Integrating Six Sigma and Lean Into the Improvement Toolkit

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“Health systems that have done the hard work of developing a systematic approach to process improvement . . . will incorporate methodologic advances into their toolkit when it makes sense in the service of their overall process improvement activities.”

—VanKooy (p. 532)
In a rapidly aging population, two-thirds of persons over the age of 65 have multiple chronic conditions, which has provoked urgent discussions of how society will provide for its health care needs. The concept of an enabling society has been suggested as one way to enhance the abilities of citizens with chronic illness to successfully meet their own needs. Within the context of health care, enablement has been referred to as patient empowerment, self-management support (SMS), and collaborative care. The New Model of Care for family practice, for example, proposes a patient-centered team approach, which has been further elaborated into the concept of the patient-centered medical home, which includes SMS as one of its nine core components. Although the need to empower persons with chronic illness is apparent, it is less clear what specific steps health care providers can take to enhance self-management among their patients.

There is increasing evidence that effective self-management is essential to optimizing health outcomes for people with chronic conditions. This article seeks to identify approaches to SMS within routine clinical practice which can enable patients to successfully care for their chronic conditions.

The research team developed the Chronic Care Model (CCM) and, with the Institute of Healthcare Improvement (IHI), has been extensively involved in the IHI Breakthrough Series collaboratives’ work with health care teams in attempting to implement the CCM—which includes SMS. Through a nominal group process, the authors used their extensive experience in clinical and quality improvement to identify key practices or processes that could guide clinicians or organizations in implementing SMS. We then used these elements to guide the literature review to identify interventions that could then be distilled into a set of principles.

We based our review on a definition that self-management consists of a set of tasks that includes developing knowledge of the condition(s) and treatment; medication management and...
adherence; self-monitoring of disease and symptoms; managing the effects of illness on physical, emotional, and social role function; reducing health risks; preventative maintenance; and working collaboratively with health professionals.6,14 SMS includes actions by health care providers (formal and informal) that assist self-management.6,12 This definition assumes that optimal self-management is the product of a partnership between the patient, the family, and health care providers.

By including reduction of health risks and preventative maintenance of chronic conditions in the definition of self-management, we broadened the focus of the evidence from disease-specific self-management to alcohol, smoking, and related lifestyle domains, where much of the research on effective interventions to change behavior has been directed. We acknowledge the challenges in implementing SMS in routine practice and provide an example of how the principles may inform practice change by linking the principles to three phases of an enhanced primary care visit: (1) enhanced previsit assessment, (2) focused clinical encounter, and (3) expanded postvisit options. Finally, we comment on the need for more evidence of the cost-effectiveness of SMS interventions.

Methods

Literature Search. The set of practices or processes identified by the researchers was used to guide a literature search undertaken in October 2008–January 2009 to identify evidence from structured reviews and meta-analyses and summarized under key principles for implementing SMS in primary care. We focused the search strategy on evidence regarding a wide range of chronic conditions and behavioral risk factors. The English-language medical literature published between January 1980 and October 2008 was searched using the MEDLINE database of the National Library of Medicine and the Nursing and Allied Health database (from 1982). The Medical subject headings (MeSH) searched were Asthma, Diabetes, Coronary Arteriosclerosis, Heart Failure, Congestive, Depression, Pulmonary Disease, Chronic Obstructive, HIV/AIDS, Smoking Cessation, Alcohol-related Disorders, and Exercise, Self Care, and Primary Care. We also used a text word search of both databases using the term self-management. We limited the publication types to meta-analyses and systematic reviews. We also hand-searched all the systematic reviews of the Cochrane Effective Practice and Organization of Care (EPOC) group for those having relevance to SMS by affecting practice patterns.

Review of Relevance. The titles of the articles extracted by the search were reviewed for their relevance to the effectiveness of SMS. If potentially relevant, the full-text articles were retrieved, and one author [J.S.] reviewed the studies for applicability.

Development of Thematic Content and Derivation of Principles. A second author [M.V.K.] reviewed the full-text articles, developed thematic content, and derived the 12 principles. The project team identified 123 reviews and meta-analyses, of which 83 were included. Evidence-based principles were chosen if they were supported by one or more reviews.

