (31%), depressive symptoms (35%), and school dropout (30%).

Outcomes
The program had a positive impact on adolescent mothers’ parenting attitudes and beliefs. Compared with their control counterparts, home-visited adolescents had significantly improved changes over time in total AAPI scores and 2 of the subscales (Table 2). Among the home-visited group, adolescents received fewer curriculum sessions than intended, 39% in this group completed fewer than 75% of planned sessions. Home-visited teens who completed 75% or more of the parenting curriculum scored 8.3 points higher than control teens on the AAPI (P < .005) (Table 3). On average, high-exposure recipients were older (16.8 vs 15.8 years, P < .05), but exposure level was not related to depression, domestic violence, or relationship with the baby’s father.

We observed a trend toward greater consistent condom use among home-visited adolescents, but no impact on use of hormonal contraception, repeat pregnancy or birth, or depressive symptoms (Table 4). Thirty percent of teens had dropped out of school at baseline. Significantly more home-visited teens than control teens returned to school and graduated by 2 years postpartum (71% vs 44%, P < .05).

At the year 2 follow-up interview, 61% of home-visited adolescents vs 44% of control adolescents reported having a regular personal doctor (P = .25) (Table 5). Teens who reported having a personal doctor were younger and more likely to be depressed at the year 2 follow-up interview. Controlling for age, baseline depressive symptoms, and domestic violence, having a personal doctor was associated with depressive symptoms at the 2-year assessment (adjusted odds ratio = 3.9; 95% confidence interval, 0.9-17.9; P = .08) and continuous insurance (adjusted odds ratio = 4.5; 95% confidence interval, 1.0-20.9, P = .06), but not with program participation.

**DISCUSSION**
Our paraprofessional home-visiting program significantly improved adolescent mothers’ parenting attitudes and beliefs.

---

**Table 1. Baseline Characteristics of Adolescents in the Third Trimester of Pregnancy, Overall and by Study Group**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall (N = 84)</th>
<th>Group</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>16.9 (1.4)</td>
<td>16.4 (1.4)</td>
<td>.40</td>
</tr>
<tr>
<td>African American, %</td>
<td>91</td>
<td>94</td>
<td>.27</td>
</tr>
<tr>
<td>Medicaid insurance, %</td>
<td>77</td>
<td>78</td>
<td>.59</td>
</tr>
<tr>
<td>Received TANF in past month, %</td>
<td>27</td>
<td>27</td>
<td>.57</td>
</tr>
<tr>
<td>Lives with mother, %</td>
<td>65</td>
<td>72</td>
<td>.26</td>
</tr>
<tr>
<td>Continuous health insurance for past 12 months, %</td>
<td>64</td>
<td>68</td>
<td>.34</td>
</tr>
<tr>
<td>Dropped out of school, %</td>
<td>30</td>
<td>37</td>
<td>.16</td>
</tr>
<tr>
<td>Pregnancy and parenting history</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age at first pregnancy, mean (SD), y</td>
<td>15.6 (1.4)</td>
<td>15.4 (1.3)</td>
<td>.27</td>
</tr>
<tr>
<td>Prior birth, %</td>
<td>13</td>
<td>13</td>
<td>1.00</td>
</tr>
<tr>
<td>Abuse and violence exposure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beaten or physically harmed by parent, %</td>
<td>18</td>
<td>15</td>
<td>.51</td>
</tr>
<tr>
<td>Victim of sexual abuse, %</td>
<td>10</td>
<td>10</td>
<td>.89</td>
</tr>
<tr>
<td>In a physical fight in past 12 months, %</td>
<td>31</td>
<td>33</td>
<td>.36</td>
</tr>
<tr>
<td>Household violence: total CTS score, mean (SD)*</td>
<td>26.5 (19.9)</td>
<td>25.1 (18.0)</td>
<td>.52</td>
</tr>
<tr>
<td>Mental health</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depressive symptoms (CES-D score &gt;21), %</td>
<td>34.5</td>
<td>35.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Substance use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Used tobacco in past 30 days, %</td>
<td>10</td>
<td>8</td>
<td>.72†</td>
</tr>
<tr>
<td>Used alcohol in past 30 days, %</td>
<td>5</td>
<td>5</td>
<td>1.0†</td>
</tr>
<tr>
<td>Used marijuana in past 30 days, %</td>
<td>5</td>
<td>3</td>
<td>.62†</td>
</tr>
<tr>
<td>Parenting attitudes and beliefs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total AAPI score, † mean (SD)</td>
<td>111.3 (14.5)</td>
<td>114.4 (13.8)</td>
<td>.04</td>
</tr>
<tr>
<td>Characteristics of baby’s father</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>19.7 (3.6)</td>
<td>19.7 (4.1)</td>
<td>1.00</td>
</tr>
<tr>
<td>In jail, %</td>
<td>14</td>
<td>14</td>
<td>1.00</td>
</tr>
<tr>
<td>Married, living together, going with baby’s mother, %</td>
<td>63</td>
<td>63</td>
<td>.94</td>
</tr>
</tbody>
</table>

**TANF = Temporary Assistance to Needy Families; CTS = Conflict Tactics Scale; AAPI = Adult-Adolescent Parenting Inventory; CES-D = Center for Epidemiologic Studies Depression.**

* Higher scores indicate greater household violence.
† Higher scores indicate better parenting.
‡ By the Fisher exact test.
HOME VISITING FOR ADOLESCENT MOTHERS

Table 2. Program Impact on Parenting Attitudes and Beliefs

<table>
<thead>
<tr>
<th>Parenting Measure</th>
<th>Group</th>
<th>Mean Score (SD)* by Year of Follow-up</th>
<th>Difference in Score Change† Home Visit vs Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Year 1 (n = 62)</td>
<td>Year 2 (n = 63)</td>
<td>β‡ 95% CI P Value</td>
</tr>
<tr>
<td>Total AAPI score, mean (SD)</td>
<td>Home visit</td>
<td>119.6 (14.6)</td>
<td>122.0 (17.2)</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>110.1 (13.7)</td>
<td>111.8 (14.7)</td>
</tr>
<tr>
<td>AAPI subscale scores, mean (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appropriate expectations</td>
<td>Home visit</td>
<td>24.4 (2.8)</td>
<td>24.9 (3.3)</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>23.0 (2.3)</td>
<td>23.3 (2.4)</td>
</tr>
<tr>
<td>Empathy</td>
<td>Home visit</td>
<td>29.2 (4.3)</td>
<td>30.9 (4.2)</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>27.0 (4.3)</td>
<td>27.5 (4.8)</td>
</tr>
<tr>
<td>Avoidance of physical punishment</td>
<td>Home visit</td>
<td>37.3 (5.2)</td>
<td>36.8 (6.9)</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>34.7 (6.1)</td>
<td>34.2 (5.7)</td>
</tr>
<tr>
<td>Avoidance of role reversal</td>
<td>Home visit</td>
<td>28.6 (6.5)</td>
<td>29.4 (7.7)</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>25.4 (5.4)</td>
<td>26.7 (6.4)</td>
</tr>
</tbody>
</table>

AAPI = Adult-Adolescent Parenting Inventory; CI = confidence interval.

* Higher scores indicate better parenting.
† A greater mean difference indicates greater benefit of the home-visiting program relative to the control condition.
‡ Determined by generalized estimating equation (GEE) linear regression analysis with change in parenting score from baseline to follow-up as the outcome, adjusting for age, baseline parenting score, and baseline depressive symptoms.

Table 3. Effect of Level of Exposure to the Parenting Curriculum on Adolescent Mothers’ Parenting Attitudes and Beliefs

<table>
<thead>
<tr>
<th>Parenting Measure</th>
<th>Level of Exposure to Parenting Curriculum</th>
<th>Low Exposure (&lt;75% of Planned Sessions)</th>
<th>High Exposure (≥75% of Planned Sessions)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>β* 95% CI P Value</td>
<td>β* 95% CI P Value</td>
<td>β* 95% CI P Value</td>
</tr>
<tr>
<td>Total AAPI score</td>
<td>0.2 −7.0 to 7.3 .97</td>
<td>8.3 3.2 to 13.3 &lt;.005</td>
<td>0.3 −1.3 to 1.9 .08</td>
</tr>
<tr>
<td>AAPI subscale scores</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inappropriate expectations</td>
<td>0.3 −1.3 to 1.9 .08</td>
<td>1.5 0.4 to 2.5 .01</td>
<td>1.4 −0.7 to 3.5 .19</td>
</tr>
<tr>
<td>Empathy</td>
<td>1.4 −0.7 to 3.5 .19</td>
<td>2.6 0.9 to 4.3 &lt;.005</td>
<td>0.04 −3.2 to 3.3 .98</td>
</tr>
<tr>
<td>Avoidance of physical punishment</td>
<td>0.04 −3.2 to 3.3 .98</td>
<td>2.6 0.2 to 5.0 .03</td>
<td>−0.9 −4.9 to 3.0 .63</td>
</tr>
<tr>
<td>Avoidance of role reversal</td>
<td>−0.9 −4.9 to 3.0 .63</td>
<td>2.1 −0.1 to 4.4 .06</td>
<td></td>
</tr>
</tbody>
</table>

AAPI = Adult-Adolescent Parenting Inventory; CI = confidence interval.

* β = the mean difference in score between intervention home-visited adolescents (with high or low exposure to the curriculum) and control adolescents, using the generalized estimating equation (GEE), and adjusting for age, baseline AAPI scores, baseline depressive symptoms, and household violence.

and increased school continuation relative to usual care; however, the program was not effective in reducing the odds of repeat pregnancy or maternal depressive symptoms. We aimed to link teens with primary care and did observe a nonsignificant trend toward this outcome.

In contrast to findings from a meta-analysis of home-visiting programs that found small changes in parenting,15 our findings found medium to large effect sizes on parenting outcomes.30 Specifically, among home-visited teens overall, the standardized effect size for improved parenting attitudes was 0.49 and was even higher, 0.72, among adolescents who had a high level of exposure to the curriculum. These effect sizes are larger than that reported by Olds et al (effect size, 0.38)31 and may have been due to our sample’s younger mean age and our use of a previously evaluated parenting curriculum that was culturally and age appropriate.25

We furthermore emphasized staff training and monitoring to ensure that staff acquired and used skills to teach, promote, and model positive parenting faithfully.20 Similar to programs that specifically target teenage mothers,15 our program significantly influenced school reentry and graduation. This effect may have been due to the home visitors’ consistent messages and case management activities delivered in the context of their ongoing relationship with the teen. Disruptions in these relationships were rare; during the program’s 4-year lifetime, only 1 of the 3 home visitors left the program. Such continuity may enhance a trusting relationship and increase the impact of messages.32

On the other hand, this program did not improve use of hormonal contraception or reduce repeat pregnancy. Prior studies of home visitation have found a similar lack of impact on prevention of additional pregnancies.16,31 A possible explanation derives from research showing that knowledge of and access to contraceptive services alone do not reduce repeat pregnancy.33,34 Motivation to avoid pregnancy is influenced by many factors, including...
partner preferences for having more children. Although our program did provide adolescents with contraceptive information and counseling, and taught them about safer sexual practices and negotiation skills, it lacked an explicit mechanism to address motivation as the key to postponing childbearing. Additionally, the program lacked specified methods to share information between the home visitors and the primary care physician. Studies suggest that defined communication protocols may facilitate a more seamless and integrated care process.

Despite the program’s focus on assessing adolescents for depression at baseline, providing therapy to those with depression, and recommending further treatment in primary care and mental health settings, the program did not

Table 4. Program Impact on Contraceptive and Pregnancy Outcomes, Mental Health, School Completion, and Linkage With Primary Care

<table>
<thead>
<tr>
<th>Measure</th>
<th>Year of Follow-up</th>
<th>Program Impact at 2 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group</td>
<td>Year 1 n (%)</td>
</tr>
<tr>
<td>Contraceptive use and pregnancy outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Used condoms “always” in past 12 months</td>
<td>Home visit</td>
<td>18/36 (50)</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>9/26 (35)</td>
</tr>
<tr>
<td>Used hormonal contraception in past 12 months</td>
<td>Home visit</td>
<td>18/36 (50)</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>15/26 (58)</td>
</tr>
<tr>
<td>Repeat pregnancy</td>
<td>Home visit</td>
<td>7/36 (19)</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>5/26 (19)</td>
</tr>
<tr>
<td>Repeat birth</td>
<td>Home visit</td>
<td>3/36 (8)</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>2/26 (8)</td>
</tr>
<tr>
<td>Maternal mental health</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depressive symptoms (CES-D score ≥21)</td>
<td>Home visit</td>
<td>8/36 (22)</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>6/26 (23)</td>
</tr>
<tr>
<td>School status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In school or graduated at year 2†</td>
<td>Home visit</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>–</td>
</tr>
<tr>
<td>Linkage with primary care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a regular personal doctor at year 2</td>
<td>Home visit</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>–</td>
</tr>
</tbody>
</table>

AOR = adjusted odds ratio; CI = confidence interval; CES-D = Center for Epidemiologic Studies Depression.

* Adjusted for baseline depressive symptoms and baseline household violence.
† Excludes the 14 adolescents who had graduated at baseline.

Table 5. Selected Characteristics of Adolescent Mothers With and Without a Regular Personal Doctor

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Adolescent Has a Regular Personal Doctor</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes (n = 34)</td>
<td>No (n = 29)</td>
</tr>
<tr>
<td>Demographics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age at baseline, mean (SD), y</td>
<td>16.2 (1.5)</td>
<td>16.9 (1.4)</td>
</tr>
<tr>
<td>Lives with mother at year 2, %</td>
<td>62</td>
<td>46</td>
</tr>
<tr>
<td>Household conflict at year 2: CTS score, mean (SD)</td>
<td>17.4 (14.5)</td>
<td>23.6 (14.5)</td>
</tr>
<tr>
<td>Continuous health insurance from baseline to year 2, %</td>
<td>42</td>
<td>26</td>
</tr>
<tr>
<td>Contraceptive use and pregnancy outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Used condoms “always” in past 12 months at year 2, %</td>
<td>56</td>
<td>35</td>
</tr>
<tr>
<td>Used hormonal contraception in past 12 months at year 2, %</td>
<td>62</td>
<td>62</td>
</tr>
<tr>
<td>Repeat pregnancy by year 2, %</td>
<td>47</td>
<td>35</td>
</tr>
<tr>
<td>Repeat birth by year 2, %</td>
<td>18</td>
<td>14</td>
</tr>
<tr>
<td>Maternal mental health</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depressive symptoms (CES-D score &gt;21) at baseline,* %</td>
<td>38</td>
<td>21</td>
</tr>
<tr>
<td>Depressive symptoms (CES-D score &gt;21) at year 2, %</td>
<td>41</td>
<td>17</td>
</tr>
<tr>
<td>Group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home visit</td>
<td>61</td>
<td>39</td>
</tr>
<tr>
<td>Control</td>
<td>47</td>
<td>53</td>
</tr>
</tbody>
</table>

CTS = Conflict Tactics Scale; CES-D = Center for Epidemiologic Studies Depression.
* n = 19.
† n = 19.
have any impact on adolescent mothers’ depressive symptoms. One possible explanation is that the program did not train the home visitors to use a standardized depression screening tool for ongoing assessment. Consequently, the program may have failed to identify adolescent mothers with incident depression between delivery and 2 years. Beyond this factor, merely identifying depression without giving adolescents specific evidence-based treatment does not improve outcomes. Even if depressed teens were referred to their primary care doctor, the program lacked a well-developed system to coordinate information between the home visitor and the teen’s physician. Consequently, when the teen visited the physician, the physician may have failed to recognize her depression. Barriers in access to care for depressed adolescents may have impacted the teen’s treatment. Consequently, the program may have failed to identify treated depression in these adolescent mothers. In recent years, federal dollars have been drastically reduced for programs that support services for vulnerable pregnant and parenting teenagers in favor of ineffective programs that support “abstinence only until marriage.” This trial reinforces prior studies showing the effectiveness of home visitation in improving important outcomes for economically disadvantaged adolescent mothers, and may be helpful in formulating evidence-based policy. It is possible that other important outcomes, such as repeat pregnancy and depression, could be altered with greater coordination of care. Community-based home-visiting programs and primary care practices may achieve greater benefits if they work together to develop and test explicit mechanisms and implementation systems that coordinate care for high-risk adolescents.

To read or post commentaries in response to this article, see it online at http://www.annfammed.org/cgi/content/full/5/3/224.

Key words: Pregnancy in adolescence; parenting; risk reduction behavior; community services; randomized controlled trials; integration; primary care; health promotion; vulnerable populations; minority groups; home visits; health care delivery; health services research

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References

Different Paths to High-Quality Care: Three Archetypes of Top-Performing Practice Sites

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Steven M. Ornstein, MD

Abstract

Purpose
Primary care practices use different approaches in their quest for high-quality care. Previous work in the Practice Partner Research Network (PPRNet) found that improved outcomes are associated with strategies to prioritize performance, involve staff, redesign elements of the delivery system, make patients active partners in guideline adherence, and use tools embedded in the electronic medical record. The aim of this study was to examine variations in the adoption of improvements among sites achieving the best outcomes.

Methods
This study used an observational case study design. A practice-level measure of adherence to clinical guidelines was used to identify the highest performing practices in a network of internal and family medicine practices participating in a national demonstration project. We analyzed qualitative and quantitative information derived from project documents, field notes, and evaluation questionnaires to develop and compare case studies.

Results
Nine cases are described. All use many of the same improvement strategies. Differences in the way improvements are organized define 3 distinct archetypes: the Technophiles, the Motivated Team, and the Care Enterprise. There is no single approach that explains the superior performance of high-performing practices, though each has adopted variations of PPRNet’s improvement model.

Conclusions
Practices will vary in their path to high-quality care. The archetypes could prove to be a useful guide to other practices selecting an overall quality improvement approach.

