Improving health outcomes with better patient understanding and education

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Abstract: A central plank of health care reform is an expanded role for educated consumers interacting with responsive health care teams. However, for individuals to realize the benefits of health education also requires a high level of engagement. Population studies have documented a gap between expectations and the actual performance of behaviours related to participation in health care and prevention. Interventions to improve self-care have shown improvements in self-efficacy, patient satisfaction, coping skills, and perceptions of social support. Significant clinical benefits have been seen from trials of self-management or lifestyle interventions across conditions such as diabetes, coronary heart disease, heart failure and rheumatoid arthritis. However, the focus of many studies has been on short-term outcomes rather than long-term effects. There is also some evidence that participation in patient education programs is not spread evenly across socio-economic groups. This review considers three other issues that may be important in increasing the public health impact of patient education. The first is health literacy, which is the capacity to seek, understand and act on health information. Although health literacy involves an individual's competencies, the health system has a primary responsibility in setting the parameters of the health interaction and the style, content and mode of information. Secondly, much patient education work has focused on factors such as attitudes and beliefs. That small changes in physical environments can have large effects on behavior and can be utilized in self-management and chronic disease research. Choice architecture involves reconfiguring the context or physical environment in a way that makes it more likely that people will choose certain behaviours. Thirdly, better means of evaluating the impact of programs on public health is needed. The Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework has been promoted as one such potential approach.

Keywords: self-management, health literacy, patient education, behavioral economics, program evaluation

Chronic disease self-management and preventive health programs mainly focus on promoting informed lifestyle choices, risk-factor modification, and active patient self-management of chronic diseases. Such a process relies heavily on better information and communication practices. The logic of health reform that emphasizes preventive and enhanced primary models of care is an expanded role for informed, active consumers interacting with responsive health care teams. Most observers agree that this central role demands improved education and understanding of health behavior and chronic disease management. However, for individuals to realize the benefits of health education also requires a high level of participation and engagement, i.e., action or behavior related to health.

In the context of burgeoning current health care costs and alarming projections of future costs, the potential community and individual payoff is immense. It was estimated...
in 1993 that half of the annual mortality toll in the US was premature.2 Significantly, it was shown that these deaths could be deferred with the modification of just 10 behaviors, such as tobacco use, diet, physical activity, alcohol consumption, and others, including exposure to microbial agents, exposure to toxic agents, use of firearms, sexual behavior, motor vehicle crashes, and illicit use of drugs. Nearly 80% of premature deaths were attributed to just three behaviors in the list—tobacco use, dietary pattern, and physical activity level.3 More recent evidence from a cohort study of over 23,000 German adults followed for 8 years showed that four behaviors accounted for a 78% variance in the apparent risk of a serious chronic disease.4 Again, smoking, diet, and physical activity are implicated. As one of the four (maintenance of a BMI < 30) is not a behavior per se, but rather largely a byproduct of two other behaviors already on the list (eating well and being active), the “difference between life and death and health and illness is substantially dictated by just three behaviors”4. For those with all four “healthy behaviors” compared with those with none, the hazard ratio for diabetes, myocardial infarction, stroke, or cancer was 0.22 [95% confidence interval (CI): 0.17–0.28]. The presence of just one healthy behavior as compared with none cut the chronic disease risk by half (adjusted HR, 0.51; 95% CI: 0.43–0.60).3

Numerous factors go into influencing behavior, and a review of the social determinants of health is beyond the scope of this review. However, to give an example of the power of social factors such as inadequate access to health care, educational disparities, and poverty, consider the analysis of Woolf et al5 who examined death rates among adults with inadequate education in the US. The authors used education-associated excess mortality as a proxy for this web of sociological, economic, and biological variables.3 They applied indirect standardization techniques to estimate the maximum number of deaths averted between 1996 and 2002 that is attributable to medical advances and the number of deaths that would have been averted if mortality rates among adults with lesser education had been the same as those among college-educated adults. The authors concluded that, “in comparison with the gain from medical advances, 8 times as many deaths would be averted if mortality rates among adults with an inadequate education were the same as those among individuals at higher education levels”.3 It is with this overwhelming statistic in mind that this review turns to the more limited and specific issues relating to patient or health education, usually from within the health care system.

