



# Pragmatic Evidence for Theory-Based Innovations in Diabetes Primary Care

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*Diabetes Care* 2023;46:1750–1752 | <https://doi.org/10.2337/dci23-0043>

Type 2 diabetes is the signature condition for understanding quality improvement of chronic illness management in primary care (PC). Development of safe, reliable, effective, and patient-centered diabetes care is complicated by concordant conditions that commonly present with diabetes (e.g., hypertension, hyperlipidemia) and discordant conditions (e.g., depression or musculoskeletal ailments) that interfere with diabetes treatment plans (1). The comorbid presentation of discordant or competing conditions often results in poorer diabetes outcomes (2). Therefore, comprehensive approaches to diabetes care are needed. Effective PC of diabetes requires education, prevention, and self-management support for patients; access to dietary and physical activity interventions; personalized prescribing of medications; and monitoring for treatment effects (intended and unintended) (3). Reliance on isolated physicians helping individual patients with diabetes-related symptoms and treatments during routine clinical encounters is associated with system-level barriers (staff turnover, time constraints, hesitancy to adopt change) and poorer diabetes related outcomes (4). Higher-performing PC clinics use more systematic monitoring of health status, proactive outreach to patients, and team-based approaches to diabetes care (4).

## THEORY-BASED INNOVATIONS IN DIABETES PC

Contemporary advances in diabetes PC rely on implementation of the Patient-Centered Medical Home (PCMH) approach (5). PCMH includes use of the principles of comprehensive and patient-centered care, improved access and coordination across sites and care transitions, and quality and safety outcomes measurement (6). PCMH implementation into a clinic or system requires transformation of PCMH concepts into specific, tangible processes for delivering high-quality care to various populations, including safety net systems (7). Bodenheimer et al. (8) describe such an approach as the “building blocks of high-performing primary care.” The four foundational blocks of this approach (see Fig. 1, top portion in blue) are now the expected investment by health systems when establishing PC clinics. The next tier of “building blocks” includes panel management, self-management support, continuity of care and prompt access to care, and shared decision-making (8) (Fig. 1, middle portion in blue). For diabetes care, panel management involves a staff member reviewing the status of upcoming patients (e.g., blood pressure control, hemoglobin A<sub>1c</sub> and other laboratory measurements, retinopathy screening, etc.) for prevention or monitoring. Self-management support includes community health workers, pharmacists, and dietitians providing targeted health behavior, medication, and nutrition coaching,

respectively. The highest tier of these building blocks remains daunting even for the best clinics (Fig. 1, bottom portion in blue).

## NATURAL EXPERIMENT IN DIABETES PC: THE UNITED STUDY

PCMH and the building blocks for high-performing PC provide conceptual guidance to aspiring PC practices. The next step to improving diabetes care in PC is building an evidence base of real-world examples with use of specific PC management processes representing one or more of the “building blocks.” Ideally, real-world examples would represent a spectrum of clinic sizes, locations, and patient populations with use of specific PC management processes associated with improved outcomes. Fortunately, investigators in the Understanding Infrastructure Transformation Effects on Diabetes (UNITED) study sought to address this gap by taking advantage of a natural experiment in Minnesota following legislation in 2008 (Minnesota Statute 145.986) incentivizing adoption of PCMH across the state. This legislation supported specific initiatives (i.e., public recognition of clinics obtaining PCMH status, adoption of electronic health records, use and reporting of diabetes performance measures to a nonprofit, statewide measurement organization). Variable adoption of PC change processes (Fig. 1, tan boxes) provides the context for a natural experiment.

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Foundational Building Blocks for High-Performing Primary Care			
Engaged health system and payer leadership set vision and goals	Informatics-driven performance measurement	Creating patient panels linked to primary care provider (PCP)	Interprofessional team-based care
<p><b>Examples of structural and primary care management processes associated with improved diabetes care in Minnesota primary care practices</b></p> <p><u>Legislation mandates and incentives</u></p> <ul style="list-style-type: none"> <li>• Encourage Patient-Centered Medical Home (PCMH) certification and require electronic health record (EHR) adoption</li> <li>• Require reporting diabetes performance measures to nonprofit organization</li> </ul> <p><u>Health systems encourage processes for PCMH implementation</u></p> <ul style="list-style-type: none"> <li>• Adopt EHRs and create data repositories for performance measurement</li> <li>• Organize clinics around interprofessional teams, each with identified PCP</li> <li>• Link each patient to a care team and PCP to become a member of the team's panel</li> </ul> <p><u>Primary care management processes for information and tracking and performance measurement</u></p> <ul style="list-style-type: none"> <li>• <b>System for tracking lab tests until results available to PCP</b></li> <li>• Structured clinic protocol for follow-up with patient about abnormal results</li> <li>• Clinic has a formal process for performance measurement of clinics and PCPs</li> </ul>			
Advanced Building Blocks for High-Performing Primary Care			
Patient panel care management	Self-management support	Continuity of care & Prompt access	Shared decision-making
<p><b>Examples of advanced primary care management processes associated with improved diabetes care in Minnesota primary care practices</b></p> <p><u>Primary care management processes for chronic disease management</u></p> <ul style="list-style-type: none"> <li>• Clinic scheduling encourages continuity with PCP &amp; follow-up visits</li> <li>• <b>Systematic approach to remind patients due for guideline-based testing</b></li> <li>• <b>Member of care team (usually not PCP) conducts an after-visit follow-up</b></li> <li>• <b>Systematic approach to alert PCP about guideline-based prevention during visit</b></li> </ul> <p><u>Primary care management processes for patient self-management</u></p> <ul style="list-style-type: none"> <li>• Clinic provides or refers for weigh loss management, physical activity, and self-management for diabetes</li> <li>• <b>Clinic provides or refers for self-management of cardiovascular disease</b></li> <li>• Clinic provides written materials or electronic patient portal to encourage self-management</li> </ul> <p><u>Primary care management processes for shared decision-making / Care plan</u></p> <ul style="list-style-type: none"> <li>• <b>Systematic process to conduct shared decision-making with patients</b></li> </ul>			
Aspirational Building Blocks for High-Performing Primary Care			
Identifying patient health priorities: outcome goals & care preferences	Align care to meet the outcome goals and care preferences of patients	Care coordination with non-primary care clinicians	Tailor visit modality and duration to patient needs and experiences