Findings

The 12 evidence-based principles are now provided.

Principle 1. Brief Targeted Assessment to Guide SMS: Assessment of clinical severity, functional status, patients’ problems and goals, self-management behaviors, and barriers to self-management is integral to SMS. Direct evidence for assessment is sparse because it has not been isolated as an intervention. However, assessment of needs, preferences, behaviors, readiness, and barriers to self-management is a first step in all SMS interventions and assessment, and if done appropriately, is a way of engaging patients in their own care. It is not possible to match a patient with an intervention on the basis of preferences, readiness, or current behavior without assessment. These assessments then direct patient-specific behavior change interventions, collaborative care planning, and problem solving.10 A review of the effect of self-help materials for smoking cessation15 showed that interventions with assessment-based tailoring of materials to the individual were more effective than nontailored interventions. Strongest evidence of the value of assessment comes from the Public Health Service Tobacco Treatment Guideline,16 which found that assessment of smoking status (through a reminder) actually increased rates of clinician intervention and doubled cessation rates. Ebrahim et al.17 found that for secondary prevention programs following myocardial infarction, assessment and targeting interventions toward lifestyle risk factors resulted in significant benefits to patients.

Assessment of patient attributes such as readiness to change is integral to the use of motivational interviewing, an effective substance abuse intervention when used by clinicians.14 Katon et al. found that accurate diagnosis of comorbid depression and anxiety disorders in patients with chronic medical conditions was critical in the management of somatic symptoms.23 Similarly, Bower et al., in reviewing the treatment of depression in primary care, found that accurate diagnosis was a key predictor of treatment outcomes.20
Principle 2. Information Alone Is Insufficient to Improve Patient Outcomes: Shared decision making should target evidence-based educational interventions that promote skill development. A review of adult asthma self-management education showed that information-only interventions did not have a significant effect; “difficult asthma” psycho-education reduced hospitalizations in adults and children and improved symptoms in children. In a meta-analysis of diabetes self-management education, didactic patient education by itself was not sufficient to improve health outcomes. In pediatric asthma, education, as compared with usual care, decreased the mean number of hospitalizations and emergency department visits, with more visits and interactive learning producing better outcomes. Similarly, successful educational interventions for children with asthma incorporated skill-based training—either symptom-attack management or peak-flow training. Warsi et al., who reviewed a range of self-management interventions, found evidence of reduced glycosylated hemoglobin (A1C) in diabetes, reduced systolic blood pressure in hypertension, and fewer attacks in asthma but nonsignificant changes in arthritis. Interventions that involved face-to-face contact were associated with better outcomes. The authors noted that diabetes, hypertension, and asthma are conditions for which skills can be taught in diet, blood sugar control, and medication management, as opposed to arthritis, for which goals are less easy to define.

After a comprehensive clinical assessment, shared decision making between patient and clinician is used to determine which educational interventions are appropriate for the patient. Shared decision making is guided by evidence of what works. In smoking, the review conducted by Naughton et al. showed that for pregnant women, self-help interventions nearly doubled the quit rate, as compared with standard care. However, self-help materials for smoking cessation have no additional benefit when used with advice from a health professional in adult smokers. In HIV/AIDS, patient support and education, delivered individually as opposed to in groups, improved adherence to antiretroviral therapy.

Principle 3. Use of a Nonjudgmental Approach: Clinicians more effectively support patient self-management when they provide evidence-based information with a nonjudgmental approach. Vogt et al. conducted a systematic review examining the attitudes of general practitioners (GPs) and family physicians toward smoking cessation. A “sizeable minority” held negative beliefs about talking to their patients about smoking cessation, in the belief that it was “too time-consuming” (42%) and ineffective (38%), and 22% lacked the confidence to discuss smoking with their patients. The authors concluded that interventions led by primary care physicians would be more effective if their own negative beliefs were addressed. Motivational interviewing is a directive counseling approach that explicitly avoids contradicting or judging a client. Dunn et al. found that there was substantial evidence that motivational interviewing led to improved outcomes for patients with substance abuse and promising, yet inconclusive, evidence for its efficacy in HIV risk, diet/exercise, and smoking cessation. A meta-analysis of 72 studies revealed a significant effect for motivational interviewing for body mass index, total blood cholesterol, systolic blood pressure, and blood alcohol concentration but not for A1C or the number of cigarettes per day.