There is a large and growing literature documenting the gap between expectations and the actual performance of behaviors related to participation in health care and prevention. Review topics in the Cochrane Library indicate that most interventions to increase consumer engagement include promoting patient medication compliance, chronic disease self-management, and traditional health promotion behaviors around smoking, diet, and exercise. Efforts to enhance clinical encounters have largely focused on encouraging patients to ask questions through coaching or written encouragement. Another focus has been on individuals to increase self-care, improve health literacy, and assist with clinical decision making.6 In a recent review, Coulter and Ellins7 found few trials or systematic reviews describing interventions to support navigating the health care system or promoting ease of access to care.

This article reviews some of the evidence concerning the effectiveness of some of the strategies to improve care, particularly of chronic conditions, before considering some of the issues in patient education and consumer engagement and participation that can impact on these strategies.

**Specific conditions or problems**

The most consistent positive outcome of interventions to improve self care has been improvement in self-efficacy, an important element of self-management. Most studies of self-management programs have reported improvements in patient satisfaction, coping skills, and perceptions of social support, although the focus has tended to be on short-term outcomes rather than on long-term effects.9–39 For these outcomes, the results of studies on self-management programs in diabetes have been more mixed.40–47 Diabetes education alone appears ineffective in improving metabolic control.48 Most, but not all, reviews on diabetes self-management interventions have shown improvements in glucose control, as well as improvement in quality of life.14,18,40–47 Randomized controlled trials (RCTs) of self-management or lifestyle interventions for diabetes that examine cost benefit have variously shown reductions in diabetes incidence,68,69 improvements in co-morbid depression,70 and clinical benefits,71–73 although others have shown no clinical benefits.74,75 Although studies from administrative databases49 and studies other than RCTs have indicated reduced costs for those enrolled in self-management programs, RCT evidence in diabetes management or prevention has not consistently supported this finding.76 Of note is that administrative data suggest that participation in diabetes education is not spread evenly across socioeconomic groups, with one study showing that participants were younger, more were female, located in more affluent areas, at lower clinical risk, and at higher adherence
to diabetes standards of care.\(^9\) Asthma self-management programs have produced varied results in terms of improving symptoms and quality of life, with generally better results for programs that include regular practitioner review than for education alone interventions.\(^{38,39,77-83}\) There is not much evidence that self-management programs have a clinically significant impact on health status in chronic obstructive pulmonary disease (COPD), although hospital admissions may be reduced.\(^{84-87}\)

Numerous interventions to improve adherence with medication regimens have been studied. Few have been successful in increasing medication use over the longer term. Almost all the interventions that were effective for long-term care were complex, with multiple combinations of interventions. These have included combinations of more convenient care, information, reminders, self-monitoring, reinforcement, counseling, family therapy, psychological therapy, crisis intervention, manual telephone follow-up, and supportive care. However, the improvements in adherence and treatment outcomes have been generally modest.\(^{39,68,69,88-90}\)

In patients with rheumatoid arthritis, patient education has an immediate, albeit small, beneficial effect for disability, joint counts, patient global assessment, psychological status, and depression.\(^91\) However, one systematic review found no benefit over longer follow-up times of between 3 and 14 months.\(^92\) Others have found modest improvements in ER and obstructive pulmonary disease visits but not in other clinical outcomes with self-management programs.\(^93\) Similarly, self-management programs for epilepsy may improve knowledge about epilepsy and reduce seizure frequency. However, the evidence is limited and has tended to include higher proportions of people with partial seizures than would be expected in a community sample, making it difficult to make conclusions.\(^94\) There is strong evidence that exercise therapy for multiple sclerosis has a positive effect on exercise tolerance and mobility.\(^95\) However, self-management research in multiple sclerosis is limited, particularly with regard to comprehensive programs.\(^96\) In people with coronary artery disease, education and stress management programs have been shown to improve outcomes.\(^28,97\) Heart failure management programs that include initiating self-management interventions also demonstrate a positive effect on outcomes such as hospital readmissions, quality of life, and mortality. However, a recent review found that improvements are not always significant and noted methodological shortcomings, limiting the quality of the published evidence. The authors called for further research to determine independent effects of self-management interventions and different combinations of interventions on clinical and patient-reported outcomes.\(^98\)

