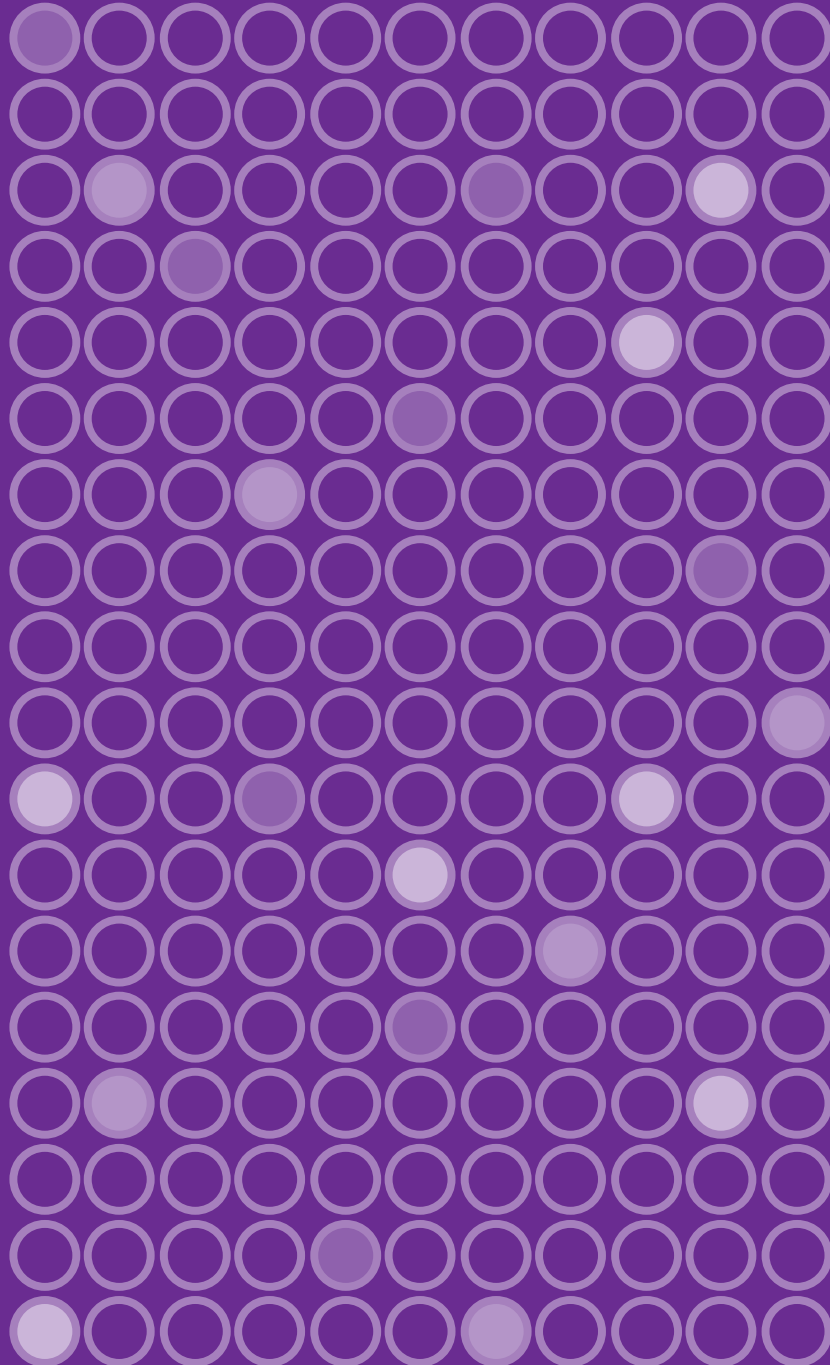


Building the Business Case for Diabetes Self Management:

A HANDBOOK FOR PROGRAM MANAGERS



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DIABETES INITIATIVE

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Kerry E. Kilpatrick, PhD
Carol A. Brownson, MSPH

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Preface

The *Diabetes Initiative* of the Robert Wood Johnson Foundation was designed to demonstrate sustainable diabetes self-management programs in “real-world” settings. Through 14 demonstration projects around the country, the initiative examined ways to advance diabetes self management in primary care settings and to improve the network of community supports for self management. Projects demonstrated improved patient engagement in diabetes care and strong clinic-community partnerships resulting in healthier self-management behaviors and improved clinical outcomes for the people they serve. An issue that surfaced repeatedly was how the individual interventions could be sustained over the long term. This issue of sustainability was of great interest to us at the National Program Office and also to our sponsor, the Robert Wood Johnson Foundation.

