Editorial

Taking AIM at a Moving Target
The Challenge of Improving on High-Performance Care

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In the last half century, the challenge for clinicians in many areas of medicine has evolved from reaction, to prevention, to, most recently, population management. In hypertension, that evolution has meant a gradual broadening of responsibilities from treating the complications of hypertension to controlling blood pressure in individual patients over time, and now to controlling hypertension in an overall population, particularly in high-risk groups such as patients with diabetes mellitus. Disease management programs are now increasingly used to improve the reliability with which patients receive optimal care. These programs are often well conceived and executed. But experience is teaching us that even well-designed programs are surprisingly like medications—they may not work even when logic suggests that they should, and they may work differently, or may not work at all, in various patient populations.

Thus, it is wise and appropriate that the evaluation of complex interventions in real-world settings has become a major national (and international) research priority, mandated by the Patient Protection and Affordable Care Act of 2010 and carried out by federal agencies new (Patient-Centered Outcomes Research Institute) and old (Centers for Medicare and Medicaid Innovation, Agency for Healthcare Research and Quality, and others). Conducting and analyzing these interventions, although challenging, is critical to establishing their effectiveness and prioritizing allocation of scarce resources.

In this issue of Circulation, Heisler et al1 have risen to this challenge by testing an evidence-based approach to the common and important problem of uncontrolled hypertension in patients with diabetes mellitus, in the Adherence and Intensification of Medications (AIM) trial. The intervention was a primary care-team based, pharmacist-led outreach program that was designed to address known provider- and patient-level barriers contributing to poor blood pressure control: lack of medication intensification and medication nonadherence. This intervention was compared to usual care in 4100 patients at 2 high-performing health care systems (Veterans Affairs and Kaiser-Permanente). Usual care and high-performing are notable in this case because the two organizations in which the intervention was conducted have both been effective in implementing systems that improve quality and efficiency. Both organizations have made ubiquitous use of electronic medical records, the collection and reporting of performance data to clinicians, and team-based approaches to care.

Logic might suggest that these organizations would be the ideal setting in which to demonstrate the impact of this program. The intervention pharmacists were trained and demonstrated competency in motivational interviewing, used a computerized Medication Management Tool to identify and enroll patients, and after assessing barriers, followed medication titration protocols. Patient contact was considerable but not unrealistic: Pharmacists spent 50 minutes on intake encounters and 27 minutes on follow-up encounters, averaging 3.9 total in-person or telephone encounters. Other contact with patients’ primary care physicians was neither restricted nor reduced.

Despite these additional efforts, Heisler et al1 report that mean office systolic blood pressure (SBP) improved by 9 mm Hg in both intervention and control groups comparing the period 6 months before with 6 months after the intervention period. The intervention group did have significantly more rapid improvement in systolic blood pressure (by 2.4 mm Hg) and had more medication changes (69.7% versus 63.0%) than the control group over the course of the study.

Thus, the AIM trial used evidence-based strategies to tackle this important problem, yet convincingly failed to detect a benefit. As in all studies, when pragmatic clinical trials fail to detect a benefit, the study design, analysis, and intervention must be considered before accepting and acting on the implications.

The AIM trial was impeccably conducted, and, indeed, serves as a model comparative effectiveness trial. Patient care teams were randomly assigned, 8 to intervention and 8 to control, to avoid contamination of the control group and to allow evaluation of real-world pharmacist-care team interactions. There was appropriate adjustment for clustering by team and site. Analyses were intention-to-treat, with all intervention group patients whom the pharmacists contacted or attempted to contact included. Blood pressures were measured in routine care before and after the intervention period, minimizing ascertainment bias. There was little, if any, loss to follow-up. Data on fidelity to the protocol, the resource use required by the intervention, and many relevant and important outcomes, including quarterly blood pressure readings, medication changes, and health care use, were measured and reported, meeting and exceeding established standards for comparative effectiveness trials.2 (Although it is

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possible that 1 component of this complex intervention, motivational interviewing, may not be as uniformly effective as was previously thought.\textsuperscript{3,4} It is unlikely to have undermined the intervention.)

Given the successful conduct of the trial, then, we must take seriously the possible reasons for lack of improvement of blood pressure compared with usual care despite an apparently effective intervention.