A systematic review concluded that “the evidence is overwhelming that physical activity and diet can reduce the risk of developing numerous chronic diseases, including coronary artery disease, hypertension, diabetes, and the metabolic syndrome.”\(^99\) Few studies have examined the isolated effect of training on the prevention of diabetes in patients with impaired glucose tolerance, but there is good evidence for a beneficial effect of combined physical training and dietary modification.\(^100\) Walker et al.\(^100\) examined the evidence for diet and exercise lifestyle changes in the prevention of diabetes. They found a number of studies across different populations, which showed that lifestyle change may reduce the incidence of type 2 diabetes by 28%–59%, with the effects seen many years after the intervention.\(^73,101-106\) Regular exercise appeared necessary to maintain weight control and risk reduction. A comprehensive systematic review has found that there is strong evidence for the benefits of exercise in improving clinical outcomes in metabolic disorders such as diabetes and hypertension; coronary heart disease (CHD) and heart failure; depression; fibromyalgia and knee osteoarthritis.\(^107\) The evidence is less strong for clinically significant improvements in asthma, COPD, or other forms of arthritis. Exercise training improves exercise capacity in patients with chronic renal failure treated with hemodialysis.\(^108,109\) The benefits in quality of life are often most notable in those with the lowest baseline levels.\(^110\)

### Types of interventions

Interventions to improve coordination of care between different parts of the health care system have shown mixed results.\(^111\) A Cochrane review concluded that there was no evidence to support the widespread introduction of shared care.\(^112\) Attempts to integrate care of depression in patients with medical conditions have been generally positive with regard to depression care, but the effects on medical care are less well established.\(^113\)

Computer-based programs for people with chronic disease may combine health information with online peer support, decision support, or help with behavior change. Such programs have been shown to increase knowledge, feelings of social support, and some clinical outcomes among users.\(^31\) There is evidence that home-based information technology interventions can reduce health care costs.\(^114\) Computer-based programs can also be useful for behavioral risk reduction in areas such as smoking and diet.\(^115\) However, as the authors of a Cochrane Review noted, much work is still needed to
determine the best type and best way to deliver interactive computer programs and to establish how they have their effects for different groups of people with chronic illness.31

Decision aids aim to assist individuals in making decisions, where the balance between benefits and harms are not absolutely clear or where there is a substantial degree of uncertainty about the scientific evidence. A systematic review found that decision aids improved knowledge and accuracy of risk perception and increased people’s involvement and degree of comfort (“decisional conflict”) with decision making. The effect on actual decisions is variable, although it appears that decision aids reduce the use of discretionary surgery without apparent adverse effects on health outcomes or satisfaction. Again, the effects show substantial variations across studies, suggesting that factors not studied may be influencing the processes and outcomes.116

Information provision alone
Several studies have shown that telling people about adverse effects of their medications did not affect their use of the medications. However, not providing full information about medications has been reported to contribute to lower adherence117 and may increase medical errors.118 Patient information insets in pill packets do not help to improve adherence,64,94 but specific reminder packaging may improve adherence to long-term medication.94,120 Providing people with risk information on CHD increases the accuracy of risk perception. A recent systematic review found that interventions that provide information on a repeated basis have shown small significant reductions in predicted CHD risk (absolute differences, −0.2% to −2% over 10 years in studies using risk estimates derived from Framingham equations). However, providing risk information only at one time point is ineffective.121

Implications
A number of commentators have provided us with approaches to develop more effective ways to address chronic illness.122,123 However, as one author has asserted, “the evidence of success is slim”.124 Although, recently, progress has certainly been made, the evidence for improvement in clinical outcomes, as distinct from some processes of care or the behavior of clinicians, is far from convincing. In particular, the evidence for dramatic improvements in public health is unclear.7 The less than overwhelming results of interventions to improve self-care, education, and understanding requires us to consider what additional ingredients or alternative approaches might be of benefit. This review will consider two conceptual areas and one evaluation approach that may be used to add value to patient education, engagement, and self-management.