We recognized that even with demonstrated clinical effectiveness,* the long-term sustainability of the various interventions would be greatly enhanced if they could be shown not only to be clinically effective but cost-effective as well. In particular, we wanted to demonstrate that a strong business case for comprehensive self-management programs could be made to managers and payers. As we discussed the need to build a business case with the teams in our collaborative, we soon realized that there was no readily available set of methods we could offer that would permit our sites to develop their own business cases. Therefore, this handbook was conceived to meet the need to assemble in one place the rationale, methods and tools for building a business case for self management of diabetes.

Carol Brownson, deputy director of the National Program Office, has worked with Kerry Kilpatrick, professor emeritus at the University of North Carolina (UNC) at Chapel Hill, to develop this handbook. We hope that it will be a useful guide to those who want to develop business cases for their self-management interventions.

We also want to acknowledge the assistance we received from a number of individuals as we developed this handbook. First, this project was possible only because of the support and encouragement of the Robert Wood Johnson Foundation and, in particular, Anne Weiss, who served as senior program officer to the *Diabetes Initiative*. Second, much of the material in the handbook builds upon research and publications from a series of business case projects at UNC-Chapel Hill that were sponsored by The Commonwealth Fund, the Center for Health Care Strategies and the Robert Wood Johnson Foundation. Colleagues at UNC, whose work we build on here, include Sheila Leatherman, Kristin Reiter, Sandra Greene and Kathleen Lohr. At Washington University, Victoria Anwuri, Candice Graham, Carrie Stetz, Mary O’Toole and Stephanie Tower contributed to developing literature searches and editing. Finally, Debra Ritzwoller of the Institute for Health Research, Kaiser Permanente Colorado, kindly read and commented extensively on an earlier draft.

Edwin B. Fisher, PhD
Director, National Program Office
The Diabetes Initiative

*The successes of the *Diabetes Initiative* are described in detail in a special supplement to *The Diabetes Educator*, Volume 33, Supplement 6, June 2007.

Introduction

This handbook covers a broad range of topics related to building a business case for implementing self-management interventions in diabetes. Readers who are new to the concept of establishing a business case will likely want to travel through the handbook book step by step. Others with greater familiarity with the topic may choose to read sections that pertain to their current interests. The content of the handbook unfolds as follows.

Chapter 1 provides the rationale for establishing a business case for implementing quality-enhancing interventions in diabetes, discusses procedural steps and methodological issues that must be addressed in developing a business case, and suggests conditions that should be met for an organization to embark on a successful business case analysis. It also introduces aspects of the nonfinancial business case.

Chapter 2 addresses the nonfinancial business case in greater depth. Importantly, it introduces an expanded framework for the business case, taking into account other perspectives such as those of customers, communities and regulators. Each perspective contains measures beyond return on investment that should be considered in making a business case for diabetes self management.

Chapter 3 presents the Microsoft Excel® spreadsheet templates that we have used to compute the return on investment for quality-enhancing interventions in a variety of settings. The reader who is already familiar with the general concepts of developing a business case for quality may want to page ahead to the example provided in Appendix B in Chapter 3 to see how the spreadsheets may be applied in practice to develop a business case in a clinical setting.

Chapter 4 provides a brief review of the evidence of the cost-effectiveness of self-management support in diabetes. Our goal is to present representative works from the current literature regarding established business cases for self-management support. Although reasonably thorough, this is not a systematic review of the literature. Finally, we have included a bibliography that expands on the chapter references.