**Figure 1**—Structure and management processes for building high-performing PC. Examples of structural and management processes adopted by Minnesota PC practices embedded within the paradigm of building blocks for high-performing PC. Bullet points in boldface type were associated with improvements in ODC measure (NQF no. 0729) or hemoglobin A<sub>1c</sub> levels. EHR, electronic health record; lab, laboratory; PCP, primary care provider.

UNITED is a repeated cross-sectional study from 2017 to 2019 of 330 PC practices across Minnesota, including small and large practices from urban and rural settings serving all ages and sociodemographic backgrounds, with a balance of insurance types among patients: commercial, Medicare, Medicaid. In the UNITED study data were collected from each of the eligible practices on 62 PC management processes previously validated for their association with quality of care and utilization measures for diabetes (9,10), as well as data on hemoglobin A<sub>1c</sub>, systolic

and diastolic blood pressure, statin use, and the validated Optimal Diabetes Care (ODC) measure (National Quality Forum [NQF] no. 0729 performance measure) (11).

Incentives arising from the 2008 Minnesota legislation contributed to overwhelming adoption (80.6% overall) of PC management processes by 2017, increasing to 81.5% in 2019, as described in the UNITED study (12). The management processes with the highest rates of adoption by 2019 were those in the categories of information and tracking and performance measurement (8) (Fig. 1, top). While these

processes are “foundational” in nature, direct associations with improved diabetes care outcomes were limited (12). In contrast, improvements in specific diabetes care outcomes or the ODC measure were associated with PC management processes from the categories of chronic disease management, patient self-management, and shared decision-making, which correspond to the next tier of building blocks for high-performance PC (Fig. 1, middle). In an earlier cross-sectional analysis of the 2017 UNITED cohort, investigators found an association of higher performance on the ODC measure

when three PC management processes are present: process for conducting shared decision-making (2.6% effect,  $P = 0.001$ ), checklists for diabetes monitoring (3.2% effect,  $P = 0.003$ ), and guidelines-based risk assessment reminders (5.0% effect,  $P = 0.005$ ) (13). In contrast, recent analyses of the UNITED study include description of the longitudinal effect of adopting or dropping PC management processes between 2017 and 2019 on improvements in ODC measures and diabetes care outcomes (hemoglobin A<sub>1c</sub>, blood pressure, and statin use). Implementing patient reminders for tests, after-visit follow-up by a team member, and physician reminders for guideline-based preventive services together accounted for 5.7% of the improvement in ODC performance, 68% of hemoglobin A<sub>1c</sub> decrease, 21% of blood pressure reduction, and 55% of increased statin use by 2019.

The findings of the UNITED study provide important insights for improving diabetes outcomes in routine PC. The state-wide reach, range of settings and populations, pragmatic design, and Bayesian statistical analyses are strengths. The study conclusions may be limited to diabetes care in Minnesota, however, given the significant legislative incentives for adopting PCMH. The design and analysis of the UNITED study limited measurement of the marginal effects to only the individual PC management processes in isolation. As a result, the UNITED study may underestimate the effects of PC management processes implemented simultaneously or the sequential effects of layering PC management processes over time.

## LESSONS OF THE UNITED STUDY

The findings from the UNITED study offer the following implications for designing PC practices focused on high-performing diabetes care.

1. Insurance and government payers should incentivize PCMH certification and information systems that enable collection and reporting of performance data.
2. Health systems should promote structures where patients are assigned to panels with a consistent primary care provider supported by an interprofessional team.

These foundational building blocks are essential but not sufficient for improving

diabetes outcomes. Once measurement systems are in place, passive monitoring or tracking of guidelines, checklists, and flowcharts is insufficient.

3. Timely alerting at the point of care is more effective, including notifying clinicians that prevention services are due and alerting patients that they are due for diabetes-related testing.
4. Members of the care team, other than the primary care provider, should conduct after-visit follow-up for care management, including support for self-management and appropriate referrals.
5. The presence of shared decision-making processes helps establish personalized care plans to improve diabetes outcomes, but shared decision-making is an advanced process that may be less helpful for clinics early in their PCMH transformation.

Despite this significant progress, in the UNITED study few examples were described resembling the aspirational building blocks for high-performing PC, including formal processes for identifying patients' health priorities and then aligning care plans to achieve those priorities (14,15). In clinical trials, comprehensive, patient goal-aligned care processes are associated with improved outcomes (16–18) but require substantial implementation efforts (7,19). However, the UNITED study demonstrates that building high-performing PC can improve diabetes outcomes even at earlier stages (12,13).

**Funding.** A.D.N. is supported by the Nancy P. and Vincent F. Guinee, MD, distinguished chair at the UTHealth Houston Institute on Aging and the Southeast Texas Geriatrics Workforce Enhancement Program (Health Resources and Services Administration grant HRSA U01QHP33068). Additional support is provided by Center for Innovations in Quality, Effectiveness and Safety (VA HSRD CIN 13-413) at the Michael E. DeBakey VA Medical Center.

**Duality of Interest.** No potential conflicts of interest relevant to this article were reported.

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