Introduction

Given widespread evidence of problems with quality in health care,1-3 researchers and practitioners alike are looking to map out successful paths to improvement. Research conducted in large medical groups and smaller independent practices finds aspects of organizational culture or motivation to be important.4-7 Prescriptions for quality also frequently call for information technology,1,8-10 yet trials of electronic medical record (EMR) tools have met with mixed success.11-15

In response to the need for more research into effective ways to improve quality in the health care system, the Agency for Healthcare Research and Quality funded 21 Partnerships for Quality demonstration projects.16 Among these was Accelerating the Translation of Research into Practice in a Practice-Based Research Network (the A-TRIP study) conducted by the Practice Partner Research Network (PPRNet). A-TRIP joins researchers, an EMR vendor, and primary care practices in an effort to increase adherence to clinical practice guidelines in 8 clinical areas: heart disease and stroke, diabetes mellitus, cancer screening, adult immunizations, respiratory disease/infectious disease, mental health and substance abuse, nutrition and obesity, and medication prescribing in the elderly. The practices use the same EMR, elected to join a research network.
focused on quality improvement, and agreed to participate in the A-TRIP demonstration project. They transmit quarterly data extracts from their EMR and receive, in return, quarterly performance reports for the indicators being studied. Additionally, the practices can elect to receive site visits or attend annual network meetings, both of which are designed to assist the practices with improvement efforts.

In an earlier study, PPRNet identified strategies that were significantly related to higher achievement in clinical process and patient outcomes in small practices and grouped them into 5 categories: activities among practice leaders that (1) prioritize performance and (2) involve all staff, and organizational changes to (3) redesign delivery systems, (4) activate patients, and (5) use EMR tools. Strategies in the first 2 categories enable organizational change and in the latter 3 define specific changes in the delivery of care. The combined set of strategies were packaged as the PPRNet TRIP (Translation of Research into Practice) improvement model and are promoted in A-TRIP practices to guide improvement efforts. Each practice is encouraged to experiment to find the combination of strategies that works best in their setting.

Feedback from the practices indicated that some wanted a more-organic picture. They wondered whether there were specific combinations of strategies that would be more effective in particular situations. They wanted to know what the most successful practices were doing. The study reported in this article was conducted in response to these questions. The aim was to examine the adoption of the PPRNet TRIP improvement model among sites with the best outcomes. Archetypes have been identified that could suggest a path to improvement.

**METHODS**

The design was observational case study research including retrospective and prospective data. How or why questions that focus on contemporary events over which a researcher has little control are ideal for case study research.

The A-TRIP project continuously enrolled practices from October 2002 through September 2005, ultimately including 101 primary care practices. The medical director or owner of each practice consented to participate in the A-TRIP study on behalf of the whole practice. A-TRIP was approved by the Institutional Review Board at the Medical University of South Carolina. A-TRIP process evaluation was approved by the Institutional Review Board at the University of Southern California.

A composite quality score, called the Summary Quality Index (SQUID) was calculated quarterly for each practice participating in the A-TRIP project. The practice-level SQUID is the average percentage of adherence to all applicable clinical guideline indicators among adult patients eligible for at least 1 of the indicators. Altogether, 31 process and 5 patient outcome indicators were included. The 10 practices showing the greatest adherence to the clinical guidelines as indicated by their SQUID at 2 different time points were selected as cases for further study. The 2 time points represented the first 2 quarters after the intervention midpoint, which allowed for an adequate pool of practices active for a year or more, as well as sufficient time to study the selected case practices before the project’s end. Using 2 points in time for selection allowed us to evaluate trends and ensure that a practice was not selected whose high performance at 1 point in time could be explained by a data anomaly.

We combined qualitative and quantitative methods and structured and flexible approaches to data collection to maximize case completeness and validity. We reviewed every available source of data from the A-TRIP project and extracted pertinent information. One data set, created in SPSS 11.5 (SPSS Inc, Chicago, Ill), included quantitative information about adoption of the PPRNet TRIP improvement model. The data came from a survey completed by the medical director of A-TRIP practices, as well as ratings based on structured observations documented in site visitors’ field notes. A second data set, created in NVIVO 2.0 (QSR International, Australia), included qualitative information about each case practice gleaned from comments made by clinicians and staff in each practice, on-site visit evaluations, e-mail follow-up between researchers and the practice, listserv messages posted by practice physicians, best practice presentations made by case study sites at the project’s annual meetings, and notes from key informant interviews with members of the case study sites. Data were collected from different participants and provide multiple perspectives. To minimize reporting bias, we did not explicitly state the intent to develop case studies from our observations until we were at the stage of confirming our findings.

A conceptual framework is useful in case study research to guide data collection and analysis. In addition to general practice characteristics, we specifically sought information to describe how case practices were adhering to the PPRNet TRIP improvement model. The framework allowed us to make cross-case comparisons. Information in the NVIVO data set was coded and written up as similarly structured individual case summaries. These summaries were reviewed by site visitors and discussed by the research team. The within-case analyses were conducted first.
to maximize validity. Cross-case comparisons were then conducted, and additional information was sought if needed. Case-ordered matrices of model adoption were constructed to compare approaches, and qualitative themes were compared among cases to identify case types. These types and their distinguishing features were discussed among the research team with an aim to identify any inconsistencies or alternative explanations. The resulting case practice types, or archetypes, are designed to serve as models for other practices with similar features. In describing the archetypes, differentiating characteristics to which other practices might relate have been emphasized to increase personal meaning or relevance. The report was shared with case practice sites and presented at the final project network meeting to validate findings. Additional details of the study methods can be found in the Supplemental Appendix, which is available online at http://www.annfammed.org/cgi/content/full/5/3/233/DC1.

RESULTS
Selecting the top 10 practices at 2 time points midway into the intervention (January and April 2005), resulted in a pool of 11 medical offices. When we compared these case practices with the 89 other practices in the A-TRIP study using data available for April 2005, we found the case practices had significantly higher SQUID values (using t tests: 54.5% ± 4.9% vs 33.0% ± 8.0%; P < .001). The patient population may have been slightly more complicated among case practices compared with the other practices. For example, the mean age among patients in case practices was higher (albeit not significantly) than among patients in other practices (52.8 ± 6.8 years vs 48.5 ± 5.4 years; P = .26), and the number of eligible quality measures per patient (of a possible 37) was significantly higher in case practices compared with other practices (13.2 ± 2.4 vs 11.1 ± 1.3, P = .025).

Three of the 11 practices were semi-independent offices within 1 medical group and were combined for qualitative study, yielding 9 cases, or practices, altogether. From these practices, 3 main approaches to improving guideline adherence emerged: practices that relied mostly on high-end use of EMR tools (the Technophiles), practices that focused first on engaging staff and clinicians and experimented with a variety of improvement strategies (the Motivated Team), and practices that resembled motivated teams but also organized improvements with focused care management (the Care Enterprise). Information about each of the practices is summarized in Table 1 by archetype. The practice characteristics that are provided do not vary predictably by archetype.

Common Features
Case practices shared several traits that are likely to have contributed to their high performance. The practices were older and well established and were in no apparent financial distress. The newest practice was started by a physician who had a successful history of opening and expanding medical offices. Additionally, a leader prioritized performance in each practice at baseline, and regardless of whether individuals had reservations about improvements, they were able to work together as a practice to support their leader’s vision of excellence. To guide their efforts, most practices used the A-TRIP practice performance reports, as well as corresponding patient-level reports that function as a registry. The practices were realistic about performance measurement in the understanding that the ultimate goal was providing the best care for each individual patient. The practices also worked in close partnership with their patients. They used care plans and patient education to ensure that patients played an active role in guideline adherence.

Variations in adoption of PPRNet’s improvement model are depicted in Table 2. Technophiles used a smaller variety of strategies than the other archetypes. As a group, the case practices adopted more strategies than their A-TRIP peers.

The Technophiles Archetype
All practices in the A-TRIP study used an EMR. Five of the high-performing case practices were distinguished by their quick adoption and consistent use of EMR tools.

The practices in this archetype developed problem-based templates that guide clinicians and staff to perform and document routine tasks consistently. A template might guide a nurse to record blood pressure and prompt a screening assessment of alcohol use. A template could also guide a clinician through routine management of a particular chronic condition. The template could import the patient’s last laboratory results or blood pressure, temperature, pulse rate, and respiratory rate, and include reminders about care recommended in new guidelines, as well as links to patient education. Improvements were seen in all 5 Technophile practices in both process and control measures: after 36 months, for example, the mean percentage of patients with diabetes who had a glycosylated hemoglobin (HbA1c) test in the past 6 months increased from 66.1% (SD 8.1) to 78.6% (SD 4.7), and the mean
The percentage of patients whose low-density lipoprotein cholesterol was <100 mg/dL increased from to 43.3% (SD 6.0) to 65.0% (SD 5.9). The mean percentage of patients with hypertension whose last blood pressure measurement was <140/90 mm Hg increased from 57.2% (SD 12.2) to 72.2% (SD 4.8).

The Technophiles used interfaces that electronically load laboratory results into the EMR. They took advantage of features that automate the physicians’ review of test results. They developed personalized patient letters that provided tests results and education. They established protocols and assigned responsibility to run regular recalls for care, notifying patients that visits or tests were needed, and they used their scheduling software and reminders to make sure patients got follow-up care when they needed it for conditions such as diabetes.

The clinicians in this archetype made good use of internal messaging features in the EMR. Messages were sent by physicians to themselves to remind them to do follow-up items. Messages sent between staff

### Table 1. Description of Practice Characteristics, by Archetype

<table>
<thead>
<tr>
<th>Ownership and Region</th>
<th>Specialty, No. of Doctors* and Other Clinicians</th>
<th>Payer Mix†</th>
<th>Description of Patients</th>
<th>Year Practice Opened, Year EMR Acquired</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technophiles</td>
<td>Physician partnership, Mid Atlantic</td>
<td>Internal medicine, 2</td>
<td>Medicare,† 22% Other insurance, 74% Self-pay, 4%</td>
<td>Most are working, middle to upper-middle class</td>
</tr>
<tr>
<td></td>
<td>Multiple physician partnership, South</td>
<td>Family medicine, 4 Nurse-practitioner, 1</td>
<td>Medicare, 20%-25% Medicaid, 5%-10% Other insurance and some uninsured make up remainder</td>
<td>Representative of community: from jobless/literate to some doctors/professors. Mostly middle class, less than one half with college degrees</td>
</tr>
<tr>
<td></td>
<td>Physician-owned service corporation, Midwest</td>
<td>Internal medicine, 6</td>
<td>Medicare, 35%-40% Medicaid, 5%-10% Other insurance, 50%-60% Uninsured, &lt;2%</td>
<td>Representative of metro area: from limited-income elders to a few advanced-degree professionals; 60%-70% working class</td>
</tr>
<tr>
<td></td>
<td>Physician partnership, incorporated, South</td>
<td>Family medicine, 2 Nurse-practitioner, 1</td>
<td>Medicare, 18%-20% Medi/Medi, 12%-15% Other insurance, 65%-70%</td>
<td>Low-education levels, high unemployment (poverty rate in community is 35%). Practice draws from 3-4 small counties and also serves college and industry employees</td>
</tr>
<tr>
<td></td>
<td>Physician partnership, West</td>
<td>Internal medicine, 2 Physician’s assistant, 1 Nurse-practitioner, 3</td>
<td>Medicare, 25% Medicaid, 1% Other insurance, 74%</td>
<td>Majority are upper-middle class</td>
</tr>
<tr>
<td>Motivated Team</td>
<td>Physician partnership, incorporated, Midwest</td>
<td>Family medicine, 2 Nurse-practitioner, 1</td>
<td>Medicare, 32% Medicaid, 5% Other insurance, 55% Self-pay, 8%</td>
<td>Rural, mostly middle-income and lower education levels, range includes uninsured farmers and top officials in companies</td>
</tr>
<tr>
<td></td>
<td>Hospital, Midwest</td>
<td>Family medicine, 8 Physician’s assistant, 1</td>
<td>Medicare, 16% Medicaid, 4% Other insurance, 77% Self-pay, 3%</td>
<td>Urban, mixed-race/ethnicity, representative of blue-collar community</td>
</tr>
<tr>
<td>Care Enterprise</td>
<td>Physician, Gulf Coast</td>
<td>Internal medicine, 1 Nurse-practitioner, 1</td>
<td>Medicare, 60% Medicaid, 5% Other insurance, 35%</td>
<td>Geriatric practice, most are retired military. Spectrum from very poor to very wealthy</td>
</tr>
<tr>
<td></td>
<td>Physician, South</td>
<td>Internal medicine, 2 Nurse-practitioner, 2</td>
<td>Medicare, 33% Medicaid, 3% Other insurance, 62% Uninsured, 2%</td>
<td>Largely blue-collar but includes aerospace engineers. About 25% African American, 2% Hispanic</td>
</tr>
</tbody>
</table>

A:TRIP = Advanced Translation of Research into Practice; SQUID = Summary Quality Index; EMR = electronic medical record; Medi/Medi = Medicare Medicaid crossover.

* Number of individuals, may be part-time or full-time.
† Other insurance includes private insurance, commercial insurance, and preferred provider organizations, eg, Blue Cross, Cigna.
‡ Proportions are based on charges; the percentage of visits that are Medicare in this practice is higher.
and clinicians made care coordination more efficient. The best practices in this archetype also used consistent diagnostic nomenclature, which made it easier for them to query their EMR data using the built-in EMR query functions to identify subgroups of patients needing follow-up care.

At the core of each of the practices in this archetype was a physician who was driven to achieve both good care and efficiency. This physician was dedicated to finding new ways to use the EMR, and tended to speak in terms of the time it takes to get things done. Some have described themselves, and have been described, as compulsive. These physicians were innovators and could modify the EMR quickly and easily to include reminders and links that automate care decisions, coordination, and documentation. These physicians also stimulated practicewide improvement by their role as a change champion. One physician explained at a network meeting that when she wants to implement a change in her practice, she sets up a tool in the EMR so that there is no faster or easier way to do the job. Her innovation made it easy to convince other clinicians and staff to adopt the change. An innovator in another practice customized all the encounter templates for medical conditions that might require aspirin prophylaxis. She was able to design this customization during a practice meeting as others were discussing ways to increase aspirin prescribing. She then explained to her practice team how to use the new codes. The practice saw how it worked and decided to adopt this strategy. Their solution to low prescribing rates for aspirin therapy was implemented in a matter of minutes.

The Motivated Team Archetype

All high-performing case practices described in this article participated in biannual site visits and/or annual network meetings to assist them with their change efforts. Two high-performing case practices are distinguished by the additional effort they put into motivating and enabling their staff to play important roles in their improvement efforts. In the larger practice, this focus on engagement extended to clinicians as well. Multiple clinicians frequently deliver care in different ways and may need to be convinced to make changes to conform to practicewide efforts for quality improvement. The motivation in this practice was enhanced by bonuses from a local pay-for-performance program.

The practices in this archetype used multiple strategies to get everyone involved. A lead physician promoted the importance of new activities in conversations and behavior, which staff feedback indicated was a critical first step. Further, because the doctors are usually viewed as the person in charge, this step gave staff employees permission to move forward. The practice leaders in this archetype shared the A-TRIP performance feedback with their staff and ensured that staff members had training about guidelines so that they were aware of the goals behind new tasks. The leaders held practice meetings, in addition to site visits, to check progress and make plans.

The practice staff worked with the clinicians to select indicators they wish to improve and designed activities to achieve improvement. As an example, nursing staff in one practice checked to determine
whether health maintenance items were up-to-date and scheduled patients for services, if needed. Mammography rates in the past 2 years for women aged 40 years and older rose from 77.2% to 88.4% in 12 months and remained high, at 89.5%, after another 2 years. Staff in these practices set the tone for visits and saved their doctors some time by providing information about routine care that was due. One licensed vocational nurse said, “By bringing up health maintenance goals before the doctor comes in, patients are prepared for services or discussion.”

The higher-performing practice in this archetype devoted an additional half-day each quarter to making improvements. The office was closed, and all practice employees gathered for meetings and concentrated activity, such as reviewing patient-level reports (a form of registry generated by the A-TRIP project). The physician-owners of the practice emphasized that improving quality is as important as anything they do. Among their experiments was testing a staff incentive plan using graduated individual retirement account contributions.

In comparison with the Technophiles, the practices responded to their leaders' efforts to include and motivate them. Staff feedback to their leaders, as well as anonymous surveys for the project, confirmed that the staff valued quality, recognized the importance of their expanded role to their practice, and appreciated the additional training and tools. For example, a medical assistant explained that her motivation to take on extra work to deliver higher-quality care comes from the knowledge that her effort was in the best interest of the patients. Another practice's medical assistant said that from her participation in the A-TRIP project, she learned she can be more helpful. A receptionist said, “I like education and being informed … checklists, specific goals, and deadlines motivate me.”

In comparison with the Technophiles, the practices in this archetype were more likely to express mixed feelings about their EMR software. In the beginning, individuals were pessimistic about adopting particular EMR tools, and many needed EMR skill development.

**The Care Enterprise Archetype**

As part of their solution to improving care, 2 high-performing practices took a business approach that was influenced by customer service and risk management. They organized special service lines in the form of focused care management clinics, hiring corresponding staff as needed (eg, certified diabetes educators or nurse-practitioners focusing on women's health). The problem-focused clinics were designed to provide comprehensive, competitive, guideline-adherent care that was convenient for the patient and that ensured the doctor has done everything possible to manage care appropriately. One physician explained the personal value of his approach: “The ability to reduce risk of harm to my patients and simultaneously reduce risk of litigation is an important benefit.”

The care enterprises could be considered a special form of motivated teams. The leading physicians in these practices delegated care management responsibilities to their staff and provided regular supervision, such as weekly care coordination meetings between nurses and physicians. They excelled in redesigning delivery systems to support their special service lines and their general practice. The practices conducted point-of-care tests and used an in-house laboratory so that test results were available during the visit. Standing orders for routine monitoring tests and immunizations for designated populations were used to delegate components of the care management process. One practice abandoned annual physical visits with patients, instead scheduling intake visits with nurses alone and shorter follow-up visits with the physician. The practice arranged additional follow-up in nurse blood pressure or anticoagulation clinics, and in nurse-practitioner women's health or diabetes foot clinics, as well as physician medical follow-up based on practice protocols. Staff tracked and enforced the condition-specific schedules.

The practices in this archetype also incorporated a population approach to quality management. In one practice, staff were delegated to use EMR queries to identify patients with specific needs. They conducted outreach to patients when guidelines were not met. These efforts contributed to improvements, for instance, the percentage of patients aged 65 years and

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### Table 2. Comparison of PPRNet Improvement Model Adoption, Spring 2005

<table>
<thead>
<tr>
<th>Practice Archetype</th>
<th>Prioritize Performance</th>
<th>Involve All Staff</th>
<th>Redesign Delivery Systems</th>
<th>Activate Patients</th>
<th>Use EMR Tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technophiles</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Motivated Team</td>
<td>✡✦</td>
<td>✡✦</td>
<td>✡✦</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Care Enterprise</td>
<td>✡✦</td>
<td>✡✦</td>
<td>✡✦</td>
<td>✡✦</td>
<td>✡✦</td>
</tr>
</tbody>
</table>

PPRNet = Practice Partner Research Network; EMR = electronic medical record.

older or with conditions requiring pneumococcal vaccines who were immunized in the past year rose from 36.9% to 62.5% in the first year and continued to rise to 87.6% after 3 years.