Chapter 1

Building a Financial Business Case for Self-Management Support in Diabetes Care

Why Should We Care About the Financial Business Case?

Interventions to improve patient care are implemented because clinicians, patients or payers expect these quality-enhancing interventions (QEIs) to be worthwhile, but the published evidence that QEIs are sustainable from a financial perspective is remarkably sparse.¹ Even though the efficacy of self-management support (SMS) is well documented, we are interested in establishing a financial business case for SMS in diabetes care. With today's increasing demands on providers' time, a convincing business case will help SMS interventions to be broadly implemented and sustained over the long run. Given several QEIs to choose from, decision-makers and payers are more likely to implement interventions that improve patient care *and* show a positive financial return on investment (ROI). Operating managers of both private-sector health care delivery organizations and government agencies charged with funding or delivering health care services are reluctant to invest scarce resources in QEIs that cannot be shown to pay for themselves within a relatively short time. Even in the most enlightened organizations, managers charged with maintaining the financial solvency of the entity are concerned with the impact of new programs in the current budget year.²

Demonstrations can only go so far toward convincing providers and payers to adopt QEIs on a widespread basis. This is even true when the intent is to spread the interventions within a specific delivery organization beyond the clinical site that has participated in the original demonstration project or collaborative. For community organizations, the challenge is even greater; communities participating in SMS programs have unique characteristics not replicable in other

communities to which the intervention could be spread. Thus, if the ultimate goal is to attempt to align the financial incentives to pay for quality,³ we need to measure explicitly the costs and savings attributable to the interventions and compute the ROI for the intervention.

The fact that deficiencies in the quality of health care remain prevalent despite an increasing body of evidence to guide the implementation of proven quality interventions⁴⁻⁶ demonstrates the importance of having a strong business case. Policy-makers, payers and employers continue to

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express their frustration that QEIs of demonstrated effectiveness are not being implemented on a broad basis. Even after decades of careful, evidence-based practice research, one of the principal reasons that individual providers, hospitals, health care delivery systems and payers in the United States give for not implementing promising health care QEIs is that no business case for quality can be made. Recent case studies have confirmed that, in the absence of a convincing business case, quality interventions have a low probability of widespread adoption and a lower probability of being sustained over time.⁷

What Is a Business Case?

The general notions encompassed in the development of a business case for quality are mostly drawn from nonhealth care industries. For health care, the recent interest in the business case was

generated by the seminal article in *Health Affairs* by Leatherman et al.⁷ In that article, the authors defined the business case and provided an analysis of a series of case studies that sought to confirm the existence of a business case in a variety of commercial settings:

A *business case* for a health care improvement intervention exists if the entity that invests in the intervention realizes a financial return on its investment in a reasonable time frame, using a reasonable rate of discounting.* This may be realized in “bankable dollars” (profit), a reduction in losses for a given program or population, or avoided costs. In addition, a *business case* may exist if the investing entity believes that a positive indirect effect on organizational function and sustainability will accrue within a reasonable time frame.

As the definition suggests, a business case may exist even in the absence of a direct financial return on investment for the organization that implements the intervention. Those situations are addressed in Chapter 2.

Components of the Business Case Analysis

To compute a financial business case for a QEI, three things must be estimated:

1. The costs incurred to develop the intervention
2. The continuing costs of operating the intervention over time
3. The savings, increases in revenues or other quantifiable financial benefits that accrue to the organization that implements the intervention

10 Steps to Create a Financial Business Case

The material that follows outlines and discusses the 10 steps required for any business case analysis:

1. Determining the perspective
2. Describing the QEI
3. Identifying the effects of the intervention on structure, process or outcome measures associated with improved quality of care
4. Designing the study
5. Identifying and measuring cash flows
6. Reporting the effects of capacity constraints
7. Selecting a measure of return on investment
8. Determining the time horizon
9. Determining the “right” discount rate
10. Adjusting costs and savings for inflation

Surprisingly, in our review of the literature,¹ we found that organizations were frequently able to report on the savings or other benefits of a QEI but did not report — or perhaps did not know — what the cost was to develop and operate the intervention over time. Chapter 4 continues this discussion of the literature on the costs of interventions to enhance self management.