Principle 4. Collaborative Priority and Goal Setting: Collaborative identification of priorities, goals, and specific plans for goal achievement improves self-management and outcomes. Locke et al. provide extensive evidence for what are considered the essential elements of goal setting and task motivation for improved outcomes. A review of interventions in chronic illness showed that collaborative problem definition, followed by setting realistic goals and developing a personalized care plan, led to improved outcomes. Harrington et al., who reviewed 20 studies that examined interventions aimed at improving communication and patient participation in medical consultations, found evidence that improvements in patients’ perceptions of the amount of control they have over their health, patients’ level of activity in maintaining their health, clinic attendance, and adherence to medical recommendations were associated with improved clinical outcomes. In patients with congestive cardiac failure, comprehensive discharge planning and postdischarge support reduced hospital readmissions, reduced all-cause mortality, and improved quality of life. A review of self-management education for adults with asthma identified improved outcomes, particularly when the interventions involved a written action plan, self-monitoring, and regular medical review. In chronic obstructive pulmonary disease (COPD), action plans helped people to recognize and act on an exacerbation of COPD symptoms. For children and adolescents with asthma, there is limited evidence that a written plan alone produces better outcomes than no plan. However, there is clear evidence that symptom-based plans are superior to peak flow-based plans. In Type 2 diabetes, self-management education was found to improve A1C levels three months after the intervention. The education programs included knowledge gain; lifestyle change; collabora-
Principle 5. Collaborative Problem Solving: Collaborative problem solving improves self-management and outcomes. Problem solving consists of a set of steps whereby individuals define a problem, brainstorm possible solutions, chose a strategy, try it, evaluate the response, and repeat the process. Problem solving therapy (PST) teaches patients how to use problem solving to identify strategies for achieving successful adoption of new behaviors and for overcoming barriers to change and enables the translation of techniques for self-management into specific plans and behaviors. A frequently cited intervention, the arthritis self-management program, includes problem-solving training. This program resulted in improvements in pain of 20% compared with control groups, sustained for four years after the course. Lorig et al. emphasize that it is important to help people learn the skill of problem solving (as opposed to having a clinician do the problem solving for them) so they develop the capacity to address barriers themselves. A systematic review of problem solving in adults with diabetes showed that there was consistent evidence of an association between problem solving and A1C levels mediated through improvements in dietary behaviors. Problem solving was one of a combination of strategies in successful programs focusing on lifestyle change for diabetes. Better problem solving was associated with better self-care behavior but had little effect on diabetes control.

PST delivered by nurses in primary care improved depression outcomes for patients with depression. PST was effective in 72% of studies in a range of mental health problems in adults, children, and adolescents. Improved outcomes were associated with an increased number of sessions. In a meta-analytic review of coping, problem-focused coping correlated with improved health outcomes. Support for problem solving was found in studies of self-management programs for arthritis.

Principle 6. SMS by Diverse Providers: Diverse professionals and laypersons can effectively deliver SMS interventions if they have clearly defined tasks and roles and are trained to use evidence-based interventions. In a systematic review of diabetes education, Loveman et al. found that group programs achieved lifestyle change independent of which health professionals conducted the program as long as they were well trained. A number of reviews have found improved health outcomes compared with controls when nurses or pharmacists were part of multifaceted interventions for diabetes, depression, and preventive services. In a small number of trials of limited quality, dietitians were more effective than physicians in lowering blood cholesterol in the short to medium term, but there was no evidence that they were more effective than self-help resources or that they provided better outcomes than nurses. Nurses have been key to successful interventions for depression in primary care by providing telephone counseling for medication adherence, PST, and care management. Thomas et al., who examined nurses’ use of guidelines targeting management of hypertension, back pain, and hyperlipidemia, found that three of five studies reported improvements in processes of care and that six of another eight studies reported improvements in health outcomes. However, the authors advised caution in generalizing the findings because of methodologic problems in the studies. A systematic review of 18 studies of the use of community health workers in the care of patients with diabetes found positive effects of both lifestyle and self-care outcomes, as well as decreased “inappropriate health care use.” Foster et al. found that self-management interventions led by laypersons led to statistically significant improvement in patient confidence, health behaviors (exercise), small changes in pain, disability, fatigue, and depression but not quality of life. A meta-analysis of studies that compared nurse practitioners to physicians in primary care found greater patient compliance with treatment recommendations, greater patient satisfaction, and resolution of pathological problems, for the nurse practitioners, although limitations of the studies reviewed were noted.