The 2 practices in this archetype implemented changes in their settings quickly. They did not appear to need to negotiate for investment within their team. The practices’ improvement efforts had a greater focus on A-TRIP indicators related to diabetes and heart disease than other areas.

**DISCUSSION**

Improved information systems are believed to be the key to unlocking the health care system’s potential for higher quality care. The question remains: How can this technology be implemented in the context of day-to-day practice, particularly in busy primary care settings? The A-TRIP project conducted by PPRNet is investigating ways to stimulate improvements in guideline adherence in practices that have already invested in an EMR. It has become eminently clear that the EMR or decision support alone is insufficient to produce high-quality care.14,15,28,29 The EMR is a useful tool in a practice’s improvement efforts, yet its role in improvements depends on other characteristics of the practice.

In this study, we used retrospective and prospective data to analyze the path to high-quality care in the 9 highest achievers midway into an improvement project. We found these could be defined by 3 archetypes.

Not surprisingly, in this practice-based research network that emphasized EMRs, the Technophile archetype describes the largest number of high-achieving practices, supporting the important role ascribed to information tools for achieving quality. The approach to excellence exemplified by this group also fits the suggestion of other researchers that point-of-care reminders and opinion leaders are the best solution for lapse errors (such as failing to deliver care recommended in clinical practice guidelines).9 In these practices, the ability to use the EMR was facilitated by having an in-house computer-loving physician. This physician, usually one of the practice owners, designed modifications and fine-tuned the EMR software to provide the practice with the specific reminders and documentation they needed. This EMR expert was also a change champion and led the practice to skilled use of EMR tools to deliver and document quality care. The Technophiles achieved high performance with less time and energy devoted to organizing people and delivery processes in the practice.

The existence of 2 other archetypes suggests a practice does not have to start out technically focused to be among the best. These 2 archetypes may be more easily emulated examples for late adopters of health information technology. These practices used an EMR, but drove their quest for quality with other approaches. One group was oriented toward making the most of its human capital; the other used teams, along with a service-oriented model of developing focused care management clinics, to organize improvements. The Motivated Team archetype looked at new ways of using existing resources to improve quality. Because staff and clinicians were taking on new roles, improvement strategies addressed communication, motivation, and competence. The Care Enterprise archetype selected clinical areas of focus, brought in staff, if needed, and designed award-winning care systems. Both experimented with multiple changes to roles, delivery systems, and patient activation. Secondary to these approaches, and with varying degrees of comfort, both archetypes tested, accepted, and adopted EMR tools. As did the Technophiles, these practices also had change champions promoting the improvement agenda and encouraging participation; the difference is they encouraged a wider variety of strategies to meet improvement goals. Others have noted the pivotal role of a change champion in improvement efforts.30–32 The presence of an effective champion in each of these archetypes is likely an important component of their success.

The A-TRIP intervention promoted best practices within the network. Not surprisingly, the top performers also ventured to learn from each other and evolved to resemble each other as they adopted the other’s improvement strategies. We believe the Technophiles served as role models to the other archetypes, demonstrating that EMR tools were both efficient and feasible. The Motivated Teams and the Care Enterprises learned about strategies from the Technophiles and grew in their willingness to try them in their own practices. Technophiles decided in turn to add group activities to address planning and motivation when they heard staff from the other archetypes speak enthusiastically of the changes in their practice. Additional study is needed to verify the importance of role models in a network’s improvement process. It appears that a new practice purchasing an EMR and wanting to use it to its best advantage should join a user’s group that focuses on improvement and fosters interaction between experts and novices. In such a forum, new users might access technological expertise, as was offered by our Technophiles.

It is difficult to compare practices across studies because of differing measurement approaches; however, another report suggests that the performance of practices in A-TRIP was better than national averages.33 For illustration, the 2004 National Healthcare Quality Report (NHQR) indicated that among
patients with diabetes, HbA1c was less than 7% in 37% of patients with diabetes, whereas A-TRIP practices achieved this target in 51% of patients. The subset of A-TRIP practices described in this report achieved better results than their peers across a wide range of areas, from diabetes and hypertension care to mammogram screening and adult vaccinations.

**An Organizational Culture Perspective**

Although this study provides insights regarding practice behavior from a qualitative perspective, recent interest in identifying organizational culture characteristics as factors influencing the quality and cost of care have prompted evaluation of several quantitative tools for potential use in health care settings. The competing values framework (CVF) has measured organizational culture in various settings outside health care. CVF identifies 4 organizational archetypes derived from Jungian influence: Clan (focused on teams), hierarchy (involved in coordination and control), adhocracy (concerned with value innovation), and market-driven (motivated by competition). The organization's dominant characteristics influence its members' values and assumptions, the way they think, and how they process information. The archetypes of high performance that we found in our study have features in common with the CVF types.

The Technophiles archetype fits with CVFs adhocracy culture. This archetype values innovation and flexibility and develops electronic solutions to the demands of a quality-driven practice. The Motivated Team archetype fits a clan culture. These practices share a passion for cohesion, employee involvement, and commitment to team development. We observed a high degree of semiautonomous behavior in the practices that engaged their staff in cycles of improvement. By empowering the staff to come up with relevant solutions to identified problems, the Motivated Team practices were successful with change. The Care Enterprise archetype has additional features similar to the market-driven and hierarchical cultures. This archetype has strong leadership, organizes itself well, studies the community, and defines and packages services that are needed. Care Enterprise practices valued productivity and arranged for comprehensive convenient care for patients.

There are limitations to case study research. The findings are subjective, they are not meant to be representative or externally valid. In this study, only the best cases were observed, so controls for poor performance are lacking. The analysis is open to additional bias from the selection of data, confounding, and the researchers' interpretations. The study implies that archetype features have led these case practices to their high achievement, but we need additional study comparing these practices with lower-performing practices to verify whether this finding is indeed true.

Another limitation is that case studies are meant to provide illustrations to which a reader can relate. One might feel we are lacking important details about the practices. It is already known that variations in health care quality cannot be explained on the basis of fee-for-service or managed care, size of the community, or type of insurance. The problem is believed to reside in how medicine is practiced, and we may have missed or misinterpreted key components. One strength of case study research is that results can be used to generate new hypotheses or insights. We highlight rare observations, such as the high performers, and consider their context. The analysis investigates how high performers approached improvements, and why their performance might be high—questions not easily answered in a large-scale outcome experiment. We encourage others to test the ideas generated here.

In conclusion, high-performing practices in the A-TRIP study adopted variations of the PPRNet TRIP improvement model. There were many common strategies among them, but they organized change using different approaches. No single approach dictated superior performance. Additional study is needed to assess whether better outcomes are caused by the approach of these archetypes and whether adoption of these approaches would translate to high achievement in other practices.

To read or post commentaries in response to this article, see it online at http://www.annfammed.org/cgi/current/full/5/3/233.

**Key words:** Quality improvement; quality assurance, health care; primary health care

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**References**


A National Survey of Primary Care Practice-Based Research Networks

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ABSTRACT

PURPOSE Increasing numbers of primary care practice-based research networks (PBRNs) are being developed in the United States to perform research relevant to everyday practice. To assess the current status and potential value of this resource, we surveyed US primary care PBRNs in operation from late 2003 to early 2004.

METHODS We performed a Web-based survey and structured interviews with PBRN directors and administrative officers, assessing PBRNs' history, size, location, organization, resources, operations, and productivity (funding obtained, studies performed, and articles published).

RESULTS Of 111 primary care PBRNs identified, 89 (80%) responded to the survey. The 86 (77%) meeting the criteria for primary care PBRNs contained 1,871 practices, 12,957 physicians (mean 152 per PBRN, median 100), and 14.7 million patients (mean 229,880 per PBRN, median 105,000). Minority and underinsured patients were overrepresented. The average PBRN was young (4.4 ± 5.7 years): one-half had performed 3 or fewer studies. Three-quarters were affiliated with universities. Common research foci included prevention, diabetes, cardiovascular risk factors, and mental health. Respondent PBRNs had published more than 600 articles in peer-reviewed journals. PBRNs studying questions posed by outside researchers had more federal funding (84% vs 27%, P = .006). PBRNs citing funding as a weakness relied more on local resources to fund research projects (70% vs 40%, P = .036).

CONCLUSIONS American primary care PBRNs are mainly young, diverse, and pursuing a variety of research foci. Most have university links and provide a dynamic town-gown relationship that could be a vital national resource for improving primary care, translating research into practice, and meeting the National Institutes of Health Roadmap goals. PBRNs merit further attention from both private and public funding agencies and researchers interested in studying the delivery of primary care.


INTRODUCTION

In its landmark indictment of the quality of health care in the United States, the Institute of Medicine lamented that many proven effective treatments do not become incorporated into everyday care.1 One review showed that only 14% of research findings filter down to everyday practice, and those that do take an average of 17 years.2 In 2003 Elias Zerhouni, director of the National Institutes of Health (NIH), responded by increasing the NIH’s emphasis on translation of research into practice, establishing new research networks as a major step in NIH’s Roadmap for Re-Engineering the Clinical Research Enterprise.3

The disconnect between research and everyday practice is in large part because most research is performed in academic medical centers, where less than 1% of Americans visiting physicians receive their health care.4 Such research often excludes patients commonly seen in community-based primary care: elders, patients with multiple medical conditions, patients...
nonadherent to treatment, and those suffering from substance abuse or psychiatric disorders. Studies performed in academic centers also tend to examine patient and clinician behaviors under controlled situations. It is not surprising, then, that the results of such studies are often not applicable to many community-based primary care patients or their clinicians. Kroenke et al have shown that most patients seeking primary care have nonspecific complaints to which the results of published research may not be relevant. Thus, primary care physicians trying to practice evidence-based medicine are frequently hampered by having little evidence to apply to the problems they face. As a consequence, their patients often leave unsatisfied.

There are therefore 2 major disconnects between research and practice: research may not translate expeditiously to everyday practice, and clinical problems encountered in everyday practice are often underinvestigated. PBRNs were established in the United Kingdom in the 1960s to overcome these disconnects and subsequently spread to other European countries. The first major PBRNs in the United States came in the 1970s: the Family Medicine Information System and the Cooperative Information Project. These PBRNs were comprised mainly of community-based family medicine practices that had joined together to perform research relevant to the problems of delivering community-based primary care. In the United States, however, where federally funded research remained focused on academic medical centers, PBRNs have been slow to catch on.

In 2000, Congress responded by charging the Agency for Healthcare Research and Quality (AHRQ) to identify and support primary care practice-based research networks as a resource for accelerating the translation of research into practice and performing research relevant to everyday primary care. This act specifically states:

In order to address the full continuum of care and outcomes research, to link research to practice improvement, and to speed the dissemination of research findings to community practice settings, the Agency shall employ research strategies and mechanisms that will link research directly with clinical practice in geographically diverse locations throughout the United States, including ... provider-based research networks, including plan, facility, or delivery system sites of care (especially primary care), that can evaluate outcomes and evaluate and promote quality improvement ...

AHRQ pursued this congressional directive by providing specific funding opportunities for primary care PBRNs, first in 2000 and again in 2002. The first round offered 19 PBRNs 1-year grants to “assist new or established PBRNs in planning for activities to enhance their capacity to conduct research in primary care settings and translate research findings into practice.” AHRQ also collaborated with the Robert Wood Johnson Foundation to fund additional PBRNs to participate in a multisite research project focused on promoting healthy behaviors among patients in primary care settings. More than 100 PBRNs applied for these funding opportunities, suggesting to AHRQ that there was an expanding number of PBRNs that might help fulfill their congressional mandate to translate research into everyday practice. To identify and describe existing US primary care PBRNs, AHRQ funded this systematic survey of all active primary care PBRNs in the United States. The goal was to describe their diversity in specialty, structure, function, and history, as well as their potential for translating research into practice and answering questions of importance to primary care practitioners and their patients.

METHODS

This study was approved by the institutional review boards of Indiana University and the National Opinion Research Center. In the fall of 2003, we identified currently active primary care PBRNs that had all the following criteria established by AHRQ in its PBRN initiative:

- A director
- A formal administrative structure that transcended individual studies
- At least 15 separate primary care practices or clinicians
- More than 50% of the members practicing primary care in the United States
- Some mechanism for soliciting advice and feedback from the community of patients served by the network's clinicians

To find primary care PBRNs, we looked for those currently or previously funded by AHRQ or the Robert Wood Johnson Foundation's Prescription for Health Initiative, those belonging to the Federation of Practice Based Research Networks (the Federation) affiliated with the American Academy of Family Physicians, those we found through published articles, and as many other PBRNs as we could find through discussions with AHRQ, leaders of the Federation, and existing PBRNs.

We developed a Web-based questionnaire that collected the following information from the PBRNs: director and/or administrator; descriptions of the PBRN (name, office location, age, administrative structure), the member practices and clinicians (number and locations of practices, number of physicians or other primary care clinicians, and clinicians’ medical specialties), patients served (number per practice and demographic data including age, sex, race/ethnicity, insurance status, if known), types and sources of research funding, productivity (number of studies performed and num-
ber of subjects included), and research foci, including research themes (eg, specific population age or research methodology) and specific diseases and nondisease health conditions (based on a closed-ended list of common research foci). We also queried the PBRN directors or administrators on self-assessed strengths and weaknesses, whether their member practices had incorporated research results into their practices, and barriers to translating research into practice. Response categories were developed based on the research teams’ knowledge of practicing PBRNs. Thirty-five of the 45 questions were closed-ended to facilitate efficient completion of the questionnaire and data analysis. The survey questionnaire was pilot tested with 5 PBRNs and revised to reflect their input on interpretability, clarity, and feasibility of completion. The final instrument is available from the authors upon request.

We administered the questionnaire using UltimateApps (Prezza Technologies, Cambridge, Mass) by sending an e-mail to the director of each PBRN we identified, and we invited him or her to complete the questionnaire by clicking on a link to the survey Web site. Each director gave consent on the first page before proceeding to the questionnaire. We sent reminders to all PBRN directors who did not complete the questionnaire within 1 month. After 1 additional month, one of the authors called each nonresponding PBRN director and invited him or her to complete the questionnaire; if desired, they could complete it on paper and return it by mail or fax.

After a PBRN director or administrator completed the questionnaire, we invited the director to participate in a semistructured telephone interview using a standard protocol that included questions about current and anticipated research projects, decision-making procedures at the network, current challenges facing the network, and potential interest in participation in a national study. Qualitative data from the telephone conversations were used to supplement the survey data and, in some cases, complete missing items from the questionnaire.

We tabulated and analyzed all data using SAS version 8.02 (SAS Institute, Carey, NC). We assessed differences using corrected χ² tests and Fisher exact tests for categorical variables and Student t tests for continuous variables. Differences associated with P values >.05 were considered statistically significant. When cell sizes were small, we collapsed multilevel variables to create the most relevant dichotomous variables.

RESULTS

We found 111 primary care PBRNs that met our inclusion criteria, 89 (80%) completed the questionnaire. Three did not meet the criteria for a primary care PBRN and were excluded. The locations of the administrative offices of the final 86 PBRNs (77% of the 111 originally contacted) are shown in Figure 1. (The 86 PBRNs providing data and their locations are listed in the online-only Supplemental Appendix, which can be found at: http://www.annfammed.org/cgi/content/full/5/3/242/DC1). At the time of this survey, these 86 PBRNs included 1,871 practices, 12,957 physicians (mean 152 ± 229, median 100, range 15-1,760), and 14.7 million patients (mean 229,880 ± 424,880, median 105,000, range 1,200 to 2.7 million). Eighty PBRNs (90% of respondents) provided addresses for all of their practices, and the 46 AHRQ-funded PBRNs provided detailed information on their practices, clinicians, and patients and completed semistructured telephone interviews. As shown in Figure 1, the 68 PBRNs providing practice addresses had member practices in all 50 states and Puerto Rico, although the heaviest concentrations were in the eastern states and the Midwest. Three PBRNs were nationwide, with member practices in multiple states and affiliated with professional organizations: the American College of Physicians, the American Academy of Family Physicians, and the American Pediatrics Association. The rest had practices in a single state or adjoining states.

PBRN Characteristics

There were 4 primary care specialties represented in PBRN practices: family medicine, pediatrics, general internal medicine, and family nurse-practitioners. As shown in Table 1, 33 (38%) of responding PBRNs were made up of clinicians with a single primary care specialty, the most common being family medicine. Of the 53 primary care PBRNs having clinicians from multiple primary care specialties, almost all included family physicians, whereas three-quarters included pediatricians and internists. Nearly all 86 responding PBRNs provided care to pediatric patients either through clinicians trained as pediatricians or family medicine specialists.

On average, respondent primary care PBRNs were young: they had been functioning for a mean of 4.4 ± 5.7 years, median of 3 years, range <1 to 32 years (Table 1). Three-quarters were affiliated with a university; most others were affiliated with a nonprofit or professional organization. Most received some support (direct and indirect) from their affiliated organizations. Funding for PBRN studies came from a variety of sources. Most PBRNs received project-specific funding from federal agencies and from their sponsoring organizations, whereas one-half also received project-specific funding from foundations.

Originally PBRNs were established as a structure
in which their members could perform research; however, only 1 in 7 of the responding PBRNs relied solely on their leaders or members for research ideas (so-called bottom-up PBRNs). For one-quarter of respondent PBRNs, research ideas came mainly from outside investigators (top-down). Most relied on both their members and outside investigators for generating research ideas. Of note, only 27% of the self-described bottom-up PBRNs had ever received federal funding for research compared with 84% of PBRNs having a top-down or mixed method for generating research proposals (P < 0.006).

Sixty PBRNs reported having a general research theme, the most common being a specific disease or treatment. A substantial minority focused on a particular research method, such as interventional or observational studies. Eight-five PBRNs reported on the clinical focus of their research, the most common being prevention, diabetes, cardiovascular risk, and mental health.