For many organizations, determining the costs to implement the intervention and operate it over time should be relatively straightforward. However, someone has to keep track of these costs. If an organization receives external funding to participate in a quality improvement project, resources for tracking investment and operating costs may be

*Discounting in this definition recognizes that \$1 in hand now is worth more than \$1 in the future. That is because a present \$1 can be earning interest or put to work in other ways. For example, if you can invest \$1 at 5 percent, you should be indifferent to having \$1 now or \$1.05 a year from today. You should also be indifferent to having 95.2 cents now and \$1 a year from now because 95.2 cents will grow to \$1 a year from now if invested at 5 percent. Thus, 0.952 is the discount factor for a 5 percent annual rate of return. In our models, we typically discount future savings or expenditures back to the present time. Thus, we express the differences between what we spend on the intervention and what we save as a net present value. A positive business case will result in a positive net present value. Because of this discounting process, future savings (e.g., savings from reduced foot amputations) do not affect the business case calculations as much as savings that occur now.

built into the budget. The Excel templates in Chapter 3 can help an organization track and record the relevant costs.

In the event that no cost savings or revenue increases are anticipated as a result of the QEI, a positive financial business case cannot be shown. A positive nonfinancial business case, however, may be possible (see Chapter 2).

Although the *10 Steps to Create a Financial Business Case* are presented in a linear order, an organization may need to revisit and modify a prior step because of lessons learned. For example, a clinical practice may have initially designed a pre-post study of establishing group visits to augment its diabetes SMS program. Once the study was underway, the practice might have determined that another clinical site was using a similar SMS program and had a similar patient population but was not offering group visits. Under this scenario, the study design could be changed by adding a parallel comparison group even though one was not contemplated at the outset.

1. Determining the Perspective

A financial business case considers only the perspective of the organization investing in the QEI. That is, expenditures required for developing, implementing and operating the QEI and any associated decreases in costs or increases in revenues resulting from the QEI are scored only from the investing entity's perspective. Thus, if a physicians' group practice, for example, implements an SMS system for diabetes care, a business case analysis will only count the cost of implementing the QEI to the physicians' group and the savings or revenue increases directly realized by the group. The business case analysis will not count reductions in emergency department (ED) visits or hospitalizations, which may change costs or revenues for other entities, such as a hospital or payer in the health care system. Neither would it include a monetized value of increases in patients' quality of life or reductions in lost days of work or school from improved outcomes.

This constrained — some may call it myopic — perspective is what differentiates a business case analysis from a cost-effectiveness analysis, which instead takes a societal perspective and thus accounts for costs and savings from the QEI regardless of whom it affects (e.g., the provider organization, the patient, the hospital, other organizations or society as a whole). In their article, Leatherman et al.⁷ compared the “business” case with both the “economic” case and the “social” case. The economic case takes into account the discounted financial benefits and costs, “whether they accrue to patients, employers, providers or payers, or some other segment of society.” The social case extends the perspective to society as a whole, scoring benefits such as increased productivity and improved quality of life. Thus, the economic and social cases expand the perspective beyond the entity making the investment in the QEI.

In a sense, defining the financial business case from the perspective of the entity that invests in the intervention “loads the dice” against interventions that have high front-end or operating costs, that do not reduce costs or produce additional revenues for the intervention site, and that do not pay off in the short term. When these characteristics are encountered, they may serve as a prompt to examine a broader perspective. For example, if an SMS intervention does not pay off for the primary care practice site that initially implements the QEI but results in reduced downstream costs, such as reduced ED visits or reduced hospitalizations, then the insurer to whom these savings accrue should be willing to share its gains with the primary care providers.