Principle 7. Self-Management Interventions Delivered by Diverse Formats: Self-management interventions can be effectively delivered via diverse modalities, including individual-, group-, telephone-, and self-instruction formats. Much of the evidence for the benefits of diverse modalities comes from the smoking-cessation literature. Group programs for smoking cessation were better than no intervention and equal to one session of individual counseling. There was some extra but small benefit of group programs in addition to nicotine replacement but there was a wide variation in acceptance, with low uptake and more than a 30% dropout rate in some studies. Another review showed that telephone counseling using four to six phone calls led to higher quit rates than self-help materials alone, with no additional benefit from individual counseling or nicotine replacement. Group training in self-management for people with Type 2 diabetes was effective in improving fasting blood glucose, A1C, knowledge, and need for diabetes medication. Information technologies have emerged as innovative deliv-
ery systems with the potential to increase access to SMS. Kaltenhager et al. found some evidence that computerized cognitive-behavioral therapy (CBT) for anxiety, depression, and phobias was as effective as therapist-led CBT. A review of randomized trials of information and communication technologies (ICTs) for chronic disease management did not show improvement in clinical outcomes except for cardiac diseases, which also showed lower mortality and health service utilization. Systems for improving education and social support were effective. Bussey-Smith et al. found that computerized asthma education programs were effective in improving patient knowledge and symptoms but that clinical outcome effects were more varied. A systematic review of telemonitoring for patients with diabetes showed substantial decreases in A1C and complications and increases in patient self-efficacy, education, and receptiveness. More specifically, in a review of five studies of patients with diabetes, in which electronic monitoring was used to identify deficient medication compliance, adherence improved by 61%–79%. Verhoven et al., who reviewed teleconsultation and videoconferencing in diabetes, found improved metabolic control and cost reduction but no change in quality of life. A meta-analysis of 22 articles comparing Web-based and non–Web-based interventions for behavior change showed improvement in knowledge of nutritional status and asthma treatment, greater health care participation, and less health decline.

**Principle 8. Patient Self-Efficacy: Enhancing patient self-efficacy regarding key chronic illness management tasks improves the process and outcomes of care.** Self-efficacy is defined by Bandura as “people’s beliefs about their capabilities to produce designated levels of performance that exercise influence over events that affect their lives.” Self-efficacy is not a process; it is an intermediate outcome or mediator of patient adoption of self-management behaviors and health behavior change. A review of fibromyalgia notes the extensive work of Lorig and colleagues on self-management by patients with rheumatoid arthritis and osteoarthritis. Behavior and health status changes could be explained by patients’ attribution of improved control over symptoms. This sense of control is implicit in the definition of self-efficacy, that is, confidence in one’s ability to perform a task. The most powerful component of self-efficacy is mastery learning, which comes from achieving success in performing a new behavior. The arthritis self-management program, as cited earlier, provides training in problem solving (Principle 5) and action planning, which are used to achieve a sense of mastery over new tasks. A meta-analysis of psychological interventions for arthritis that featured combinations of relaxation, CBT, stress management, and coping skills training, either in groups or individually, found evidence that pain and disability improved compared with controls. Significant effect sizes in coping and self-efficacy suggested that these factors may contribute to these outcomes. Asthma patients with enhanced self-efficacy (ability to self-adjust medications) showed more improvement in lung function than patients who relied on physicians to adjust their medication. Similarly, in COPD, “self-sufficiency” in managing medical regimes was associated with a reduction in hospitalization. Self-efficacy includes self-prediction; a meta-analysis found that making a behavioral self-prediction significantly improved health-related behaviors.