**Patient Characteristics**
Sixty PBRNs (70% of respondents) provided demographic information on the patients in their practices (Table 2). Compared with 2002 national population estimates and persons seeking health care (as determined by the National Health Interview Study), PBRNs serve a more diverse patient population. PBRN patients tended to be slightly younger than the general population and more often of minority race and of Hispanic ethnicity compared with both the general population and persons seeking health care. PBRN patients have lower socioeconomic status (as indicated by a greater share of patients having insurance through state or federal programs, mainly Medicaid) than the general population seeking care.

**Research Experience**
As multi-institutional collaborations, PBRNs sometimes face complicated research governance issues. Nearly one-half reported being covered by more than 1 insti-
Whereas the majority indicated they had to interact with between 1 and 5 institutional review boards, a substantial minority reported their practices were covered by more than 6. Additionally, one-third of PBRNs report they had more than 1 source for human subjects certification.

Slightly more than one-half of the respondent PBRNs were actively engaged in research at the time of the survey, and one-quarter reported not having completed a study (Table 3). Of the 45 PBRNs with at least 1 completed study, 38% completed between 1 and 3, 38% completed 4 to 7, and 24% completed more than 7. Currently, the AHRQ National Resource Center for Practice-Based Research Networks has compiled a list of more than 600 peer-reviewed articles emanating from research performed in primary care PBRNs (available from the authors upon request). Of the 46 PBRNs with at least 1 prior or ongoing study, 38 (83%) had enrolled more than 100 patients in their largest study, whereas 20 (53%) had enrolled more than 1,000 patients (Table 3). The mean number of patients enrolled in each PBRN’s largest study was 2,279 (median 707). Three PBRNs (Crozer-Keystone Health Network, Pediatric Research in Office Setting, and Pennsylvania Family Health Network) have been awarded the AHRQ Practice-Based Research Network of the Year Award for their contributions to the field of primary care research.

Table 1. Practice-Based Research Network (PBRN) Characteristics (N = 86)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-specialty PBRNs (n = 33)</td>
<td></td>
</tr>
<tr>
<td>Family medicine</td>
<td>20 (61)</td>
</tr>
<tr>
<td>Pediatric</td>
<td>10 (30)</td>
</tr>
<tr>
<td>Family nurse-practitioner</td>
<td>2 (6)</td>
</tr>
<tr>
<td>General internal medicine</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Obstetrics, gynecology, and midwifery</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Multispecialty PBRNs (n = 53): specialty of PBRN physicians</td>
<td></td>
</tr>
<tr>
<td>Family medicine</td>
<td>51 (96)</td>
</tr>
<tr>
<td>Pediatric</td>
<td>38 (72)</td>
</tr>
<tr>
<td>General internal medicine</td>
<td>38 (72)</td>
</tr>
<tr>
<td>Other specialties (PhDs, dentists, specialized medicine)</td>
<td>21 (40)</td>
</tr>
<tr>
<td>Family nurse-practitioner</td>
<td>7 (13)</td>
</tr>
<tr>
<td>Affiliation</td>
<td></td>
</tr>
<tr>
<td>University</td>
<td>65 (76)</td>
</tr>
<tr>
<td>Nonprofit organization</td>
<td>9 (10)</td>
</tr>
<tr>
<td>Professional organization</td>
<td>6 (7)</td>
</tr>
<tr>
<td>Other, none, or not stated</td>
<td>6 (7)</td>
</tr>
<tr>
<td>Support from affiliated organization (of 83 with an affiliation)</td>
<td></td>
</tr>
<tr>
<td>Direct</td>
<td>8 (10)</td>
</tr>
<tr>
<td>Indirect</td>
<td>12 (14)</td>
</tr>
<tr>
<td>Both</td>
<td>39 (47)</td>
</tr>
<tr>
<td>Neither direct nor indirect</td>
<td>19 (23)</td>
</tr>
<tr>
<td>Not stated</td>
<td>5 (6)</td>
</tr>
<tr>
<td>Funding for PBRN studies (multiple responses allowed)</td>
<td></td>
</tr>
<tr>
<td>Federal funding agency, project-specific</td>
<td>72 (84)</td>
</tr>
<tr>
<td>Home institution (eg, university, or nonprofit or professional organization)</td>
<td>64 (74)</td>
</tr>
<tr>
<td>Foundation, project-specific</td>
<td>48 (56)</td>
</tr>
<tr>
<td>Professional organization</td>
<td>21 (24)</td>
</tr>
<tr>
<td>Philanthropic</td>
<td>15 (17)</td>
</tr>
<tr>
<td>Other unspecified source of funds</td>
<td>8 (9)</td>
</tr>
<tr>
<td>Source of research ideas (n = 85 reporting)</td>
<td></td>
</tr>
<tr>
<td>PBRN leaders and clinicians (bottom-up)</td>
<td>12 (14)</td>
</tr>
<tr>
<td>Outside investigators (top-down)</td>
<td>23 (27)</td>
</tr>
<tr>
<td>Both PBRN leaders/clinicians and outside investigators</td>
<td>50 (59)</td>
</tr>
<tr>
<td>General research theme (multiple responses allowed)</td>
<td></td>
</tr>
<tr>
<td>Methodology: Interventional studies</td>
<td>25 (29)</td>
</tr>
<tr>
<td>Methodology: observational studies</td>
<td>23 (27)</td>
</tr>
<tr>
<td>Specific population: age</td>
<td>14 (16)</td>
</tr>
<tr>
<td>Specific population: ethnicity</td>
<td>14 (16)</td>
</tr>
<tr>
<td>Specific population: urban/rural</td>
<td>12 (14)</td>
</tr>
<tr>
<td>Specific population: race</td>
<td>11 (13)</td>
</tr>
<tr>
<td>No general theme</td>
<td>25 (29)</td>
</tr>
<tr>
<td>Health condition or treatment focus (multiple responses allowed)</td>
<td></td>
</tr>
<tr>
<td>Preventive medicine</td>
<td>48 (56)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>41 (48)</td>
</tr>
<tr>
<td>Cardiovascular risk factors</td>
<td>29 (34)</td>
</tr>
<tr>
<td>Mental health</td>
<td>26 (30)</td>
</tr>
<tr>
<td>Heart disease</td>
<td>21 (24)</td>
</tr>
<tr>
<td>Cancer</td>
<td>21 (24)</td>
</tr>
<tr>
<td>Lung disease</td>
<td>16 (19)</td>
</tr>
<tr>
<td>Substance abuse</td>
<td>10 (12)</td>
</tr>
<tr>
<td>No condition or treatment focus</td>
<td>10 (12)</td>
</tr>
</tbody>
</table>

Table 2. Demographic Characteristics of PBRN Patients’ Compared With National Benchmarks

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>PBRN Patients*</th>
<th>National Figures†</th>
<th>Persons Seeking Health Care‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (female)</td>
<td>57</td>
<td>51</td>
<td>60</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-18 y</td>
<td>34</td>
<td>26</td>
<td>NA</td>
</tr>
<tr>
<td>19-59 y</td>
<td>48</td>
<td>61</td>
<td>NA</td>
</tr>
<tr>
<td>≥60 y</td>
<td>18</td>
<td>16</td>
<td>NA</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>64</td>
<td>81</td>
<td>85</td>
</tr>
<tr>
<td>African American</td>
<td>23</td>
<td>13</td>
<td>10</td>
</tr>
<tr>
<td>Native American</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>5</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Other race</td>
<td>6</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Hispanic ethnicity</td>
<td>18</td>
<td>13</td>
<td>14</td>
</tr>
<tr>
<td>Health insurance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private</td>
<td>45</td>
<td>71</td>
<td>75</td>
</tr>
<tr>
<td>State or federal</td>
<td>42</td>
<td>14</td>
<td>18</td>
</tr>
<tr>
<td>No insurance</td>
<td>13</td>
<td>14</td>
<td>7</td>
</tr>
</tbody>
</table>

PBRN = practice-based research network; NA = not available.

* Mean value among 60 PBRNs reporting patient data.
TINGS, AND RESEARCH ASSOCIATION OF PRACTICING PHYSICIANS) HAD EACH ENROLLED MORE THAN 10,000 PATIENTS IN A SINGLE STUDY. PRACTICE PERSONNEL WERE OFTEN INVOLVED IN RECRUITING RESEARCH SUBJECTS (TABLE 3): MORE THAN ONE-HALF OF PBRNs REPORTED THAT THE PRIMARY PERSON RECRUITING SUBJECTS WAS A PRACTICE CLINICIAN, NURSE, OR CLERK, AND THREE-QUARTERS USED A RESEARCH ASSISTANT DEDICATED TO EITHER THE PROJECT OR THE PRACTICE.

Table 4 contains examples of active research projects at the time of the survey that the authors believe represent the spectrum of PBRN research. They were a mixture of health services research, prevention research, and research answering clinical questions. PBRN projects often focused on improving clinical practice and patient outcomes in areas where there is a known intervention that has been shown to be effective in some situations but is not a routine aspect of everyday clinical practice.

**Strengths and Weaknesses**

Reflecting the diversity of network experience, community involvement was listed as a self-reported strength for one-third of the respondent PBRNs (Table 5), but it was listed as a weakness by one-quarter of them. In semistructured interviews, those PBRNs identifying community involvement as a weakness generally indicated that they lacked the infrastructure to engage the community and were seeking information from colleagues listing community involvement as a strength. Those networks with a community advisory board had found them helpful in identifying cogent research questions. Similarly, research experience was the second most common strength, whereas lack of research experience was the fourth most common weakness. Lack of information technology was also a common weakness.

Difficulty in securing funding, however, was by far the most commonly listed weakness, selected by one-half of the PBRNs responding. Of these, 70% relied upon local funding for research support compared with 40% of those not citing funding as a weakness \( (P = .036) \). Conversely, only 51% of PBRNs listing funding as a weakness had received federal funding for research compared with 82% of those not listing funding as a weakness \( (P = .016) \). In semistructured interviews, frustration was exhibited by a number of PBRN leaders over the difficulty of maintaining research infrastructure (space, personnel, equipment) between funded studies.

**DISCUSSION**

A substantial number of primary care PBRNs were extant in 2003. Their wide geographic distribution and involvement of all primary care specialties make them a strong potential resource for performing research that is relevant to practicing primary care clinicians. Many are young, however, most are affiliated with universities, and poor and minority patients are overrepresented in their practices. Thus, this potential resource will need cultivation before it matures as a potent tool to meet the NIH Roadmap goals and the AHRQ congressional mandate of addressing the full continuum of care, linking research to practice improvement, and speeding the dissemination of research findings to community practice settings.


### Table 4. Ten Examples of Active Practice-Based Research Network (PBRN) Research at the Time of the Survey

<table>
<thead>
<tr>
<th>Project Type</th>
<th>Project Title</th>
<th>Description</th>
<th>Name of PBRN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health services</td>
<td>How community pediatricians use electronic technology</td>
<td>A survey of community pediatricians in a practice-based research network using a self-administered form to describe how they use electronic technology for work-related tasks, level of competence for specific technology-related activities, and interest in learning these skills.</td>
<td>Washington University/Pediatric/Adolescent Consortium</td>
</tr>
<tr>
<td>Clinical research</td>
<td>Child self-reporting asthma symptoms</td>
<td>Asking the question, “When is it appropriate for children to report for themselves?” this study aims to assess the acceptability, feasibility, and psychometric quality of administering asthma-related quality-of-life questionnaires to children.</td>
<td>Cincinnati Pediatric Research Group</td>
</tr>
<tr>
<td>Clinical research</td>
<td>Pediatrics recognition of maternal depressive symptoms</td>
<td>A project examining the factors that influence pediatricians’ recognition of depressive symptoms in mothers with young children. It aims to develop and pilot an intervention that addresses barriers to recognition in the pediatric primary care setting and improve pediatrician’s ability to recognize and refer mothers with depressive symptoms.</td>
<td>Rainbow Research Network</td>
</tr>
<tr>
<td>Health services</td>
<td>Defining patient visits study</td>
<td>A study to learn about patients and problems seen in “typical practice” and to allow for a comparison of data with national survey data and an assessment of the extent to which study practices represent the nation’s pediatric practices.</td>
<td>Pediatric Research in Office Settings</td>
</tr>
<tr>
<td>Prevention research</td>
<td>How patients decide on prostate cancer screening</td>
<td>Evaluation of shared decision making around prostate cancer screening to determine the effect of viewing a Web page or mailed brochure on prostate cancer screening on the decision-making process between a patient and physician.</td>
<td>Virginia Ambulatory Care Outcomes Research Network</td>
</tr>
<tr>
<td>Prevention research</td>
<td>Multilevel approaches to colon cancer screening</td>
<td>An exploratory study designed to investigate the effectiveness of strategies to increase colorectal cancer screening in rural family practices. The primary outcome is the rate of adherence with the US Multi-Society Task Force on Colorectal Cancer.</td>
<td>Arkansas Research Collaborative</td>
</tr>
<tr>
<td>Prevention research</td>
<td>Improving colorectal cancer (CRC) screening in primary care</td>
<td>A study to characterize CRC screening practices across a variety of primary care clinics of a practice-based research network. It will provide information about the relationship between practice characteristics and CRC screening delivery and short-term outcomes.</td>
<td>Oklahoma Physicians Resource/Research Network</td>
</tr>
<tr>
<td>Prevention research</td>
<td>Osteoporosis study</td>
<td>A study designed to determine whether chart reminders or patient education information for osteoporosis screening improved diagnosis and treatment of low bone density in older women. Preliminary analysis shows that chart reminders, but not patient education, improved osteoporosis diagnosis and screening.</td>
<td>Iowa Research Network</td>
</tr>
<tr>
<td>Health services</td>
<td>Cardiovascular risk education and social support</td>
<td>Elaborate on a 3-year study of a practice-based intervention designed to harness the power of social support to improve adherence to prescribed treatments among diabetic patients with the ultimate goal of reducing their risk of heart attack and stroke.</td>
<td>Kentucky Ambulatory Network</td>
</tr>
<tr>
<td>Health services</td>
<td>Practice improvement project</td>
<td>A study to assess the rates of influenza immunization in asthma patients within the primary care practices to (1) identify the organizational and patient barriers to influenza immunization of asthma patients, (2) randomize patients to dissemination of the research findings, and (3) tailor interventions to improve immunization of asthma patients.</td>
<td>Duke Primary Care Research Consortium</td>
</tr>
</tbody>
</table>

### Table 5. Self-Assessed Strengths and Weaknesses of PBRNs (n = 83 reporting)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>PBRNs ListingCharacteristic</th>
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<tbody>
<tr>
<td></td>
<td>As a Strength (%)</td>
</tr>
<tr>
<td>Community involvement</td>
<td>33 (40)</td>
</tr>
<tr>
<td>Research experience</td>
<td>29 (35)</td>
</tr>
<tr>
<td>Data collection</td>
<td>17 (20)</td>
</tr>
<tr>
<td>Research administration</td>
<td>15 (18)</td>
</tr>
<tr>
<td>Information technology</td>
<td>13 (16)</td>
</tr>
<tr>
<td>Research design</td>
<td>13 (16)</td>
</tr>
<tr>
<td>Survey research</td>
<td>11 (13)</td>
</tr>
<tr>
<td>Data analysis</td>
<td>10 (12)</td>
</tr>
<tr>
<td>Ability to secure funding</td>
<td>10 (12)</td>
</tr>
<tr>
<td>Writing journal articles</td>
<td>6 (7)</td>
</tr>
</tbody>
</table>

PBRN = practice-based research network.

Existing PBRNs use a mixture of their own clinicians (bottom-up) and outside investigators (top-down) to choose research foci and individual projects. As a result, using PBRNs as a research resource will require efforts to establish more-effective communication among funding agencies, investigators, PBRN administrators, and PBRN clinicians. Furthermore, this communication should be bidirectional: (1) the PBRNs and their clinicians should be cognizant of the research interests and needs of federal and other funding agencies, and embrace those that are consistent with the needs and capabilities of the PBRNs and their practices; and (2) the funding agencies should use the PBRNs and their practices to better understand (and direct funds toward answering) the questions that everyday clinicians need answered so they can deliver high-quality, cost-effective care.
Although most PBRNs are affiliated with universities, the 2 largest we surveyed are affiliated with professional organizations. Specifically, the American Academy of Family Physicians has established the AAFP National Research Network (formerly the National Network for Family Practice and Primary Care Research), which includes 206 practices and 200,000 patients, and Pediatric Research in Office Settings is affiliated with the American Academy of Pediatrics and contains 1,760 practices and 2.7 million patients. The American College of Physicians also supports the American College of Physicians Network, which at the time of this survey was 1 year old and growing, with 400 practices and 34,000 patients; as of this writing, it has 730 practices representing all 50 states. Affiliation with a national organization can facilitate a PBRN’s involving a great many disparate practices with a wide geographic distribution that would improve external validity and generalizability of research results. In return, the PBRN provides the organization with a specialty-focused research venue that can serve the organization’s specific research goals and objectives.

Funding PBRN activities, infrastructure, operations, and research projects is the principal barrier to realizing a PBRNs’ potential as a research resource. Affiliation with universities and professional organizations provides some security to PBRNs, but this support could come with demands on access to the practices and research directions. Thus, financial dependency could deflect the PBRNs from their research mission and be responsible for the preponderance of top-down or mixed models of decision making about research directions and individual projects. Through a peer learning group facilitated by the AHRQ National Resource Center for Practice-Based Research Networks, the PBRNs are sharing experiences and evolving to more stable financial configurations.

This study has limitations. There was no central resource for identifying primary care PBRNs, and the definitions of what constitutes primary care and what is a PBRN, although formally established by AHRQ, are somewhat arbitrary. Our focus on primary care excluded the expanding number of disease-specific PBRNs, eg, those studying cancer and asthma, and those by disciplines other than medicine, eg, dentistry. Moreover, 20% of those primary care PBRNs we did identify declined to participate in this survey, which could bias our results. Also, many of the PBRNs we surveyed were young and could have matured or failed since the survey. Finally, our results may not be typical for primary care PBRNs in other countries, where PBRNs are older and more mature, and the relationships between generalists and specialists may differ substantially from those in the United States.