Health literacy
An emerging area of research in the field of consumer education and engagement is health literacy, ie, the capacity to seek, understand, and act on health information.125 There is a clear presumption in the literature that low literacy and numeracy means health communication is poorly understood, leading to inadequate self-management and perceptions of health responsibility and inappropriate health care utilization.126 Health literacy is also cast as a social determinant of health (as is functional literacy) both for individuals and for populations due to its impact on socioeconomic status, employment, and ability to access services.126 It is known that self-management practices127 and self-management skills128 vary by patient’s level of health literacy. Functional health literacy (FHL) has been identified as a predictor of self-efficacy in diabetes and HIV self-care.129,130 An independent association between health literacy and self-efficacy has also been found regarding participation in, and to seek information about, cancer screening programs.131 There is also evidence that low FHL is linked with poor health outcomes.132,133 The scope of the problem is dramatic, with 45% of adults at risk for limited health literacy,134,135 which indicates that many people with adequate general literacy may have difficulty applying this in specific health contexts.125,136 Numeracy, particularly regarding statistics, is another important related concept.137 A recent study found that, of a sample of American and German adults, 64.5% and 68.5%, respectively, could answer nine simple questions related to statistical numeracy, with wide disparities across social class seen especially in the US.138 Only 24% of the Americans were able to express 1 in 1,000 as a percentage.138 A Swiss Government analysis indicated that 3%–5% of all health care spending can be attributed to low health literacy.139

Despite all this, few studies have specifically taken health literacy into account for delivering an intervention program, by attempting to take low health literacy into account as a risk factor to be managed. A number of interventions have attempted to specifically tailoring programs to individuals with low health literacy, with some success in improving outcomes in conditions such as diabetes.140 A relatively small number of studies have aimed to improve health literacy with a variety of complex interventions and then examined the impact on health behavior and outcomes. Clement et al141 have recently reviewed these studies. The authors noted that most trials reported improved outcomes, but only 8 of the
15 trials included in their review measured direct clinical outcomes. Knowledge and self-efficacy were the class of outcome most likely to improve. A variety of strategies were used in a number of different combinations across different health conditions, including care management; simplifying language in written materials; use of pictorial information, videos, and audiotapes; specifically checking for understanding, spacing information, and training professionals in communication techniques.141

There is some evidence suggesting ways in which health literacy impacts on education interventions. Evidence shows that adults with limited health literacy are less likely to ask questions to clinicians.142 People with poorer reading skills describe the density of text in a decision aid in a colorectal screening program as “intimidating and frightening”.143 Individuals with less than university education are less likely to classify themselves as information seekers.144 Limited health literacy is also problematic once information has been accessed. Men with lower health literacy skills were found to be 4 times more likely to refuse the offer for colorectal cancer screening, even if it was recommended by their physician.145 Lower literacy skills were associated with considerably less accuracy in portion-size estimation when participants were asked to serve a single serving of various foods.146

One of the difficulties in applying the notion of health literacy to interventions has been lack of consensus over the definition of the concept. A person’s skills in literacy and numeracy as they relate to health have been described as “FHL”.123 However, while the associations between health literacy, health-related knowledge, and attitudes are significant, previous studies have found that these associations only partially account for people’s actual performance. As Peerson and Saunders note,147 “although knowledge is often considered a prerequisite for change in attitudes and behaviors that lead to better health, that relationship is not always direct, positive, linear, or even necessarily present”. Rubinelli et al148 contend that, “critical health literacy reflects the individual’s capacity to contextualize health knowledge for his or her own good health to decide on a certain action after a full appraisal of what that specific action means for them in their own world”. Because FHL only partly accounts for health-related behavior,136 the definition of health literacy has been expanded to include factors that can influence health decisions and behavior. These encompass the ability to find, understand, evaluate, and select information from different sources and then put this to use in decision-making in that specific context.125,149–151 There is, however, little or no empirical research evaluating this wider concept.147 Furthermore, these expanded definitions do not appear to consider the possibility that someone may possess and understand health information without using it in health-promoting ways.147 It is axiomatic that “to effectively access, understand, and apply received health messages, individuals must be motivated to receive and process the information”.152 It may therefore be useful to distinguish between possessing information; understanding it; and the inclination and ability to act on it appropriately.147

One suggestion has been to screen for “patient activation”153,154 or readiness to better determine the likelihood of engagement by individuals and of success in achieving better understanding and behavior change.155 The value of establishing “psychotypes” would be analogous to “personalized medicine” in determining genotypes for targeting therapeutic pharmaceutical interventions. As a means of better targeting scarce resources, this approach deserves further consideration. However, the risk is that by focusing on the patient, this approach tends to let the health care system off the hook in its responsibility to give people real control and choice about whether, how, where, and when they use health services, supported by access to evidence-based information that facilitates informed choices, as a platform for creating an agile and self-improving health system.136 It is all too easy to label someone as “not ready” or “disengaged” when the interaction with the health care system is confusing, inconsistent, or involves labyrinthine system navigation.