**Principle 9. Active Follow-Up: Ongoing follow-up, supported by feedback and reminders to both clinicians and patients, helps sustain self-management behaviors and improves patient outcomes.** Most self-management interventions reported in the literature include some form of follow-up. Meta-analyses and reviews of multifaceted trials of diabetes, depression, asthma, and heart failure have supported the role of reminders and follow-up to both patients and providers in improving health outcomes. Best outcomes in depression were achieved when follow-up was maintained for at least 12 months. Two follow-up sessions to discuss medication substantially improved adherence, and nurse care management delivered over the telephone showed improved outcomes for depression. For heart failure, follow-up to specialized clinics or home visits was effective, whereas telephone follow-up to support primary care was not. For diabetes, patient tracking systems for regular follow-up improved processes. In reviewing studies assessing the effects of involving primary care physicians in routine review for complications of diabetes compared with specialist follow-up, Griffin et al. found that computerized recall for patients and their physicians could achieve standards of care as good as or better than outpatient care by specialists, at least in the short term. Telemonitoring showed substantial decreases in A1C and increased patient self-efficacy, and telecare, including nurses’ telephone follow-up of elderly people, improved clinical indicators for a range of chronic conditions.

Providing systematic follow-up is supported by evidence that follow-up increases rates of patient behavior change. Similar conclusions regarding the success of multiple strategies apply to the implementation of risk factor prevention in primary care settings; follow-up consisted of teleconference, newsletter, or individual instructions. Overall, the reviewed
studies suggest that although reminders to attend appointments support self-management, follow-up's value depends on review of patient data, monitoring of progress toward goals, and use of problem solving to address barriers to achieving those goals.

**Principle 10. Guideline-Based Case Management for Selected Patients:** Case management can improve self-management and patient outcomes if (and only if) it is goal directed and guideline based. In reviewing case management, the dominant model of community mental health care, Marshall et al. noted its various definitions.\(^8\) These range from coordinating care to clinical case management (which is provided by a mental health professional using a therapeutic approach). In contrast, in assertive community treatment (ACT), a client is assigned to the team rather than an individual case worker.\(^8\) Marshall et al. found that in comparison to standard care, case management increased the number of community contacts and nearly doubled the number of admissions.\(^8\) Case management was no better on psychological, quality-of-life, or social measures. Marshall et al. recommended that community teams use ACT. Reviews of chronic care for depression describe case management as effective when it is targeted through behavioral approaches to selected cases, is goal-directed, enhances self-management, and provides direct feedback to the client and delivers psychological therapy.\(^8\) Collaborative care for depression is effective when nurse case managers work with psychiatrists and primary care physicians.\(^8\) A review of studies where the intervention was a specialist nurse in diabetes care alone, compared with usual care in hospital clinics or primary care, found that the nurse intervention may have improved A1C levels in the short term but that there was no difference from control groups during a 12-month period.\(^8\) In addition, quality of life and emergency admissions were no different between groups. In minority ethnic groups with diabetes, case management improved A1Cs.\(^8\) In another review, in which case management in primary care was defined as "a program that uses physicians or nonphysician providers to maintain continuous contact with patients via telephone or in-home visits in order to prevent disease exacerbation through intensive assessment and education techniques," only two of nine studies showed significant reduction in hospital admissions or bed days.\(^8\) Both of the two studies examining clinical outcomes showed improvement, and six of the studies showed improvements in quality of life, patient satisfaction, and functional status. Interventions targeting specific diseases were more successful than general conditions supervised by generalists.