Nonetheless, PBRNs are gaining momentum and recognition both nationally and internationally. There is increasing interest in using PBRNs as a test-bed to address clinical and public health issues that are of great national interest. For example, one primary care PBRN and a consortium of primary care PBRNs were among the 12 research networks funded by the NIH Roadmap program, Re-Engineering the Clinical Research Enterprise, to initiate a national electronic research infrastructure. The Robert Wood Johnson Foundation funded 19 primary care PBRNs to study methods to help enhance patients’ healthy behaviors. PBRNs have attracted the attention of several NIH institutes (including the National Institute of Mental Health, National Institute of Diabetes and Digestive and Kidney Diseases, National Heart, Lung, and Blood Institute, and National Cancer Institute) whose leaders see the potential of PBRNs as bidirectional venues for translating research into practice and practice into research. The funders of PBRN research and the PBRN community should collaborate on establishing a cogent research agenda, and the funding agencies should target funding programs toward PBRNs. The PBRNs should also collaborate among themselves to enhance their value as a network of PBRNs by sharing experiences (grasping opportunities and overcoming barriers) and collaborating on individual studies. Creative local and national investment in PBRNs will be necessary to continue their evolution into effective and productive primary care research laboratories and fulfill the NIH and AHRQ vision of “putting research into practice and practice into research.”

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Improving Medical Practice: A Conceptual Framework

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ABSTRACT

PURPOSE The purpose of this article is to produce a relatively simple conceptual framework for guiding and studying practice improvement.

METHODS I summarize the lessons from my experience with a variety of quality improvement research studies during the last 30 years, supplemented with relevant literature from both medicine and other industries about the issues associated with successful quality improvement.

RESULTS My experience suggests that organizational leadership with an urgent vision for change, ability to manage the change process, and selection of systematic changes capable of fulfilling the vision are each critical for successful quality improvement. Published literature from other industries emphasizes the importance of a goal-directed change process managed by leaders who recognize the need to engage their employees and other leaders in a disciplined but flexible way that accommodates external and internal factors and uses teams and group learning. It also suggests the importance of organizational context and the level of external and internal barriers and facilitators for change. The resulting model proposes that priority, change process, and care process content are necessary for measurable improvements in quality of care and patient outcomes, although internal and external barriers must also be attended to and addressed.

CONCLUSION This framework may provide a guide to those in the front lines of care who would like to make the care transformations that are needed to greatly improve care. It may also be helpful to those who are developing or testing interventions and recruiting medical practices for such change efforts.


INTRODUCTION

Crossing the Quality Chasm, the landmark 2001 report from the Institute of Medicine (IOM), crystallized and dramatized the challenge facing American medicine by pointing out that incremental improvement was inadequate: “[B]etween the health care we have and the care we could have lies not just a gap, but a chasm.” This report, along with the earlier IOM report on medical errors, also highlighted the need to change the environment in which health care professionals provide care. Both reports clearly recognized the quality chasm as a problem of systems, not people.

As with most paradigm shifts, these recommendations didn’t come from nowhere. They were built on a growing body of research evidence about the inexplicable geographic variations in care, the inadequate implementation of evidence-based guidelines, and the need to shift from single interventions to change the behavior of individual physicians to focus instead on the practice systems and organizations in which physicians work.

Although there has been slow improvement in care quality, especially for some chronic conditions, the reports have not yet led to the dramatic improvements they called for. I suspect that this lack of improvement is due partly to the time needed for realignment of financial incentives and widespread acceptance of the need for change, and partly to continuing uncertainty.
among medical practices about what to change and how to change it. The Chronic Care Model (CCM) is increasingly accepted now as a conceptual framework for what needs changing, not only for chronic conditions, but also for acute and preventive care. Similarly, the Model for Improvement is seen as an advance from the earlier Continuous Quality Improvement and Total Quality Management approaches to how to make change, and regional or national collaboratives provide a way to facilitate its implementation. Neither of these models, however, has penetrated widely into the small- to medium-sized medical practices that provide the great majority of medical care in the United States. They are also often seen as separate and conflicting, rather than complementary, approaches to improvement. So, if medical practice is to be transformed, it might be helpful to the physician and administrative leaders of that effort to have a relatively simple conceptual framework that shows how these models fit together in relation to other important factors.

To construct such a framework, I have relied on several sources. First are the lessons from my experience during the past 35 years in both practice redesign efforts and many research trials or studies of quality improvement efforts. Second is a growing and important literature on organizational change and quality improvement, both in medical care and in other industries. Finally, the 2 articles our research group published recently in this journal used a multimethod approach to studying an attempt by one large multispecialty medical group to implement the CCM. Those articles provide a current illustration of the framework.

It is hard to identify a specific conceptual starting point for this framework, because the ideas the CCM articles reflect have built slowly for many years. The ideas have developed primarily because most of my research trials have combined quantitative and qualitative methods, providing needed deeper information about how and why the care process changes occurred (or did not). But they also developed from the group reflection that was driven by the fact that most of those trials did not produce the degree of quantitative changes expected. I can truly verify there may be more learning from failures than from successes. The 2 recently-published studies provide especially rich fodder for reflection and for further extending an understanding of change efforts, while also providing an opportunity to demonstrate example details. I recognize that the individual ideas in the framework described here are not new, but I hoped to bring them together in a coherent way that is simple enough to serve as a guide for those wishing to transform care or study improvement efforts without elaborating all the complexities of most other models that tend to serve as roadblocks to action.

**EXPERIENCE**

For many years, I have been intensively involved in both applied research and personal practice change efforts, culminating during the past 5 years in an intensive observational study of the transformational change efforts of a large multispecialty medical group. Fortunately, that study was supplemented by studying the approach to change by a small and exemplary family practice group. Some of my previous experiences that are especially worth highlighting follow.

IMPROVE was a randomized controlled trial in 44 primary care practices of an intervention designed to teach early Continuous Quality Improvement methods and systems content for improving the delivery of 8 preventive services. Although it failed to show greater improvement in service rates in the intervention arm during the 2 years of the trial, most of the subject practices were enthusiastic about what they had learned, and many other practices subsequently requested similar training. Many local leaders would today credit the understanding of systems thinking and planned change that started with IMPROVE for the unusually high quality of care in this region. This effort may have failed quantitatively in part because of the short research timeline, but it was also clear that there had been inadequate motivation for change, organizational ability to manage change, choice of targeted change content, and use of the recommended change process.

IDEAL was a nearly simultaneous but smaller randomized trial of similar methods to improve diabetes care. This trial showed improvements in care processes, but not outcomes, in part because of limited practice leadership support, but also because the intervention also may not have emphasized the right types of care changes.

DIAMOND tested a more current version of quality improvement for depression care in a controlled trial that worked well, but had no effect because it did not have sufficient leadership support and still required that individual physicians initiate the new care process, so most patients were uninvolved. Wagner, in an accompanying editorial, said that “the elegant failure of Solberg and colleagues should be required reading,” demonstrating that strong leadership and “fundamental system change affecting the care of all patients” was essential.

Our studies of our HealthPartners Medical Group’s earlier very successful implementation of an advanced access scheduling system reinforced the importance of priority, strong medical group leadership, and a clear collaborative change process (both centrally and at individual clinics). It also reinforced the importance of paying attention to both concurrent changes and to various barriers and facilitators, from clinic demand-
capacity ratios to the mental models, practice styles, and work effects for individual physicians.

In each of these studies, our research team used quantitative and qualitative methods to best understand what happened in the change effort. This background has been invaluable and perhaps essential for an ability to draw lessons from both successes and failures. I have also been integrally involved in the front lines of each change, so personal awareness and reflection could be added to the more objective analyses as observers.

**LITERATURE**

The bulk of relevant organizational change and quality improvement literature from other industries consists of case studies or prescriptions from consultants or participants in the drive to make various businesses more successful in economic and quality terms. In the last 50 years, these authors have included such quality gurus as Deming and Juran, as well as a host of management experts.³¹,³² Their principal messages have been addressed to organizational leaders as the main agents of change. Their recommendations can be divided into those that favor a “hard,” or theory E, approach that focuses on economic value through dramatic structural changes, and a “soft,” or theory O, approach that instead aims to develop the right organizational culture and human capability.³³ Most successful examples, however, have included some use of both approaches.

For health care, some of the most salient lessons from other industries have come from those emphasizing the softer approach. For example, one leading writer on managing change, Kotter, emphasizes the importance of having vision, strategy, a guiding coalition with a sense of urgency, excellent communication, and widespread empowerment.¹⁴,¹⁵ Senge and colleagues put that change management approach in context by identifying the essential need to understand and use 5 disciplines: personal mastery, mental models, shared vision, team learning, and, most importantly, systems thinking (which integrates the other 4).³⁴,³⁵ Finally, Collins, is one of the very few to use a formal group-research process to identify the characteristics of companies that succeed economically over the long term. In *Good to Great* he emphasizes the need for discipline in companies that are successful.³⁶ The key factors he identifies include disciplined but not charismatic or authoritarian leaders at all levels that fit the vision, disciplined thought to face brutal facts and support the central “hedgehog concept” of the company, and disciplined action that uses technology selectively to accelerate momentum.

Moving from the literature of other industries to health care, Koeck has noted that “[a] student of management and organization theory could only be stunned by how little the efforts to improve quality [in health care] have learnt from current thinking in management and from the experience of other industries.”³⁷ An overview of how this literature applies in health care by Ferlie et al³ emphasizes the rise of management that provides a challenge to previous clinical domination, the need to respond to a market as other industries must, and the need for understanding how to manage change. Rhydderch et al³⁸ summarize the “big 4” organizational theories in health care that can help general practice respond to the quality problems caused by system failures:

1. **Systems theory**, which sees practices as inertial and change as intentional, taking place at the level of a single organization and using clear goals and standards, measurement, and feedback loops to guide change.

2. **Organizational development theory**, which sees change as a negotiation between 2 or more social worlds where the direction is driven by opportunities for congruence.

Garside³⁹ has done a particularly good job of addressing Koeck’s concern, reviewing the literature and making specific recommendations. First, she highlights the need for a vision that is clearly articulated and strongly committed to the desired end state through the inevitable resistances that will develop. Second, she notes the necessity of an organizational culture that is supportive of the change direction. To create and sustain such a culture, leaders and organizational policies must work at effective communication, training, and staff involvement and engagement in the change process. Finally, she emphasizes that implementation must be managed well with effective project leaders and multidisciplinary team planning to provide some early successes while recognizing major change takes time and resources.

What I take from all these mostly synergistic lessons from the literature in other industries and in health care is that almost all (except for the complexity advocates) see change as a goal-directed process managed by leaders who recognize the need to engage their employees
and other leaders in a disciplined but flexible way that accommodates external and internal factors and uses teams and group learning to create vision and manage change. Importantly, the change process they all focus on is separate from the actual changes needed and requires considerable attention, time, and resources. For an example of a practice change model based on complexity theory, see the model of Cohen et al.43

A FRAMEWORK FOR IMPROVING MEDICAL PRACTICE

From this web of personal experiences and the literature, a basically simple framework for change has evolved for me, one that can help practices of any size keep an eye on the forest while still being capable of attending to the trees: the inherently complex details and confounding factors. This framework (Figure 1) focuses on the 3 main elements that must all be present to a substantial degree so that desired improvements in the quality of care processes and patient outcomes can be produced: priority, change process capability, and care process content. A particularly important feature of this framework is its emphasis on a clear separation of the change process from the care process content. This distinction is one that seems to be missing in most efforts to improve care. For example, the CCM itself notably does not include any dimension for how to implement its elements, so it should be seen as only providing guidance for the care process portion of the framework.

Priority

As with any major behavior change for an individual (smoking cessation, weight loss), it seems obvious that unless there is strong desire and resource allocation for the specific change, as well as freedom from competing or more important priorities, major change is unlikely to happen. Every source noted above identifies the importance of this factor, either explicitly or implicitly. At the same time, it is clearly not enough for top leaders to say that a particular change is a priority; that priority must be shared by other personnel at all levels and reinforced by focused actions and commitment of resources. The equivalent of a burning platform may be the best metaphor for this factor.

Change Process Capability

Strangely, this factor important to improvement may be the least mentioned. The Institute for Healthcare Improvement has done a good job of highlighting its importance and, through the Model for Improvement, identifying a framework for thinking about the steps involved.12 Our research team’s work with “insightful implementers” who have had successful improvement experience in various medical groups has helped to identify many of the factors involved in this capability, as well as additional useful strategies.44 The qualitative study of HealthPartners Medical Group’s change efforts suggests that at least the following factors are important17:

1. Strong effective leadership, both centrally and locally
2. Commonly understood framework and infrastructure for managing the change process
3. People at all levels with change management skills
4. Adequate resources and time devoted to the change process
5. A mature and capable clinical information system
6. Good communication and measurement skills
7. A high degree of trust and teamwork
8. Individual accountability
9. A high degree of involvement and engagement by personnel at all levels

Care Process Content

Although the CCM is vague about the exact nature of the care process changes to be made, it does emphasize systems-level changes in the practice environment rather than asking individuals to simply do better or to do things unlikely for human beings (such as having perfect memory or completely consistent actions). Many care process examples identified within the 6 elements of the CCM have moderate to good evidence of effectiveness in studies of those individual components, at least those that fit within the 4 elements of delivery system redesign, self-management support, decision support, and clinical information system.45-49

Depending upon the degree to which the 3 factors in my framework are present, a medical group or practice will be able to develop, implement, and sustain improved care quality for its patients, measurable by both improved services and improved patient outcomes. Ideally, this result would include all 6 domains of the IOM definition of quality.

The quantitative and qualitative papers that report the study of the HealthPartners Medical Group’s efforts to implement the CCM help to illuminate that framework.16,17 While our quantitative study needed to restrict its scope to a focus on effectiveness...
measures, it showed that there were some improvements in some care processes and patient outcomes for patients with diabetes, heart disease, or depression. Measures of other processes and outcomes did not improve, however, especially for depression. This mixed outcome might have been predicted by the problems identified by the qualitative study, since there were deficiencies in each of the 3 factors in the conceptual framework.

Of course, an improvement effort does not take place in a vacuum. There are a great many other factors, both internal and external to a practice, that serve as facilitators and barriers. For example, organizational priority is clearly facilitated not only by external incentives or penalties, competition, and key customers, but also by such internal factors as competing priorities and the mission (whether articulated or not). Change process capability requires adequate resources, skilled people, a supportive culture, an understanding of measurement and systems, clinician champions, and a capable clinical information system. Effective care processes are facilitated by the existence of other practice systems and support for care standardization, team care, population management, and patient-centeredness. The absence of these facilitators becomes barriers.

Others have identified additional factors that appear to have an effect on either the priority or the capability of a care system to improve quality. For example, Bodenheimer et al, in their qualitative study of 158 leaders of varied care delivery systems nationally, found that the most commonly mentioned barriers were poor financial situation, reimbursement that does not reward high quality, inadequate information technology, physician resistance, and physicians that were too busy. The two most commonly mentioned facilitators in that study were strong leadership and an organizational culture that valued quality. Other quantitative results from a related study of 1,104 care systems found that factors positively associated with offering health promotion programs included outside reporting of quality measures, public recognition for quality measure success, clinical information technology systems, being a medical group, and ownership by a hospital or health plan.

To improve care, each of the 3 main factors must be addressed in an overall environment that minimizes barriers while it maximizes facilitators. Of course, if any of the 3 factors is missing or of limited strength, or if there are major barriers, little will happen or the change will not be sustained, which has been the case for most improvement efforts. In such a case, the framework should be helpful to those interested in change. First, by assessing each of the 3 factors, the main area to target should be clear. Then, by considering which of the barriers are most amenable to change, external or internal change agents may be able to affect that factor selectively. In the absence of external stimuli for affecting priority in a medical group lacking that factor, however, there may be little that can be done until such time as those stimuli develop or the organization enters a crisis that leads to new leadership with a different vision and sense of urgency.

Finally, how does this conceptual framework fit with the recommendations in the Future of Family Medicine report? Those recommendations could be seen as similar to the CCM in providing a vision for the elements of a desirable practice of the future. In that sense, they relate primarily to the care process content part of the framework. As with the CCM, however, they do not provide any guidance about the change process needed to achieve that vision or the factors important to stimulating the change (such as organizational priority), so they are important but incomplete.

Although this framework will not solve the national need to cross the quality chasm highlighted by the IOM report,1 such a simpler framework can at least provide a clearer guide to those in the front lines of care who would like to make the care transformations that are needed. It can also be helpful to those who are developing or testing interventions and recruiting medical practices for such change efforts. Do the practices have sufficient priority for this change and will they have enough capability for managing the process of change? Have the best and most feasible care process targets been chosen for improvement? Are there internal or external barriers that will prevent success no matter how well the other stars are aligned? On the answers to these questions may rest the likelihood of a chasm-leaping transformation in medical practice.

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Key words: Chronic disease; delivery of health care; disease management; models, organizational; quality of health care; physician’s practice patterns; health services research

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Disease Management: Panacea, Another False Hope, or Something in Between?

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ABSTRACT
Disease management is being promulgated by many policy makers, legislators, and a burgeoning new disease management industry as the next major hope, together with information technology and consumer-directed health care, to bring cost containment to runaway costs of health care. Many expect quality improvement as well. The concept is being aggressively marketed to employers, health plans, and government in the wake of managed care's failure to contain costs. There is widespread confusion, however, about what disease management is and what impact it will have on patients, physicians, and the health care system itself. In this article I give a current snapshot of disease management by briefly addressing (1) its rationale and growth, (2) its track record concerning costs and quality of care, and (3) its impacts on primary care.


RATIONALE AND GROWTH OF DISEASE MANAGEMENT
It is currently estimated that about 125 million Americans have 1 or more chronic diseases, one half of whom have 2 or more chronic illnesses. Although chronic conditions cut across all age-groups, they are most common among the elderly.¹ The care of chronic illness accounts for almost 75% of total health care expenditures each year.² Just 5 chronic diseases—hypertension, heart disease, diabetes, asthma, and mood disorders—account for almost one half of US health care spending.³ As our population ages and the prevalence and costs of chronic disease increase, it is becoming increasingly clear that our current health care system, oriented as it is to acute care, is ill-suited to the optimal care of chronic conditions, where care instead of cure is the major goal.

The management of disease has long been a central goal of medicine. The term disease management, however, is a new buzzword, confusing to many, that has arisen in response to the economic and societal burden incurred by the care of chronic illness and the need to improve the quality of care for the growing populations of patients who have chronic disease.⁴ An additional driver of disease management, especially during the last 15 years, has been aggressive marketing by a growing commercial disease management industry seeking profits in a new market. The pharmaceutical industry, especially pharmacy benefit management companies (PBMs), has spearheaded this development since the early 1990s.