The essential questions to be addressed when establishing the perspective in a business case are: Who shoulders the costs? and Who enjoys the savings? Carefully exploring these questions can help identify misalignments of incentives and may suggest ways in which health system incentives could be better aligned. In one case example, a primary care practice had developed improved processes of care for its adult diabetic patients that

produced demonstrable improvements in hemoglobin A1c (HbA1c) levels and blood pressure. The practice also showed lower utilization of the ED and fewer inpatient admissions. Unfortunately, these results were not greeted with enthusiasm by the chief financial officer of the health system in which this practice was embedded because the reduction in utilization meant reduction in revenues for the system. In this example, improved care aligns with a business case at the level of the health insurer that ultimately pays the bills. Recognizing this alignment, some health insurers are now paying quality bonuses to practices that improve diabetes care.

2. Describing the Quality Enhancing Intervention

Only QEIs expressly designed to enhance the quality of health care services provided in a specific delivery setting are considered. The QEI must represent a discrete, identifiable change in the structure or process of care with an identifiable starting point. The selection of a specific intervention should be based on several criteria, including an understanding of the patient population needs and evidence that a particular intervention can positively affect health outcomes. The QEI typically involves a specific segment of the patient population characterized by diagnosis, prior physiological measures, health services utilization, sex and age. The description must specify the intervention, when it began, where and how it was implemented, and what patient population was targeted. A complete description also provides details on the measures of structure, process and outcomes to be tracked over time and some indication of the anticipated changes in those measures resulting from the intervention. The description should also cite the evidence base that persuaded the organization to implement the QEI.

The implementation of a multimodal diabetes SMS program would meet these criteria. The QEI description could include, for example, details of

nutrition education, exercise goal setting, use of community outreach workers, a media center and other components. The description should be sufficiently detailed that other organizations could consider how this SMS might be replicated in their practice or community.

The criterion of a discrete, identifiable change rules out generalized public health measures or media campaigns implemented in a broader community setting. It also rules out generalized quality improvement or productivity improvement programs that, although potentially effective, by their nature continuously select process changes from a broad menu and evolve over time so that patients would be affected by substantially different QEIs at successive points in time.⁸ For example, if an organization conducted in-service training in the principles of quality improvement for its staff, the payoffs in improved efficiency and quality of care could be significant. However, because the impact of many small changes in the system would affect patients with different conditions at different points in the treatment process at various points in time, determining which interventions affected which type of patients and by how much would be impossible.

3. Identifying the Effects of the Quality Enhancing Intervention

An integral part of a business case analysis should be a summary of the effects on quality of care for the affected population in parallel with the cost and revenue consequences. Although changes in quality are not monetized in business case analyses unless they directly affect the cash flows of the investing organization, the presumption is that an intervention must positively affect quality to be worthwhile, regardless of the return on investment. Moreover, budget-neutral interventions that improve quality of care would likely be of interest to most health care organizations. In contrast to QEI-related costs and revenues, quality measures need not be limited to the perspective of the

investing organization — they should also reflect benefits to the patients targeted by the intervention. The only criterion for including a quality measure is that it must reflect care processes or health outcomes that can be directly affected by the intervention. For an organization implementing a QEI that improves patient care but has a negative business case, quality data can provide a solid foundation from which to begin negotiations for realigning payments.

Although quality improvements may be measured in terms of changes in structure, process or outcomes, measures will most likely reflect care processes, such as the percentage of patients receiving follow-up care after an ED visit, the average annual number of *promotora* (community health worker) visits per patient or intermediate outcomes such as HbA1c levels in diabetic patients. Ultimate outcomes such as survival rates or reductions in limb amputations may be difficult to capture in the constrained framework of a business case analysis because patients may be lost to follow-up or the study period may end before such events occur. If data on HbA1c, blood pressure, body mass index or other physiological measures trend in the right direction, it may be possible — using published data — to project savings from the reduction in long-term complications. This approach is explored in greater depth in Chapter 4.

4. Designing the Study

The gold standard for a business case analysis, as with the evaluation of new technologies or drug therapies, is the randomized controlled trial (RCT).⁹ In practice, few business case studies can achieve this level of rigor. First, the presumption of implementing the QEI is that patients in the intervention are receiving improved care based on available evidence. Thus, in some circumstances providers will find randomly assigning patients to a “usual care” control group to be unethical. Second, our experience suggests that many QEIs

are tested within narrowly defined settings and populations. Therefore, carving out a control group might result in sample sizes so small that statistical power would be compromised and contamination that occurs as providers share best practices with colleagues might be impossible to avoid. Third, the research capacity to conduct RCTs may not exist in many health care delivery settings.