**Principle 11. Linkages to Evidence-Based Community Programs:** SMS should include community-based self-management programs that are evidence-based. Community-based telephone counseling for smoking cessation was shown to produce higher quit rates than usual care.\(^8\) The Arthritis Self-Management Program (ASMP), developed by Lorig and colleagues at Stanford University\(^8\) (and cited earlier\(^6,8\)) is the most rigorously evaluated community-based program. This six-week, peer-led group program has produced gains in pain and fatigue management up to four years after the course.\(^8\) A generic program for a range of chronic conditions based on the ASMP has produced improvements in pain and fatigue, as well as reductions in utilization and hospitalization at two-year follow-up.\(^9\) Newbold et al., in reviewing the ASMP and generic courses, documented a range of benefits from both programs and comparable outcomes when delivered by peers or health professionals.\(^8\) The use of ethnic link workers contributed to the benefits of diabetes management in ethnic minority groups\(^8\) and group interventions for chronic disease management held in culturally specific community settings had positive outcomes.\(^8\)

**Principle 12. Multifaceted Interventions:** Multifaceted interventions are more effective than single-component interventions. Effective SMS is typically provided by multifaceted rather than single-component interventions.\(^6,8,12,44,93\) Multifaceted interventions include patient registries that identify patients with specific chronic conditions\(^94\) and linkage to appointment recall systems,\(^95\) evidence-based guidelines, and outcome measures. In a review of trials of smoking cessation involving physicians and nonphysicians, Kotke et al. concluded that multifaceted interventions were more successful when teams of providers were involved and that combinations of group and individual sessions produced better outcomes than either alone.\(^96\) Better outcomes were predicted by the number of interventions and the number of reinforcing sessions.\(^96\)

**Discussion**

We have provided a set of principles underpinned by evidence from randomized controlled trials to inform implementation of SMS in primary care. Evidence for the effectiveness of a number of these principles used in the Breakthrough Collaboratives has been described by Glasgow et al.\(^11\) We acknowledge that these recommendations are most likely to be implemented when health care systems are able to afford to offer comprehensive programs for the patients who are willing and able to participate. The more comprehensive and intensive the programs,
The more likely they are to be effective in improving patient outcomes. In contrast, for disadvantaged populations, arguably the people who most need SMS, limited access may impede the implementation of the recommendations. In any case, embedding these principles into routine clinical practice is difficult; SMS is the least implemented of the six elements of the CCM.12 Bodenheimer et al. documented the barriers to CCM, which included time, costs and the lack of reimbursement, inadequate information technology, and physician resistance to implementing chronic care management.97 They recommended three redesign elements: (1) pre-activating patients before the clinic visit; (2) planned visits with a care manager who provides education and medical management to patients, either individually or in groups; and (3) sustained follow-up, either face to face, by telephone, or electronically provided98 by a care team.99 Glasgow et al.12 provide a more detailed, sequential approach to integrating SMS, which is consistent with Bodenheimer, and expand the sustained follow-up to include linkages with community support and education programs.

Table 1 (above) shows how the 12 principles can be implemented via the three phases of patient care. By focusing on the enhanced assessment before the visit and on expanded post-visit options (for example, case management, self-management skills training, risk factor reduction), it may be possible to focus and strengthen SMS in the clinical encounter with only modest change in clinician behavior during the visit.

We have limited data on whether SMS interventions are cost-effective. Cost-effectiveness analyses are complex; the cost per quality adjusted life years saved (QALYS) is the recommended outcome measure when comparing the cost-effectiveness of different interventions.100 However, the impact on health outcomes with behavioral or self-management interventions may not be evident for many years, making QALYS and return on investment difficult to estimate. Although well-designed longitudinal studies should be conducted to measure the cost-effectiveness of self-management interventions, accurate cost analyses of interventions provides an intermediate step of benefit to both policy makers and funders. Readers are encouraged to collect their own cost data using feasible cost collection procedures.101

Conclusions
Health care is in the midst of a transition from expectations that disease will be managed primarily by physicians to a system that enables patients to effectively assume primary responsibility for managing chronic conditions. There is now a substantial evidence base that can be used to guide efforts to improve the abilities of health care teams to enable their patients to successfully manage chronic illness. The challenge before us is to integrate these evidence-based principles into routine patient care.1

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