There are two basic types of disease management programs—those based on primary care and integrated within a managed care organization (eg, Group Health Cooperative and Kaiser Permanente), and commercial vendors to which employers and health plans may outsource their disease management functions. The former has been well accepted within the medical community as an important advance in the care of chronic disease. Group Health Cooperative and Kaiser Permanente have pioneered new
approaches to chronic disease management based upon a new paradigm, the Chronic Care Model. For example, primary care teams are provided support in the form of electronic diabetes registries, evidence-based guidelines, patient self-management support, and decentralized on-site consultation with a diabetes expert team (a physician and a nurse specialist).

Commercial disease management programs are quite different. As carved-out programs, they are not integrated with primary care, are for-profit ventures, and are marketed to employers and health plans primarily as a cost-containment strategy. With sophisticated information systems, disease management companies focus on patient education and more-effective patient self-management, especially by use of telephone calls, mailings, and the Internet. Commercial disease management programs often provide minimal communication with primary care physicians, and reception of these programs by physicians is frequently antagonistic. Physicians may at times receive telephone calls from several nurses in distant call centers about the same patient with multiple chronic conditions.

Early commercial disease management programs were designed to identify high-risk patients with a single disease and then to sell a program of patient education and self-management to employers and managed care organizations. Although these programs were marketed as strategies to contain costs and improve the quality of care of patients with chronic diseases (such as diabetes or asthma), pharmaceutical manufacturers could expect to gain increased profits in several ways. Disease management programs could support their own product lines, increased sales could be leveraged by pharmacy benefit management companies contracting with employers and managed care organizations, and patients not yet taking medications could be identified.

Whereas early disease management programs were directed mainly at enlarging target populations for drug therapy and increasing patient compliance with drug regimens, second-generation disease management programs have evolved in recent years toward a broader, population-based approach. A large commercial disease management industry has emerged that utilizes claims data to identify patients with selected chronic diseases. Commercial disease management vendors increasingly sell their programs for multiple diseases. Although participation in a disease management program has remained voluntary for patients, the trend in the disease management industry is to include all patients with selected chronic diseases unless they opt out of the program.

Although some health plans develop their own disease management programs, many contract with private vendors to provide this function. A health plan or employer contracting for a disease management program will pay a per-member-per-month fee for a package of services, such as patient and clinician education, patient self-management, reminders, and alerts. The vendor agrees to specific performance guarantees, such as a certain percentage of cost savings and perhaps some health outcome measures. Fees may be at risk if performance goals are not met, but vendors are not obligated to pick up any added treatment costs and avoid clinical risk or responsibility for patient care.

Two thirds of employers with 200 or more employees in 2005 had a disease management program in their job-based insurance plans; more than one half of all workers with employment-based insurance had a disease management program. The most common disease management program is for diabetes, closely followed by asthma, hypertension, and high-cholesterol programs. On the public sector side, more than 20 states are contracting for one or another kind of disease management programs for their Medicaid enrollees, and Medicare has already signed up 100,000 beneficiaries for disease management programs through 8 companies.

**DOES DISEASE MANAGEMENT CUT COSTS AND IMPROVE QUALITY OF CARE?**

Evaluations of disease management programs are methodologically challenging, and most studies are limited by not having a control group or data on longer-term outcomes. The evidence to date is stronger for quality improvement in such programs than for cost savings, and many studies do not factor in the full costs of the disease management interventions themselves. To date, there are no studies that directly compare the outcomes of disease management programs integrated in primary care settings with outcomes of commercial programs.

Some institutions that have introduced disease management programs based on a Chronic Care Model have achieved improved quality of care as a result, sometimes with modest short-term cost savings. One example is at Group Health Cooperative in Seattle, which adopted the Chronic Care Model in 1995. During the next 2 years overall costs went down by 11% for 15,000 diabetic patients (except for pharmacy costs, which went up by 16%), and both specialty visits and hospital admissions were reduced by 25%; at the same time, quality improved as measured by sustained reductions of glycosylated hemoglobin (HbA1c) levels. Another example is a Kaiser Permanente program in Northern California, where substantial quality improvement, but no cost savings, was achieved in a multidisciplinary disease management program for coronary artery disease, heart failure, diabetes, and asthma during a 6-year period from 1996 to 2002. In a later summary of 39 studies of outcomes from use of
the Chronic Care Model, positive patient outcomes and/or care processes were found in 32 studies, with outcomes depending on how many of the 4 Chronic Care Model components were used (self-management, decision support, delivery system design, and clinical information system).17

Results are more ambiguous when one looks at the overall track record of all disease management programs, including those of the growing number of commercial vendors largely disconnected from primary care. There are 3 recently published meta-analyses to draw upon. Tsai and colleagues18 examined 112 studies involving disease management programs based on the Chronic Care Model for asthma, congestive heart failure, diabetes, and depression. They found beneficial results across all these conditions, but noted mixed effects on quality of life (no benefit for asthma and diabetes), as well as publication bias for congestive heart failure and some asthma studies. Krause19 evaluated 67 studies involving more than 32,000 patients with diabetes, concluding that disease management programs are more effective when provided to severely ill enrollees and that even though a small to moderate positive impact was found, further study of comorbidity and costs incurred by enrollees is needed. A third meta-analysis was recently reported by Neumeyer-Gromen and colleagues for disease management programs for depression.20 On the basis of 10 randomized controlled trials in the United States, they found significant improvements in quality of care at acceptable costs ranging from $9,051 to $49,500 per quality-adjusted life-year.

There are many smaller studies, especially those reporting experience by commercial disease management vendors, that show lower costs by such measures as hospitalizations and emergency department visits. One recent example is a 1-year report of telephonic nursing disease management for elderly patients with congestive heart failure, which resulted in a 10% cost saving after accounting for intervention costs.21 Several other recent outcome assessments cast doubt on disease management as a cost-containment strategy.
• A 2006 analysis of the number needed to decrease costs calculated that disease management programs will need to decrease hospital admissions by 10% to 30% to cover program fees alone.22
• The Congressional Budget Office stated in 2004 that “there is insufficient evidence to conclude that disease management programs can generally reduce overall health spending...”23
• A 2005 report by David Eddy and colleagues on the long-term effect of disease management on cost savings in diabetes concluded, “Even for the most optimistic picture—a 30-year horizon and assuming no turnover (patients stay with the same plan for 30 years)—the net effect on diabetes-related costs would be an increase of about 25%.24

DISEASE MANAGEMENT AND PRIMARY CARE

The expanding disease management industry has emerged as a result of deficits in the quality of chronic disease care in many primary care settings across the country. Many factors account for this problem, including inadequate design of office practice for team management of chronic illness, underreimbursement of chronic disease care, lack of time, and lack of enabling information technology.25

Disease management programs based on the Chronic Care Model and integrated with primary care have shown promising results, likely to be lasting, for quality improvement.

Group Health Cooperative has taken its expertise and lessons on the road in an effort to train primary care teams in other parts of the country. With funding from a federal grant, disease management experts from Group Health have worked with more than 1,100 teams in more than 500 community clinics across the country to implement the Planned Care Model for management of diabetes, cardiovascular disease, depression, asthma, and obesity. After 13 months of training and collaboration, 82% of the pilot sites reported decreases in patients’ average HbA1c levels in diabetes from 8.4% to 7.6%, and combined cardiac risk reduction scores showed an absolute risk reduction of 2.4%.14

These excellent results require commitment, expertise, and adequate funding, together with an infrastructure that includes electronic medical records, disease registries, decision-support systems, patient reminders, and self-management materials. Those needs are not available in most primary care practices across the country, which are already grossly underreimbursed by private and public payers for the challenge of improving coordination and quality of chronic disease care.

Optimal management of chronic conditions is complex, particularly for patients with multiple chronic diseases. It is best done by well-trained primary care physicians working closely with other health professionals on a team basis. Management decisions are often difficult and must be individualized to each patient and family in a continuity of care relationship. How would it be possible, for example, for a nurse working with a commercial disease management vendor from a distant call center, without a relationship with the patient and primary care physician, to decide how to proceed in calibrating dosages of β-blockers, angiotensin-converting enzyme inhibitors, antidiabetes drugs, and antidepressants in a frail elderly patient on Medicare?
More often than not, disease management today is being bought and sold between health plans, employers, and commercial vendors, without any real connection to the primary care system. Table 1 displays some major differences between not-for-profit institutional disease management programs and their commercial nonintegrated counterparts.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Integrated</th>
<th>Nonintegrated</th>
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<tbody>
<tr>
<td>Ownership</td>
<td>Not-for-profit managed care organizations</td>
<td>For-profit commercial vendors</td>
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<tr>
<td>Locus</td>
<td>Institutional-based</td>
<td>Outsourced</td>
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<tr>
<td>Linkage to primary care physicians</td>
<td>Strong</td>
<td>Weak to none</td>
</tr>
<tr>
<td>Patient participation</td>
<td>System-based for all</td>
<td>Optional</td>
</tr>
<tr>
<td>Program horizon</td>
<td>Long-term</td>
<td>Short-term</td>
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<tr>
<td>Motivation</td>
<td>Quality-oriented</td>
<td>Profit-oriented</td>
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Table 1. Basic Types of Disease Management Programs

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Key words: Disease management; managed care programs; comprehensive health care; delivery of health care; primary health care

References


Reflection

The Impotence of Being Important – Reflections on Leadership

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ABSTRACT
An observed doctor-patient encounter, in which impotence and importance were confused, led me to a reflection on leadership. A sense of importance can be destructive in leadership, leading to failure to perform, or impotence. Understanding the dangers of self-importance, I am challenged to ensure that I regularly reflect on my leadership style.

What is wrong with this gentleman?” asked the recently arrived British doctor of the nurse-interpreter in the outpatients department of Manguzi Hospital, a community hospital in a remote district in South Africa. After a brief exchange in Zulu with the elderly male patient, the nurse replied, “He says he is important.” A long pause followed as the concerned doctor tried to work out an approach to this novel problem. “How long has he been important?” seemed a good standard follow-on. “A few months now, doctor.” Not sure where to go from there, he decided to get to the heart of the matter: “Why is it a problem for him to be important?” A longer discussion in Zulu followed, during which the nurse showed some signs of discomfort, before she summarized somewhat succinctly, “He cannot satisfy his wives.” My colleague was musing about how one’s importance might prevent one from satisfying one’s wives (a fruitful exercise) when the truth dawned on him. “You mean this gentleman is IMPOTENT!”

I have often thought about this brief patient encounter on which I eavesdropped many years ago. I have come to understand that importance, or the feeling of importance, can often be a cause of impotence. Physically the phenomena may be very different, but at another level they are very close. When I believe that everything depends on me, or that I am the only person who can do the job, or that I am the best at doing something, I become impotent in my leadership and in my practice.

As I have reflected on this patient-doctor-nurse interaction, I have identified a number of ways in which self-importance can be destructive to leadership. These reflections arise from my experience as medical superintendent of Manguzi, a remote rural hospital in northern KwaZulu Natal, South Africa. The hospital served a population of approximately 100,000 people, with 280 beds, 9 permanent clinics, 3 mobile clinics, and a total staff of more than 500, including from 6 to 12 doctors depending on staffing levels. Since leaving Manguzi in 1999, I have had the chance to further reflect on my interactions while working alongside nurse-practitioners in primary care clinics in the North West province and subsequently leading an academic rural health unit within the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg. My reflections are informed by my ongoing experience as a clinician, teacher, researcher, and manager.
Thus I offer the following lessons, recognizing that I am constantly relearning them myself.

1. If I feel very important, I start to do everything myself instead of delegating responsibilities. I fear passing tasks on to others because they will not do it the way I would or as well as I would (so I believe), but I become unable to do everything myself. I become an obstacle for myself and for others because I am doing too much. Delegation is an important aspect of leadership and, distinct from off-loading work, requires that I have a balanced view of myself. I sometimes believed that “my” hospital would collapse without me, yet it has continued to function well since my departure.

2. If I feel very important, I isolate myself from the teams to which I belong. This isolation deprives my colleagues of the chance to work with me to achieve a goal, and it deprives me of positive support. To gain a team’s commitment to something they have not been involved in developing is much more difficult. At the hospital I worked with a number of teams: a management team, a health care team, a medical team, a community team, etc. In each sphere, I needed the support of other team members to achieve any vision that I may have had, ensuring the vision was a shared one. As doctors, especially rural doctors, we tend to be very independent-minded people who do not easily defer to our professional colleagues. Our patients and our practices often suffer because of that trait.

3. If I feel very important, I become less critical of myself and less able to evaluate myself. I no longer face and learn from my mistakes. The chances are that my mistakes will thus be repeated. An inflated opinion of ourselves makes it difficult for us to view ourselves honestly: the mirror becomes the instrument of deceit, as in the old fairy tale, always proclaiming us the fairest of them all. I had to make the same labor ward mistake twice to come to this realization! An honest review of poor performance as part of self-reflection is the first step to personal growth.

4. If I feel very important, I am not open to learning from others. I take on knowledge, perhaps, but the most profound learning comes through the questioning that follows the identification of our own needs. It is difficult to be aware of needs if we are enamored with our own importance. Others do not feel able to reflect the truth back to us because we will not hear or we react defensively. We also do not create the avenues for feedback from patients and staff because we cannot believe we would learn anything (or are secretly afraid of what we might learn.) This may be something of what is meant by the Biblical teaching, “Blessed are the poor in spirit.”

5. If I feel very important, my sense of invulnerability makes me vulnerable. We know that pride comes before the fall. I perforated the uterus of a patient with an incomplete abortion soon after assuring a new doctor that, in my experience of more than a hundred of these procedures, an evacuation and curettage is extremely easy to perform. I was challenged about my leadership style by a colleague to whom I had boasted of my open and participatory leadership. If we are blind to our areas of weakness, we cannot prepare ourselves for the problems that they will cause.

Thus, I believe we become impotent in our leadership if we are too filled with our own sense of importance.

As a doctor, as a manager, as a teacher, I receive much external input persuading me that I am indeed important. To guard against this sense of self-importance, I find that I need to create time and space for personal reflection on who I am (not what I am) and to establish relationships with people who will keep me honest.

To read or post commentaries in response to this article, see it online at http://www.annfammed.org/cgi/current/full/5/3/261.

Key words: Leadership; power, professional; importance; relationships; delegation, professional

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Toward an Ecosystemic Approach to Chronic Care Design and Practice in Primary Care

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ABSTRACT
Despite the increasing prevalence of chronic conditions and multimorbidities, the essential attributes of the structure and delivery of primary care continue to be defined in terms of disease-specific approaches and acute conditions. Effective improvements will require alternative ways of thinking about chronic care design and practice. This essay argues for an ecosystemic understanding of chronic care founded on a communal and a dynamic view of the response of the patient, family, and health professionals to chronic illness. The communal view highlights the cocreative nature of the response to illness and the need to integrate the skills and resources of all the participants; what and how the participants learn in the course of the illness become central to chronic care. The dynamic view draws attention to the unfolding of illness management activities over time and to the need to engage the illness at specific time points or recurring time intervals that have the potential for important change in the experience of the participants. Chronic care would then include design for community, with an emphasis on the patient and family as necessary participants in the health care team. It would also include design for emergent learning and practice whereby health professionals go beyond standardization of care processes to develop new ways to harness the participants’ imagination and learn from the changing experience of illness. Health professionals would also learn to cultivate trust, communal engagement, and openness to experimentation that facilitate collective learning, and help sharpen the participants’ responsiveness to the emergent.


INTRODUCTION
The increasing prevalence of chronic conditions and multimorbidities has stimulated numerous efforts to improve chronic care.1-5 The essential attributes of the structure and delivery of primary care continue to be defined in terms of acute conditions and disease-specific approaches, however.6 Encounters for chronic care are still treated as if they were unique events rather than a continual process of care.4,7

The aim of this essay is to suggest an alternative way of thinking about the structure and delivery of chronic care. Its central claim can be summarized as follows: chronic care is what the patient, family members, and health professionals do to achieve specific health outcomes within the evolving opportunities and constraints of chronic illness. Chronic care in this view is an ecosystemic response to illness: a collective and more or less adaptive response of the patient, family, and health professionals to the changing biological and psychosocial manifestations of the illness. In the following sections, I unpack this claim by first reviewing the main features of chronic care activities. Next, I propose 2 perspectives that can help integrate these features into chronic care design and practice. Finally, I discuss implications for chronic care design and present recommendations for clinical practice.
THE NATURE OF CHRONIC CARE ACTIVITIES

Chronic care activities have 2 main characteristics. First, they entail a conceptual shift from disease management to illness management. Disease management refers to clinicians’ understandings of the biomedical model of disease progression. In contrast, illness management refers to how patients, families, and other members of the social community perceive, explain, and cope with the illness. The confluence of these 2 perspectives encompasses the lived experience of illness, its associated cultural and social categories (spiritual, ethnic, folk, and family beliefs), and their interactions with the psychobiological processes of chronic pathology. Shared understandings among health professionals, patients, and families about the meaning of illness, suffering, recovery, and death become central to chronic care.

Second, unlike acute illnesses, chronic illnesses bring a dynamic complexity inherent in their lengthy and multifactorial nature. Caused by irreversible pathologic alterations, chronic illnesses often leave residual disability and require intermittent periods of care and complex treatment. Changing patterns of illness are created from the interaction of the disease, its consequences, and the social context—all dynamic in nature, and requiring continual monitoring and complex management.

Together, these characteristics help specify 2 features of chronic care activities: (1) they occur at the confluence of processes that are rooted in the biological, psychosocial, and cultural realms of human experience, as such, they raise issues of shared meanings and mutual dependencies among the participants, and (2) they weave together the developmental threads of chronic illness, of patient and family, and of the health care team. Chronic care appears as a collective enterprise, mobile, changing, and riddled with renewed instabilities that reflect variable qualitative and quantitative differences in how diseases are manifested over time and in how patients, family members, and health professionals respond to them. How then can we integrate these features into our conception of chronic care design and practice?

INTEGRATING CHRONIC CARE DESIGN AND PRACTICE

Two perspectives are necessary. Both draw on approaches in human ecology. The first, a communal view, recognizes the interdependent nature of illness management activities. The second, a dynamic view, recognizes the mobile and shifting qualities of illness experiences.

The Communal View of Chronic Care

In an ecosystemic approach, chronic care is a communal engagement of its participants in a set of recurring activities that are part of the same human enterprise: preserving life, establishing viable relationships with the environment, surviving together. Chronic care in this view is a communal adaptive system, an association of specific individuals who through an organization of their resources, differentiated activities, and skills, act as a unit to preserve, improve, and expand life to the maximum attainable under the prevailing opportunities and constraints of their environments (physical, biological, homes, workplaces, hospitals, clinics).