The responsibility of the health care system
Consequently, before considering the patient’s readiness, the health care system has a responsibility to proactively enable more accessible interactions and environments that promote health and well-being.156 Health literacy is primarily the responsibility of health systems, given that it is the health system that determines the parameters of health interaction, including the physical setting, available time, communication style, content and mode(s) of information provided, attitudes to the provision of information, and definitions of concepts such as sound health decision making and compliance.157 It is only then that consideration should be given to the preferences of patients regarding communication styles, content, and media.

There is a wealth of literature that identifies a number of characteristics, indicating better health professional communication behaviors, in isolation and in combination.158–160
Behaviors that clinicians can use to ameliorate the potential risks associated with limited health literacy include avoiding the use of medical jargon, showing interest in questions, explaining forms, and confirming understanding through techniques such as teach-back and use of visual aids. However, the evidence that training in communication skills for clinicians leads to improvements in health outcomes is mixed. Similarly, the evidence that patient-centered consultations can improve health outcomes is limited.

However, few of these interventions have specifically considered the preferences of people for how they receive information and interact with the health care system. This issue is compounded when the skills and competencies of people are not specifically taken into consideration. Specially targeted interventions can help to increase knowledge and understanding in people with low health literacy and seem to improve outcomes, although the number of trials is limited. Educational packages, which may include videotapes and multimedia programs, specifically developed for low-literacy populations can help to improve knowledge, while brief, group-based didactic teaching seems to be of limited value.

Ultimately though, as Kane asserts, “disease management can work only when there is a receptive patient partner”. Kane suggests that Prochaska’s readiness assessment for prevention offers one model for looking at the question of patient activation or motivation. An alternative conceptualization may be understood as a process of health competency, starting with recognition that an issue or problem is relevant to an individual, accepting that this issue exists and requires decisions to be made and some form of action be taken, seeking out and critically evaluating information, undertaking actions with regard to this issue in the light of knowledge gained, and then personalising the issue by monitoring the effects or outcomes over time. Such a conceptualization involves personal skills and competencies, attitudes, motivation, and the inclination to act with regard to health and recognizes that these may be context-specific to situations, health conditions, and modes of social and/or clinical interaction. As a personal asset, health literacy so defined acknowledges individuals’ social and cultural contexts and calls for engagement in social action for health and participation in altered social norms that can enable action on the social determinants of health. It suggests an expanded role for the health system: patient education, improving the parameters of the health care interaction and facilitating navigation through an often labyrinthine health system, and fostering development in schools, adult learning, and community development programs.

Hibbard and Mahoney have shown that low levels of activation are associated with negative effect, particularly with regard to their health. These authors suggest that this implies people who are struggling in managing their health recognize their failure and feel badly about themselves. The implications of their results are that reversing this situation involves encouraging behaviors that produce small successes, such as reading a food label. Tailoring support and education in this context requires taking the level of activation into account, as well as their skills and competencies in health literacy. Too much information can overwhelm individuals, especially if large changes in lifestyle are demanded, and this can potentially increase negative emotions and perpetuate passivity or avoidance. As the authors point out, “not understanding a patient’s activation level may mean that a routine office visit interaction could be harmful to them”.

Effective health education would then need to consider the health literacy and activation of individuals. Communication can be tailored to take into account the preferences of patients for type or media, along with frequency of contact and the skills or competencies of individuals. Some people may prefer in-person meetings, others may use the telephone, some prefer video conferencing, and still others are contented with a text message. In this way, the health literacy of individuals and families can be matched by a health care system that is health literate “aware”. Furthermore, the cost of interactions could vary by type, either via a market signal or within a public framework that provides some incentive for clinicians to participate. Such considerations will need to be included into new initiatives such as the Australian Government’s recently announced diabetes care program in primary care. If general practitioners are to be held accountable for the results of diabetes management, then some means of both assessing patients activation/motivation and enhancing it needs to be part of the program. Clinicians are unable to reliably identify the health literacy levels of their patients. Measuring health literacy in every patient is impractical, and so some health literacy experts advocate that clinicians should perform assessments on a sample of their practice patients to learn the prevalence of limited health literacy in their practice. This may in turn stimulate changes to communication practices in clinical encounters.

