



# In the Literature

## NAVIGATING THE TERRAIN BETWEEN RESEARCH AND PRACTICE: A COLLABORATIVE RESEARCH NETWORK (CRN) CASE STUDY IN DIABETES RESEARCH

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Thanks to medical advances, today there are many more treatment options for patients with chronic conditions, including diabetes, than in the past. Still, clinical research is often difficult to translate to the considerably messier world of primary care practice. Much traditional research simply does not apply to the “real world,” where patients’ limited English proficiency or health clinics’ limited resources, for example, can influence the effectiveness of a given intervention.

Enter the field of “translational research,” which seeks to bridge the worlds of clinical research and public health. Such studies attempt to implement reproducible interventions involving a broad range of patients, providers, and settings, while at the same time enabling rigorous evaluation of the intervention’s reach and effectiveness. In “[Navigating the Terrain Between Research and Practice: A Collaborative Research Network \(CRN\) Case Study in Diabetes Research](#)” (*Journal of the American Board of Family Medicine*, Jan./Feb. 2006), Margaret A. Handley, Ph.D., M.P.H., Hali Hammer, M.D., and Dean Schillinger, M.D., explore the trade-offs inherent in translational research through a case study of the Improving Diabetes Efforts Across Language and Literacy (IDEALL) Project. Major funding for the study was provided by The Commonwealth Fund and the Agency for Healthcare Research and Quality.

### The IDEALL Trial

The IDEALL trial assessed the effectiveness of two diabetes self-management interven-

tions—automated telephone calls and group medical visits—with results serving to inform the development of a diabetes disease management system. Both interventions were delivered in English, Spanish, and Cantonese, the three most commonly spoken languages among the network’s patients. In addition to receiving standard diabetes care, participating patients were randomly assigned to receive, as adjuncts to this care, automated telephone calls, group medical visits, or no additional intervention (the control group).

### Strategies and Trade-Offs

Patient diversity across populations and settings—to ensure that the results would apply to a broad range of patients—was the research team’s first goal. To achieve diversity, few exclusion criteria were applied, the intervention was offered in three languages widely spoken within the clinic population, and clinics were selected from both neighborhood and hospital settings. However, Institutional Review Board restrictions barring direct contact with patients outside the clinic setting limited participants to those patients attending clinics, meaning that those too sick to travel or who were only seen in the emergency department or hospitalized over the study period were not included in the study.

In implementing the trials, the IDEALL researchers sought to strike a compromise between diabetes patients’ need for extra care and clinics’ limited time and resources. Moreover, the interventions that were tested were those that reflected primary

care realities: both had been found effective in other settings and deemed feasible for implementation in the safety net setting as part of an integrated chronic disease care model. Thus, the interventions were provided as adjunct services to those regularly offered at the clinics, with IDEALL staff taking primary responsibility for their implementation. This allows research staff to standardize the interventions and is a way to introduce them without forcing them on practice staff.

These modifications represent a significant trade-off, the authors say. Once support for the study ends, the interventions may fade from the minds of staff and patients, jeopardizing adoption. Furthermore, with the adjunctive model of care, clinicians may not be convinced that the services can be practically incorporated into their day-to-day routines. Despite these drawbacks, the authors hope that if the interventions prove successful, clinic staff will be encouraged to incorporate them into their practices. Already, the models represented in

the IDEALL trial are expanding across the participating clinic system as part of a diabetes self-management support program.

### Conclusions

As the case study demonstrates, practical clinical trials involve a complex set of strategies and trade-offs. Researchers involved in translational research must strive to balance a study's internal validity with its external validity, and they need to make clear how their decisions may influence the interpretation of results. "We believe the decisions and trade-offs made in the IDEALL Project situates it in an intermediate zone between pure efficacy research and evaluation of a real world, full integrated set of interventions," the authors say.

Decisions over critical details of study design should be made in the context of patient, clinician, and clinic preferences. Flexibility in the conduct of practical clinical trials can increase their acceptability among clinicians.

Research Strategies Used to Increase Generalizability in the IDEALL Project

Recommended Strategy	Anticipated Impact on Generalizability	IDEALL Strategy	Challenges and Trade-Offs
<i>Patient sample reflects population strategy</i>			
Minimize patient exclusions	Results apply to broad range of patients, since a broad range was included in the study	Few clinical exclusion criteria applied, and intervention offered in three languages	Institutional Review Board restrictions for direct patient contact led to a change in study design and recruitment strategy  Some exclusion criteria, such as requiring patients to come to the clinic or to be in the area for 12 months may have restricted diversity
Recruit patients from diverse clinic settings	Results apply to broad range of patients irrespective of practice level conditions that may affect the delivery or quality of care	Inclusion of as many CHNSF clinics as possible using a targeted recruitment of clinics with the largest number of eligible patients  Balance of neighborhood and hospital-based clinics	Logistics: needing to recruit patients over a short time period and setting up group medical visits at each clinic limited the number of clinics to four
<i>Interventions are relevant across patient groups and across settings</i>			
Develop interventions that reflect primary care realities	Implementation and adoption likely smoother and higher overall at the patient, clinician, and health care systems level	Include patient, clinician, and clinic level input into the nature and design of interventions	Adjunctive care model does not address the importance of having clinics independently integrate patient self-management supports into primary care settings and may not be sustainable
Compare clinically relevant alternatives			Randomized design did not allow patients to select interventions, affecting acceptability to patients and clinics

IDEALL=Improving Diabetes Efforts Across Language and Literacy; CHNSF=San Francisco Department of Public Health's Community Health Network  
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