First, as the authors point out, is the phenomenon of regression to the mean, a problem the authors tried to prevent by using strict inclusion criteria. Patients had to have poor refill adherence or insufficient medication intensification and were included for meeting either of the following criteria: most recent systolic SBP $\geq 140$ mm Hg in the last 3 months and mean SBP $\geq 140$ mm Hg in the last 9 months, or most recent SBP $\geq 150$ and no other BP measures in the last 9 months. (Measures from urgent care settings were excluded).\textsuperscript{5} Fifteen percent of patients with diabetes mellitus met these criteria, but the authors do not report how many subjects qualified for the study based on the second criterion. Although these inclusion criteria are not at all unreasonable, patients included because of a single reading of SBP $>150$ in 9 months may have been transient outliers and may have contributed to regression to the mean in both groups.

That only 15\% of diabetes mellitus patients met the inclusion criteria, though, is itself striking. The authors report rates of blood pressure control (percentage $<140/90$ mm Hg) of at least 80\% in both study populations. This level of blood pressure control is extraordinary by any measure. The rate of blood pressure $<140/90$ mm Hg in people with diabetes mellitus is 46\% (nation-wide), based on National Health and Nutrition Examination Survey (NHANES) data from 2005 to 2008.\textsuperscript{6} Among commercially insured HMO diabetes patients, the rate of blood pressure control ranges from 66\% (50th percentile) to 76\% (90th percentile) (National Committee for Quality Assurance Quality Compass, 2011).

As the authors also suggest, the failure to find a difference between groups may reflect the success of usual care in 2 high-performing systems rather than failure of the intervention, which did succeed in lowering blood pressure more rapidly in the intervention population. While the study was ongoing, physicians received reported rates of patient blood pressure target achievement and worked with nurse care managers to help achieve blood pressure goals in both groups. At Kaiser-Permanente, pharmacists in the usual care group performed patient outreach, albeit less intensively and with less training than those in the AIM Trial. In the Veterans Affairs system, physician performance bonuses were linked to blood pressure control. It is possible, even likely, that the intervention would have been superior to usual care if care at these institutions were more usual—that is, in the absence of high-performance team-based care. Whether it is more cost-effective in the long run to redesign overall care systems to resemble more closely the organizational integration of Kaiser-Permanente and Veterans Affairs, or to use adjunct, disease-targeted programs in more loosely organized systems, remains to be evaluated.

The flip side of controlling blood pressure in 80\% of patients in a high-performing system is suggested by the 80 to 20 rule: it may take 80\% of the time (and significant resources) to reach the remaining 20\%, a group of people who evidently do not want to be reached. Of the 1997 patients whom pharmacists contacted in the intervention group, 427 (24\%) declined study participation. This does not mean that they declined to provide informed consent as in a traditional clinical trial; rather, in this clinical effectiveness trial, when pharmacists associated with their physicians reached out to assist, patients declined to engage. Some patients are simply not interested in risk factor management.\textsuperscript{7}

The differing priorities of patients and care management guidelines underscore the tension in designing patient-centered health interventions. If patient-centered care is “respectful of and responsive to individual patient preferences,”\textsuperscript{8} how much effort should the system exert in trying to compel adherence to goals the patient does not value, assuming ample motivational interviewing, education, shared decision making, or similar approaches? Other strategies, such as those from economics, may be required to shift patient preferences.\textsuperscript{9} Or, perhaps some patients, because of psychosocial or medical complexity, require an order of magnitude more assistance, an expenditure that may be justified only in very high-cost or high-risk patients (as in the care management program for high-cost beneficiaries at our own institution).\textsuperscript{10} Finally, even in the high-performing systems studied, 216 (12\%) of intervention patients could not be reached even by the persistent intervention pharmacists, which has implications for attempts at disease management in similar populations.

The AIM trial is an invaluable demonstration that care management interventions really do need to be rigorously evaluated before investing resources, even for evidence-based, rationally designed, and well implemented programs. The study also has implications for clinical innovation and research in high-performing systems. It suggests that the best long-term investment overall is in the development of high-performing delivery systems; if uniform high performance is not achievable within a given context, targeted programs may be superior to usual care and may be cost-effective. If this is the case, then from a societal perspective, the best use of the marginal health care dollar on an innovative program is likely to be in a low-performing system (though, of course, we do not allocate our healthcare dollars that way). One final challenge: a tenet of developing and evaluating complex interventions is that they must be adapted to the local context,\textsuperscript{11} just as in any randomized, controlled trial, in which the external validity and generalizability of findings must be considered.

The implications of AIM for comparative effectiveness research are also significant. High-performing systems are often ones that perform research, but they may not always provide the right setting in which to test care management programs. This fact highlights the importance of the Patient-Centered Outcomes Research Institute and Centers for Medicare and Medicaid Innovation approach of partnering with community organizations and stakeholders in developing, piloting, and, indeed, testing, the effectiveness of new and innovative care models and programs.
Disclosures

None.

References


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