While integrating health literacy and patient activation into the development of interventions to improve health care have intuitive appeal, there is little empirical work to demonstrate efficacy. As mentioned earlier, despite commentator’s enthusiasm on a variety of ways to improve the care and management of chronic illness, success has not always been
overwhelming when tested in clinical trials. Therefore, before widespread changes can be recommended, considerably more research is required.

**Behavioral economics**

Behavioral economics has gained increasing attention in public policy recently, possibly driven by several influential books such as Nudge. This has led to a greater appreciation of the need to take the context, settings, and physical environment into account when developing behavior change interventions. The focus of much patient education and self-management work has been on personal factors such as attitudes and beliefs. The evidence showing often small changes in physical environments can have large effects on behavior could lead to a rich new stream of research on patient behavior and effective communication strategies. Another relevant concept is that of “choice architecture”, where reconfiguring the context or physical environment in a way that makes it more likely that people will choose a behavior that is better for them and better for other people is achieved while fully preserving their freedom to choose alternative behaviors. Although examples exist on the concept being used in influencing choices around insurance or medication coverage, there has been less work on how choice architecture could be used in disease management programs.

As discussed earlier, motivation is regarded as a crucial factor affecting behavior. However, even highly motivated individuals often have difficulty in making decisions in the short term that favor their long-term interests. To see if medication adherence could be enhanced using ideas derived from behavioral economics, Volpp et al conducted a small uncontrolled trial in stroke patients using incentives from the behavioral economics literature, including small, frequent rewards; offering a small chance at a big reward; and the desire people have to avoid regret at missing a payoff. The objective was to increase compliance with warfarin as assessed objectively with an electronic pillbox device. Patients were entered into two daily lotteries. Participants had either a 1 in 5 or a 1 in 10 chance of winning a $10 prize and a 1 in 100 chance of winning a $100 prize, producing an expected value each day of $3 led to significant weight loss compared with a control group. As the authors suggest, “A lottery (or other reward system that provides frequent positive reinforcement) can be thought of as a way to help patients to internalize long-term benefits so that they make decisions in the short term that favor their long-term interests”. Although such small-scale, non-RCT evidence is not yet compelling, it provides encouragement for further more rigorous trials to be conducted, where ideas from outside the health field may be adapted to improve behavioral interventions and health outcomes. In particular, we need to know how behavioral effects can be maintained for longer term and whether habits can be internalized if the incentive is provided for a longer period.

**Evaluating program impact**

Most of the evidence discussed earlier provides estimates of the efficacy in clinical trials of various programs in chronic disease. Evaluation of the effectiveness of programs and their impact on public health is more difficult to establish. Indeed, the criteria for judging whether a program has produced a significant public health impact is not broadly agreed upon. Experience indicates that many programs of proven efficacy fail when implemented in real-world settings. Some authors have advocated for a broader research and evaluation perspective than the narrow focus of the clinical trial that can use standard metrics across multiple indicators to judge programs. The Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework has been promoted as one such approach. This approach recommends addressing the different elements of a program: (a) reach, or who is willing to participate; (b) effectiveness, the impact of the program; (c) adoption, the settings and staff who take part in the program; (d) implementation, how skillfully the program is delivered; and (e) maintenance, to what extent individual participants and the organizations involved sustain their involvement (see http://www.re-aim.org/). These dimensions can be examined individually or as combined impact indices. Interestingly, as one group observed, these combined indices tend to use only two dimensions because historically few studies provide data on more than two RE-AIM dimensions. Comparison of diabetes programs using multiple RE-AIM metrics has demonstrated the difficulties that exist in making choices about which program
is the “best” of various available choices. Comparing two diabetes self-management programs, Glasgow et al. found that while one program performed better on reach and consistency across different populations, another was more likely to be adopted and adopted more consistently by staff. These authors concluded that when decision makers are weighing up which direction they should go, “programs should be chosen based on the results that one’s organization values most.”

Disclosure

The author reports no conflicts of interest in this work.

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