In this ecosystem, several linkages are created among the participants’ activities and between specific niches they occupy. As Figure 1 indicates, encounters between the patient, family members, and health professionals bring together multiple cognitive and emotional representations of the illness, multiple behavioral modalities, and multiple skills that underlie behavior performance. Health professionals provide knowledge and expertise in health care. Patients provide self-care skills and the physiologic energy to accomplish self-care activities. Family members also invest time, energy, emotions, money, and other resources into coping with the illness. Chronic care appears as a more or less effective arrangement of mutual dependencies and collaborative efforts, a network of communication and relationship ties among patients, family members, and health professionals, designed to achieve common health goals.

An important corollary of the communal view is that the encounters of the patient, family, and health professionals are also those of a learning community—a group of individuals who through language and conversations negotiate meanings and learn about the illness, about each other, and about themselves. Indeed, the participants in chronic care activities are purposeful human beings whose behavior is shaped by the ideas, meanings, and interpretations that they have of themselves and their environments. Because chronic illness changes how patients and families perceive themselves and what they can do, they also develop new meanings and new ways of responding to their environments, including their encounters with health professionals. In turn, health professionals learn from the patient and family, and from the collective work and knowledge that are triggered and nurtured by the clinical encounters. Insights from complexity theory reinforce this view as they indicate that learning can emerge from the interactions and enacted differences among adaptive agents. In their conversations, for example, health professionals, patients, and family members may have differences in opinion, beliefs, behaviors, knowledge, and ways of thinking. As a result of these differences, learning—in the form of shifts of understanding and novel patterns
of thoughts, emotions, and behaviors (eg, conflicts, rules, prescribing behaviors)—can emerge and spread through subsequent conversations and interactions among the participants.33,37

A communal view therefore highlights the need to integrate the identities, skills, and resources of all the participants.28,29 It also underlines the cocreative nature of the response to chronic illness.18,34-37 What and how the participants learn in the course of the illness become central to chronic care.28,29,36

**The Dynamic View of Chronic Care**

In the dynamic view, we recognize the episodic and changing nature of the interdependencies among the participants. Chronic care requires ongoing adjustments marked by some phases when the patient is self-reliant and other phases when he or she is dependent on health professionals.38 These phases reflect the mobile nature of the locus of control over change.39 Managing this shifting reality requires flexible designs that can match the variable patterns of illness and their associated demands and resources.

In the dynamic view, we also recognize the patterned influence of time on chronic care activities. Time in chronic care shifts away from single events to recurring episodes, and from a linear view of past, present, and future to a variable integration of specific recurring activities and durations at the level of the patient, family, and health professionals. In other words, chronic care time has rhythm, and temporal rhythms must be included in the context of illness management. For health professionals, many standing patterns of behavior—blood sampling, radiographic screening, physician-patient meeting—have more or less predictable delays and occur only at certain times of the day, week, or month.26,40,41 For the patient and family, chronic care activities are also intermittent—their temporal spacing being regulated by the recurring needs for food, rest, and other daily needs—and only a subset of these activities involves the interaction of the patient with health professionals.18,32,42 Considering time also introduces a historical dimension through which these activities are understood in terms of the patient’s and family’s unique history with illness, developmental issues, expectations, resources, and vulnerabilities at different life stages.32

A dynamic view of chronic care therefore draws attention to the unfolding of illness management activities over time and to the need to engage the illness at specific time points or recurring time intervals along its lines of deployment—specific time phases that have the potential for important qualitative or quantitative change in the experience of the participants.17,32
Characteristics of the Ecosystemic Approach
In summary, an ecosystemic approach to chronic care highlights 3 units of analysis: the group of participants in care activities, their environments (biological, psychosocial, health care organization, family unit), and their adaptive response to chronic illness. What takes primacy in this triad is the adaptive component: the evolving arrangements of mutual dependencies and linkages among the participants and their environments. Effective arrangements of these linkages allow the participants to act as a unit, with shared goals, shared meaning and learning, mutual awareness and understanding of the contributions of each participant (representations, emotions, skills, behaviors), and well-timed communications. Three characteristics of this adaptive ecosystem are essential to chronic care design and practice: it is spread across and beyond the health care organization to include the patient and family as necessary participants, it has rhythm, and it is fluid—its specific structure and function emerging from the demands of the illness, the available resources to meet them, and the evolving encounters of the participants.

IMPLICATIONS FOR CHRONIC CARE DESIGN
Based on the preceding discussion, chronic care design must support community development, emergent learning, and the coordination of efforts within identifiable constraints, resources, and rhythms.

Designing for Community
There is much to know about the requirements of a design that recognizes the patient and family as necessary participants in the care team. The challenges of designing for community go beyond giving the patient and family a voice in decisions. They are those of negotiating meanings not just in conflicting multicultural encounters, but also in the clashing of the narrative logic of the experience of illness and the deductive logic of medicine. They are also those of dispersed communities (eg, health care organization, family unit), time, and fluctuating demands of the illness with varying dependence on health professionals. The challenges also reside in how to organize the relationships among the participants: how to recognize, coordinate, value, and leverage their engagement to the health care organization. An example of a useful area of investigation is the architectural and technological design of the spaces wherein the encounters among patient, family, and health professionals occur.

Designing for Emergent Learning and Practice
Chronic care activities evolve over time with potentially changing goals. Central to this adaptive system is the ability to detect changes through continual monitoring, and to use those changes as feedback that activates relevant strategies—changing roles for the patient, family members, or health professionals, developing or introducing new skills into the group. Learning in chronic care is then better conceived in terms of the emergent events and collaborative tasks that structure chronic care.

The emergent nature of chronic care activities challenges the planned didactic strategies that follow evidence-based guidelines. Designing for emergent learning and practice is more about the definition of goals, constraints, and coordination of resources than the detailed formulation of fixed competences and places for learning or practice. Examples of constraints/resources include patients' access to resources that support self-management or the physiologic factors that impinge on their energy to manage the illness. Other examples include the available technology, the relevant mix of professionals, the locations for collaborative practice (health care organization, family unit, or both), and the schedules, roles, potential partners, and financial arrangements within the practice and the family unit.

Designing for emergent learning and practice would then leave ample space for imagination, improvisation, and creative adjustment to the more or less predictable experiences of illness. To be anchored in the communal engagement of practice, imagination and improvisation would rely not only on dry runs and simulations, periodic review sessions, and keeping up with new technologies and research literature, but also on the development of an organizational culture that favors a sense of community, trust, and openness to experimentation and discovery. Ongoing experiences with process change methods such as the Plan, Do, Study, Act (PDSA) cycles suggest that the "try it and see" attitude, combined with group processes and leverage on the health care organization through its senior leaders, is an essential element of successful collaboratives. Models of communities of practice are also promising for the chronic care context for their potential to integrate learning and practice. Communities of practice can provide an effective social context for reflection on collective experience during and outside of the clinical encounters, and can help develop and refine the knowledge used in practice iteratively.

RECOMMENDATIONS FOR CLINICAL PRACTICE
The following recommendations can serve as a guide for designing for community and emergent learning and practice.
1. Develop your “village square” by assembling team members around clinical tasks and social situations. Create lively gathering places where the participants can get to know each other and develop a sense of belonging to a larger community. The village square can take different forms—Web-based forums, lively water cooler areas, workshops, and group meetings for participants to discuss their self-management strategies. The goal here is to deepen the connections with patients, their families, and team members as a group of people who have agency, a specific history with illness, and who live a particular life.

2. Elicit and foster participation. Make trust and compassion strategic requirements of chronic care, encourage self-reporting of mistakes, and target your interventions to relationships, not solely to individual patients or team members. For example, for diabetic patients to change their diet, their connection to their family members in relation to food selection, preparation, and eating schedule may also need to change; for team members to improve their collective performance, they must understand how they depend on each other.

3. Make the patient’s and family members’ perceptions and emotions an essential thrust of clinical efforts. Sincere emotional connections are the basis for trust, empathy, and insightful compassion that can improve their collective performance, they must understand how they depend on each other.

4. Ask not only what you can do for your patients, but also what the patients and families can do for themselves and for your clinical practice. Make co-creation of care plans a strategic requirement of chronic care; patients and families are primary care’s best learners and sources of healing. Develop a sense of community.

5. Link the business value (caring for patients) to the knowledge value and knit a varied quilt. Identify key activities depending on the illness, analyze them in terms of critical knowledge domains, and identify who among the participants needs this knowledge. Connect people with different expertise, and leverage the accumulation of experience by making visible both their explicit and tacit knowledge: organize their work around common tasks, record their conversations, collect and communicate their failure and success stories.

6. Learn more about narrative medicine. Know how to listen to stories and how to tell them.

7. Anticipate accumulation and decline on different accounts. Schedule visits around specific phases of the illness timeline to assess skills, self-regulation, coping behaviors, and resources; schedule assessments for all the participants, not just for the patient and family.

8. Think in terms of incremental change. Think of small experiments to test and implement change and learn from variation. Plan also for repeated measures of implementation and outcome; data accumulated over time can reveal the appropriate timing of interventions.

9. Problem-solve, yet be flexible and goal-oriented. Who is responsible for change? Is the relevant information at the level of the patient, family, health professionals, or the larger social community? Comprehensive chronic care goals are then defined as target values at different levels of the ecosystem of illness management including the biological, psychological, familial, and social realms.

10. Make a habit of reflection time. Reflection can be organized around broad phases of the illness timeline, such as a 4-stages axis including prediagnosis, diagnosis/treatment, recovery/disability, and death. Each of the phases represents a turning point to important change in the illness, its demands, and the resources to meet them. Reflection can also be done before, during, and after the visit, and can, for example, facilitate the production of visit summaries for patients.

11. Keep a record of your learning process.

12. Think longitudinally, but remember the circular nature of time. Temporal rhythms provide the beat that influences the pace of what patients do to manage their illness, with whom, when, and where they are able to do it. Create an effective rhythm by adjusting the frequencies of communications among the participants to facilitate collaborative practices, coordinated engagements in care activities, and the development of a sense of community.

13. Challenge assumptions once in a while. Keep asking, why do we do this in this way?

CONCLUSION

Design for acute care, with its standardization of process, may be likened to that of an ice cube formed in the mold of a cubic slot where water is frozen into a pregivien form. In contrast, design for chronic care is better compared with that of a snowflake that forms itself in a streaming space by tapping into the useful flows of gravity, wind, humidity, dusts, and chemical gradients. As much as each snowflake differs from any other, each patient lives a unique illness experience that generates a unique set of interactions with health professionals, or the larger social community? Comprehensive chronic care goals are then defined as target values at different levels of the ecosystem of illness management including the biological, psychological, familial, and social realms.
professionals. For patients, the streaming space that shapes chronic care includes not only their peculiar list of physiologic constraints tied to specific diseases and comorbidities, but also their need for food and rest, individual preferences, available resources, and uncertain everyday decisions. For health professionals, chronic care is shaped not only by their expertise, but also by their intuition and creativity to expand their competence by integrating the patient’s comorbidities, family and work problems, conflicting schedules, economic resources, and constraints.55

The shifts required to implement this understanding represent a cultural change. From an ethos of standardization and prefabricated structures, the move is to a streaming and tracking ethos in which health professionals develop new ways to recognize, value, and manage the communal response to illness; new ways to document and learn from the changing nature of illness experiences; and new ways to cultivate openness, trust, and communal engagement that facilitate collective learning and help sharpen the participants’ responsiveness to the emergent—all essential skills for those who want to foster and enjoy their relationship with each patient.28,46,50,65

To read or post commentaries in response to this article, see it online at http://www.annfammed.org/cgi/content/full/5/3/263.

Key words: Chronic illness; health professionals; ecosystem; family; learning community; complexity; health care delivery/health services research; psychosocial factors; systems theory; models, theoretical

Acknowledgments: I am grateful to William Miller for his helpful comments on an earlier version of this manuscript and to Robert Thivierge for directing me to some of the best readings about knowledge management and learning in clinical practice. Special thanks go to Paule Lebel for many stimulating conversations on the topic of medical education. I am also thankful to Martin Fortin, Sharon Hatcher, and Catherine Hudon for their supportive comments.

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On TRACK: Primary Care Opportunities for Filling Unmet Need

Kurt C. Stange, MD, PhD, Editor


EXPANDED PRIMARY CARE CAN FILL CRITICAL HOLES IN HEALTH CARE

The study of outpatient treatment of opioid addiction in the last issue of Annals stimulated a dialogue between the lead author and an international group of clinicians sharing their experience with buprenorphine-naloxone and relevant literature, pharmacology, and politics. Together, these comments point the way toward expanded use, training, and research on this important intervention in primary care.

The study of a primary care response to Hurricane Katrina kindled sharing of a parallel response from those caring for evacuees in the Houston Astrodome. Commentary from public health and emergency care experts draws the larger lessons about the holes in the emergency response system and the vital role of primary care in meeting emergency needs. “This pragmatic study needs to be read by every community-based department of health and disaster planner.”

Coyne challenges an inference by Gaynes et al that depressed patients should be treated as aggressively in primary care as in psychiatric care. He calls for reinterpretation of “potentially misleading implications,” as well as further research on representative patient samples using semistructured interviews for diagnosis of depression.

Keller’s discussion of the Wadland study linking primary care practice with quit lines provides evidence and expert interpretation of this promising and challenging strategy for expanding tobacco control.

The risk adjustment models used by James and colleagues generated gratitude for their utility in preventing those providing care by rural hospitals from being unjustifiably maligned and detailed discussion of the challenges of adjusting for confounding.

DTC PHARMACEUTICAL MARKETING

The discussion of direct to consumer (DTC) marketing started by the study by Frosch and colleagues continued to percolate, further stimulated by an editorial and a news item from one of the Annals’ sponsoring organizations in the last issue. Among several discussants, Krueger notes the conflict of interest of a wide variety of media outlets that have become dependent on DTC pharmaceutical ads, yet are responsible for reporting adverse effects of drugs as part of their news reporting. Frey suggests that DTC advertising bans could be a potent portion of presidential candidates’ health care plans. Shropshire calls for redirecting American Academy of Family Physicians (AAFP) leadership away from support for the pharmaceutical industry toward “our patients’ ultimate well-being…” Rather than banning DTC ads, Hallgren suggests that “our lobbying bodies (AAFP, American Medical Association) should be campaigning against it and providing the outlets of unbiased information.”

OTHER THREADS OF DISCUSSION

Diverse discussants of research capacity building bring out multiple opportunities for stimulating primary care research, while challenging us to examine the impact of that research.

The discussion of the study by Krist et al advances our understanding of the appropriate outcomes for use of patient decision aids.

The study of standardized patients raises important questions and experiential validation and interpretation of this method of growing importance for health care research.

The challenge and need for expanding clinical performance measurement is well articulated in discussion by Milstein, de Brantes, and Bennett. These calls for increased rigor in performance assessment are echoed somewhat differently in reaction to the essay on jazz as a metaphor for the art of improvisation in the medical encounter. This essay stimulated analysis and experience-based reflection and a call for increased training in the “seventh competency” of reflective practice.

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ACADEMIC FAMILY MEDICINE’S RESPONSE TO CTSA

The Institutional Clinical and Translational Science Awards (CTSAs) are the cornerstone of the National Institutes of Health Roadmap Initiative that intends to transform research by promoting new models of research and expanding research training for the future. This initiative is designed to maximize the public’s investment in the biomedical research enterprise through development of new models of clinical research and the training of new types of clinical researchers. Specifically, this model promotes collaboration between disciplines and emphasizes that many of the critical questions in medicine cannot be answered within the confines of single NIH institutes or traditional academic health centers. Additionally, CTSAs should “help deliver improved medical care to the entire population, helping to disseminate new technologies and new advances into clinical practice.”

The continuing maturation of research capacity in family medicine is occurring apace, even as the NIH’s research enterprise continues to mature in ways that invite, if not require, greater emphasis on effectiveness, what works and why, in frontline practices where millions of people are seen daily. This terrain is that family medicine knows about and needs to know much more about.

The first round of CTSA grant applications were due in March 2006. The following awardees were announced in September, 2006: Columbia University Health Sciences, Duke University, Mayo Clinic College of Medicine, Oregon Health and Science University, Rockefeller University, University of California-Davis, University of California-San Francisco, University of Pennsylvania, University of Pittsburgh, University of Rochester, University of Texas Health Science Center at Houston, and Yale University.

In addition to these full grants, 52 “planning grants” of $150,000 each were awarded. The second round of CTSA applications were due January 2007. These grants will be reviewed in May and awardees will be announced in the fall. The request for applications (RFA) for the third round of grants was released March 22, 2007 with a due date of October 24, 2007 (http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-07-007.html). The language of these RFAs has continued to evolve with a broader understanding of the concept of translation. The definition of translation includes “enhancing the adoption of best practices in the community” and has been expanded to include the “cost effectiveness of prevention and treatment strategies.”

The first sentence in the executive summary of the RFA states, “The ever increasing complexities involved in conducting clinical research are making it more difficult to translate new knowledge to the clinic – and back again to the bench.” The financing of the awards has been expanded so that NCRR K12, K30, M01, and Roadmap T32 and K12 awards that the institution already has are in addition to the CTSA funds. Pediatric research has been carved out of the main CTSA. It should also be noted that the NIH has made it clear that all CTSA awardees are expected to participate in a national community of CTSAs that will work together to develop and expand new models for clinical research and collaboration.

The family of family medicine has been aggressive about seeking and collating information about family medicine participation in CTSA grants. Following discussion of this at the August Working Party meeting by leaders of family medicine organizations, a CTSA Strike Force was formed by ADFM to organize aggressive action. NAPCRG and ADFM conducted surveys to document family medicine participation. This information was presented at a special discussion session at the NAPCRG meeting in Tucson in October. CTSAs were a major topic of discussion among the family at the ADFM Fall meeting held in conjunction with the AAMC meeting in Seattle in October. The Working Party meeting in Las Vegas in January continued these discussions. Stories of family medicine’s participation in CTSAs were collected and distributed at the ADFM annual meeting in February in Savannah.

At the NAPCRG meeting, presentations were made about the surveys and experiences at the University of Chicago and Duke. The survey of 647 members of NAPCRG yielded 92 responses. Sixty-four percent of respondents were not involved in their institutions’ CTSA application, and of these, 60% did not know
about the CTSA. Thirty-five per cent were involved in either the planning grants or the CTSA applications. The majority of those involved were working in the community outreach component, including practice-based research. Almost all became involved upon invitation by their chair, dean, or CTSA principal investigator. Forty percent were satisfied or very satisfied with their involvement (of the remaining 60%, 25% were neutral, and 35% indicated they were not satisfied with their involvement).

For the ADFM initial survey there was a 44% response rate. Forty-five percent of responding departments said that their institution submitted a planning grant, and 25% of responding departments said that their institution submitted a full CTSA application. Twenty-five percent said there was no application from their institution, and 6% did not know.

Sixty percent of the departments responding to the survey reported that they had a substantive or key leadership role in the application. Some had roles such as being invited to be part of the steering or planning committee. Many reported participation or leadership in the community engagement component. In these cases the departments said they were valued because of their practice-based research networks and community linkages. There was concern by some about not being recognized as a true partner at the table from the beginning of the grant. There was also a concern voiced that their institutions lacked an atmosphere of collaboration, put lower importance on clinical research, had a “narrow” definition of translation, and were more interested in maintaining current NIH programs than seeking innovation. One half of the respondents’ institutions were applying in the second round.

Following the survey, ADFM collected stories from individual departments about their participation at their institution. The level of involvement in the CTSA applications was quite varied. Those who participated included chairs, research directors, PBRN directors, geriatric researchers, and other established researchers. Areas of involvement included research networks, community outreach, research training, information technology related to research, expansion of definition of translation, and overall institutional reorganization. Having previously developed collaborative research relationships or having personal relationships with key research administrators was helpful. Recognition of family medicine success in forging relationships with the community was also crucial to many departments’ involvement in the CTSA process.

Some departments were invited to participate in the beginning of the process, and others felt they were invited late. In some cases, especially if the institution received a poor score on community engagement, they were invited after the grant was funded. If the grant did not get funded, and there was a weakness in community engagement noted in the reviews, family medicine was sometimes invited at that time. Some departments had to convince the dean or CTSA leadership that they could be integral to the success of the proposal.

One of the weaknesses in departments of family medicine has been a lack of research infrastructure. There is a recognition that CTSA can offer infrastructure in the forms of biostatistical support, research methods, grants management, bioinformatics, and research training. Additionally, the institution K12 awards can offer junior investigators support to get their research careers started.

Some departments expressed concern about being able to protect the community and the relationships that they have forged from the new interest of the academic health center. There is value to the trust that departments have built over time and they do not want to put that trust in jeopardy. Another concern has been whether their institutions will have the monetary and research resources to be competitive with larger or more research-oriented institutions. Some of the successful institutions put up a lot of their own money in transforming their research environment to make it more like that proposed by the Roadmap. Some chairs felt that their institutions were interested in participating in the CTSA process only to protect whatever infrastructure or funding streams they already had under the traditional NIH system rather than really being interested in transforming their clinical research enterprise.

Departments of family medicine should not look to the award as a way to get money (though some will be able to). The key is to be at the table of collaboration and able to take advantage of the many opportunities that will come up.5,6 Departments of family medicine have varied research capacities, and not all are poised to help their institution with research or a CTSA proposal. But many can, and many have.

The take-home messages from these comments are as follows:

1. It is necessary to be proactive. The department needs to go to the dean, the General Clinical Research Center (GCRC) director, or CTSA planning leadership and demonstrate what the department can offer.

2. Family medicine should try to be active on multiple levels of the application, not just the community engagement component. The real value of family medicine participation will only be realized when family physicians can speak the language of the basic scientists and truly activate the potential of bidirectional translation, and vice versa, when basic scientists can speak the language of clinical practice.
3. Do not be afraid to be bold. This transformation of clinical research is an iterative process that will be shared in a transparent manner, so that the “community” of CTSAs can learn from each other.

In January 2006 there was a meeting convened by STFM in Washington, DC, whose purpose was to determine the stance of the discipline toward NIH. This meeting was called in recognition of the increased success of family medicine researchers in getting NIH grants and the decline of funding for Title VII. There was consensus that family medicine can have influence in making NIH more accessible to primary care researchers by getting more family medicine representatives on study sections, educating NIH about the value of practice-based research networks, expanding definitions of research, and informing the language of RFAs. It is also important for family medicine as a discipline to advocate for increased funding for the NIH, particularly for practice-based research networks, training of clinicians and other arenas of clinical research that utilize primary care methods.

CTSA grants are an immediate opportunity for family medicine to contribute to the mission of the NIH and to move forward toward expanding and completing medical knowledge in frontline practice. Because it means so much to virtually everyone in the nation, those departments of family medicine who are situated such that they can enhance their institution’s research enterprise should do so.

The Family Medicine CTSA Strike Force was initiated to promote the participation of family medicine in CSTA grants. The group has met by teleconference. This group has emphasized the urgency of the CTSA (there will be a total of 50 to 60 awards made by 2012). It is important that we continue to circulate information about CTSAs to the family of family medicine to maximize our participation in improving the health of all Americans.7-9

Mark S. Johnson, MD, MPH, Ardis Davis, MSW
and the CTSA Strike Force

Members of the CTSA strike force: Mark S. Johnson, MD, MPH; Ardis Davis, MSW; Peter Carek, MD; Larry Green, MD; Carlos Jaen, MD, PhD; Norman Kahn, MD; Rick Kellerman, MD; Erik Lindblom, MD, MPH; Terry Steyer, MD; Hope Wittenberg.

References


From the American Academy of Family Physicians


ACADEMY BUILDS COALITIONS FOR HEALTH SYSTEM REFORM

The Academy has been working hard at building coalitions during the past year, and some of those efforts are beginning to pay off. In January, the Academy led 9 other medical associations to introduce 11 principles for health system reform and called on Congress to enact health system reform based on those principles. Also in January, AAFP had a seat at the table as the only medical specialty association in an alliance of health care stakeholders, known as the Health Coverage Coalition for the Uninsured. Academy President Rick Kellerman, MD, Wichita, Kan, was there when coalition members announced a proposal that would extend health care coverage to America’s nearly 47 million residents without health insurance.

Principles for Reform

AAFP was instrumental in leading a group of medical associations, including the American Academy of Orthopaedic Surgeons, American College of Cardiology, American College of Emergency Physicians, American College of Obstetricians and Gynecologists, American College of Osteopathic Family Physicians, American College of Physicians, American College of Surgeons, American Medical Association, and American Osteopathic Association, to formulate 11 principles for health system reform, including access to health care, medical liability reform and management of health care costs.

The group first came together in November 2004 at the behest of the AAFP under the leadership of...
then-President Mary Frank, MD, of Mill Valley, Calif, to create a plan for health care reform. The result is “Principles for Reform of the US Health Care System,” which represents the first time so broad a swath of medical specialists have spoken with a unified voice, according to AAFP President Rick Kellerman, MD, of Wichita, Kan.

“Doctors want Congress to take action on health system reform this year,” he said. “Physicians are coming together to support these principles because they want the best care for their patients, and if these principles are adopted, patients will be the main beneficiaries.”

Moreover, the principles offer a solid foundation on which Congress can craft comprehensive health system reform, according to Frank, who chaired meetings of the organizations.

“Congress doesn’t have to worry about infighting among the groups who support the principles, especially since the groups represent the majority of physicians in the United States,” she said. “Not only are they (the principles) comprehensive, but they don’t put the onus of the solution on any one group. That makes it more palatable to a legislator—that we say ‘We’re willing to step up to our part of responsibility, you step up to your part and we expect others to assume their part of the responsibility.’”

AAFP EVP Douglas Henley, MD, agreed. “The group represents a huge percentage of the physicians in this country,” he said. “It recognizes the need for system reform, not just providing health care coverage to people.”

According to the principles

• Health care coverage for all is needed to ensure quality of care and to improve the health status of Americans.
• The health care system in the United States must provide appropriate health care to all people within US borders, without unreasonable financial barriers to care.
• Individuals and families must have catastrophic health coverage to provide them protection from financial ruin.
• Improvement of health care quality and safety must be the goal of all health interventions, so that we can assure optimal outcomes for the resources expended.
• In reforming the health care system, society must respect the ethical imperative of providing health care to individuals, the responsible stewardship of community resources and the importance of personal health responsibility.
• Access to and financing for appropriate health services must be a shared public/private cooperative effort, and a system which will allow individuals/employers to purchase additional services or insurance.
• Cost management by all stakeholders, consistent with achieving quality health care, is critical to attaining a workable, affordable, and sustainable health care system.
• Less complicated administrative systems are essential to reduce costs, create a more efficient health care system, and maximize funding for health care services.
• Sufficient funds must be available for research (basic, clinical, translational, and health services), medical education, and comprehensive health information technology infrastructure and implementation.
• Sufficient funds must be available for public health and other essential medical services to include, but not be limited to, preventive services, trauma care, and mental health services.
• Comprehensive medical liability reform is essential to ensure access to quality health care.

Reducing the Ranks of the Uninsured

The Academy also has taken part in the Health Coverage Coalition for the Uninsured, or HCCU, which is proposing a mix of public programs and tax credits to extend health care coverage to America’s nearly 47 million residents without health insurance. The HCCU estimates that their proposal, if fully implemented, would cover more than one half of the uninsured population.

In addition to the Academy, which is the only medical specialty association in the group, HCCU members include the AMA, Families USA, America’s Health Insurance Plans, American Hospital Association, US Chamber of Commerce and United Health Foundation, as well as 9 other organizations. Coalition members have been meeting for more than 2 years to hammer out the consensus plan.

Reed Tuckson, MD, senior vice president of the United Health Foundation, moderated a news conference held in Washington, DC, at Union Station on January 18 to announce the plan. “Today, 16 powerful, influential, politically diverse and highly principled organizations, many of whom often do not come together on issues here in Washington, are gathered on this stage to announce a set of consensus recommendations—and to pledge our full and continuing support for the implementation of those recommendations,” Tuckson told reporters.

The HCCU’s proposal first focuses on expanding coverage to the nation’s 9 million uninsured children. Under the proposal, states would be given the flexibility to deem uninsured children from low-income families eligible for and enroll them in Medicaid or the
State Children's Health Insurance Program, or SCHIP, when they qualify for other means-tested programs such as food stamps.

"Surveys have shown over and over that Americans want children covered because they see the health and well-being of children as being the health and well-being of our future," AAFP President Kellerman told reporters.

Speaking as a physician, Kellerman said getting kids insured "gives us an opportunity to discover developmental delays earlier, find medical problems when we can intervene and treat, take care of acute problems before they can become complications, and provide immunizations. So this proposal is not only cost-effective but also good medical care."

The HCCU proposal also calls for a tax credit to help families with more income pay for private health insurance for their children. Families earning as much as 3 times the federal poverty level would be eligible. The credit would cover a significant percentage of the premium, with the percentage graduated on a sliding scale based on family income.

In addition, the proposal's first phase would establish a grant program to enable states to experiment with innovative approaches to expand coverage.

The HCCU proposal's second phase focuses on uninsured adults. It would give states the flexibility and funds to expand Medicaid eligibility to cover all adults with incomes below the federal poverty level. Those with incomes between 1 and 3 times the federal poverty level would get a tax credit to help them pay for private insurance.

Too often, uninsured people don't get the primary and preventive care they need; instead, they "depend on the local emergency department as their family doctor," said Kevin Lofton, chair of the American Hospital Association Board of Trustees. "Delaying action on the uninsured will only increase the human suffering, the moral urgency, and the financial costs to our society and to our health system. According to the Institute of Medicine, an estimated 18,000 people die each year because they do not have health insurance."

Leslie Champlin
Paula Binder
AAFP News Now

ABFM'S IN-TRAINING EXAMINATION

The American Board of Family Medicine's (ABFM) In-Training Examination was conceived in 1979 as part of a tripartite assessment process for family medicine residents in training. This 3-fold assessment process was developed under the aegis of the Conjoint Committee on In-Training Assessment (CONCITA), a group consisting of members from the American Academy of Family Physicians, the Society of Teachers of Family Medicine, and the then American Board of Family Practice. At that time, CONCITA had envisioned moving forward with the formulation of criteria for assessing psychomotor (procedural) skills, and a methodology for assessing interpersonal skills and attitudes (behavioral). The cognitive examination, first given with great success in 1979, and again each year thereafter, remains as the only vestige of this early work on resident assessment within our specialty.

Last year, the ABFM conducted a pilot project for its delivery of the In-Training Exam (ITE) directly to volunteer programs over the Internet. The purposes of the pilot project included the development of administrative relationships with program coordinators required for the successful implementation of the examination delivery over the Internet, as well as feedback from those program coordinators and residents. In addition, the pilot project allowed for determination of the range of technical requirements necessary for working with multiple residency programs and the impact of delivering the ITE in this manner on the ABFM's information technology infrastructure, including its broadband capacity and Web servers.

A total of 633 residents across 41 ACGME accredited residency programs participated in the Internet-Based ITE (IBITE) pilot project. In addition to the US family medicine residency programs, 2 international groups participated. The Hope Family Medicine Residency Program, located in Macau, had 4 physicians take the exam. The Australian College of Rural and Remote Medicine had 12 physicians from various geographic regions take the exam. The administration of the IBITE went very smoothly, with only minor difficulties arising which were cleared up in minutes with the assistance of the ABFM support staff. The summary statistical data comparing results of the written
ITE with the Internet-based ITE showed no significant differences in performance. The findings support the position that the ITE can be successfully and effectively administered via the Internet.

The ABFM has consistently underwritten some of the costs of the development and administration of the ITE over the years. This was in recognition of the economic factors affecting residency programs and their residents and the desire of the ABFM to limit any economic obstacles to participation in this valuable process. The fee has remained constant at $30 per resident since 1995. Our direct and indirect development costs of the ITE exam and the resulting scoring and reporting costs have consistently exceeded the amount collected.

The inflationary increase in the ABFM’s costs, plus the development and maintenance costs of the ITE, have necessitated that we raise the fee for the ITE beginning in 2007. The 2007 fee will be $50 per resident. While this is a substantial increase over the current fee, it still does not allow for the ABFM to fully recover its costs. Nevertheless, the ABFM believes that the fee fairly reflects the improved efficiencies achieved in registering residents using the Resident Training Management (RTM) software; the advent of electronic reporting of ITE results to programs, to be consistent with how certification performance reports are presently made available; and the new Resident’s Portfolio, which next year will allow residents to access their results directly.

All residents who have been entered in RTM have free availability of all of the components of the ABFM’s program for Maintenance of Certification for Family Physicians (MC-FP). While RTM has streamlined the process of registering residents for the in-training and primary certification exams, it has also created the ability to make MC-FP modules developed by the ABFM accessible online for residents. The ABFM believes that the residency program directors and residents will find these to be valuable resources to assist with the achievement of many of the 6 ACGME general competencies, which are the same competencies used to assess family physicians in MC-FP.

Jane Ireland
American Board of Family Medicine

P4 = INNOVATION

The initial goal of the Preparing the Personal Physician for Practice (P4) Initiative is innovation in family medicine residency training, in real-life situations, in various settings. After an exhaustive process of evaluation and review, 14 programs from the initial 84 applications have been selected to participate in the P4 Initiative. The portfolio of innovations represented in this group is expected to align with new models of practice to enhance the performance of family physicians as personal physicians in modernized, frontline medical practice. The announcement of these innovative programs in February was yet another major step in making the P4 Initiative a reality and kicked off another phase in the evolution of this important project.

So what is the scope of the innovations being proposed in this portfolio? In the initial call for proposals, the P4 Steering Committee identified 1 general requirement (alignment with the New Model Practice) and 5 different areas where innovation was likely to occur:

- **Scope and content** of training (eg, enhancements in chronic disease care, differentiation for a particular population)
- **Length** of training (eg, lengthened to achieve more breadth or depth of competency, or to decompress the residency experience)
- **Place** of training (eg, replacement of traditional family medicine center with other sites of training, reduced role of hospital in training)
- **Structure** of training (eg, processes of instruction and experience)
- **Measurement of competency** (eg, use of measures other than length of time)

These areas illustrated the possibilities for innovation, but were not meant to prescribe or prioritize the work of the residencies in P4. To that end, a “Wild Card” category was also included with the hope that a true “thinking outside the box” idea for training family medicine residents would emerge.

As hoped, all 5 categories are well-represented in this cohort of innovators and will be tested in this experimental initiative through a combination of adapting existing structures and creating new ones. Some of the innovations may require further modification to meet Liaison Committee on Medical Educa-
tion (LCME) and Accreditation Council for Graduate Medical Education (ACGME) requirements, but the majority complies with current Residency Review Committee (RRC) requirements. This is important to the potential generalizability of the innovations.

As the portfolio of innovations has been reviewed and refined, a number of general themes have emerged. The major components of the New Model Practice (ie, patient-centered care, use of advanced information systems, chronic disease management and prevention, practice learning teams, and systems for assessing outcomes to improve quality and safety) are well represented within each program. Based upon preliminary finding from TransforMED’s National Demonstration Project, future graduates will require additional training in change management, leadership, and organizational development. Many of the projects have already incorporated these important components of professional development into their curriculum and this aspect of the initiative will be critical in training graduates as change agents in their communities. There is significant focus on learner-centered, competency-based training that includes competency-based assessment and advancement.

Approximately one-half of the innovators are extending training beyond the current 36 months by offering a structured 4-year curriculum that allows pursuit of an area of concentration or an advanced degree. Many programs are offering significant flexibility in allowing residents to tailor their training to meet the needs of a community or accommodate their own interests and skills. Two programs are reaching back into the fourth year of medical school to assist students in gaining a higher level of competency before entering residency by providing additional, family-medicine-focused clinical experiences. Many of the programs are moving the primary location of learning from the traditional family medicine center to smaller community-based practices. With this transition comes a decrease in the time spent in the hospital and an increased emphasis on longitudinal training in ambulatory settings. Assessing the financial health and viability of these community practices will be a critical component of this transition.

In the final analysis, the P4 Initiative can be viewed as a “voyage of discovery,” and residency training can be considered as one crucial period in the lives of physicians. This voyage will be defined by the primary goals of the P4 Initiative which are to stimulate innovation in family medicine graduate medical education in real life, evaluate the innovations, study what changes are needed to prepare graduates to succeed in new practice models, and share the learnings that will inspire change in training and certification. The first goal has been realized. The other 3 will be addressed and developed over the coming months and years. The best is yet to come.

Samuel M. Jones, MD
President, AFMRD