Organizations can consider two alternatives to random assignment of patients to experimental and control cohorts. If research rigor is the goal, then a population at another practice site or in another geographic region that is sufficiently similar in relevant characteristics could serve as a comparison group. A viable comparison group helps alleviate concerns about regression to the mean (e.g., patients with extremely high costs in one year whose costs return to the average in subsequent years regardless of any intervention) and about external influences that could affect intermediate outcomes or health services utilization. For many audiences and purposes, however, a pre-post study may be the best that can be done. With sufficient baseline data (before implementation of the QEI) to capture seasonal or other secular effects and trends in the data, a pre-post study can be a sufficient means of assessing effectiveness for management decisions.

To achieve statistical power in many evaluations of QEIs, small cohort sizes dictate that new patients be introduced in the sample to replace those who drop out, in contrast to tracking a fixed cohort through time. If patients added over time are sufficiently similar to those who leave, this approach does not greatly threaten statistical validity.¹⁰ A more vexing problem is how to deal with the dose effect, meaning that patients who join during the intervention may be less affected than those who were present at the time the intervention began. One way to deal with this is to consider “time in trial” as an explanatory variable in the analysis.

5. Identifying and Measuring Cash Flows*

For a pure business case analysis, all cash flows should be incremental (i.e., outflows or inflows that would not have occurred had the QEI not been implemented) and reflect actual flows of resources rather than accrual accounting data. In practice, however, identifying truly incremental cash flows is extremely difficult. Three methodological issues are likely to arise in various settings:¹¹

1. Routinely collected administrative datasets are often the most expedient way to identify utilization changes and related costs. However, the use of administrative data not originally designed for analytic studies poses multiple challenges particular to the specific health care context of any organization. For example, insurance claim files of private-sector companies or public programs such as Medicare or Medicaid are records of financial transactions, which require careful collation to recreate the comprehensive, nonduplicative record of a health care episode. In addition, the billed charges that often appear in insurance claim files may not accurately reflect cash payments or costs. Reimbursed charges may provide a better estimate of cash flow but may not be available. In settings that use a capitation form of payment, the charge or payment information in administrative systems may be a type of “shadow” pricing used as an indicator of cost. Finally, administrative systems will probably not provide information about rate increases or inflation; these factors can confound analyses based on changes in overall service costs.
2. Identifying and measuring investment and operational costs (e.g., personnel, educational materials, equipment and supplies, space, and a share of the organization’s indirect or overhead costs) would ideally be accomplished by using cost accounting information. However, in many health services settings, cost account-

ing systems are unavailable or unable to easily provide the types of specialized data needed for business case analyses. Existing financial accounting systems will likely not provide the level of detail required to fully account for all intervention costs. To estimate the costs of implementing and operating an intervention requires either retrospective surveys or prospective effort reporting from staff involved in the intervention. For example, if a medical director in a health plan or hospital reallocates 50 percent of their time from other responsibilities to the QEI, existing accounting systems will likely not measure the actual hours they devote to the intervention design and operation or the opportunity cost associated with the transfer of hours — that is, the cash flows lost because of the reallocation of effort. Organizations may instead turn to retrospective estimates based on readily available methods of allocation. For example, 50 percent of the medical director’s salary is allocated to the QEI. Alternatively, specially designed time and effort reports can be implemented to track personnel costs for the intervention. These types of estimates might be the only economically viable alternative for obtaining the personnel cost data. However, arbitrary allocations of overhead costs are susceptible to manipulation.

3. Some interventions may precipitate changes in clinical practice, which could either cost money or save money. Again, these changes should only be costed out if they are the direct result of the intervention and not something that is done for patients receiving usual care. We have already discussed gathering cost information on personnel time and operational costs of the QEI. If the intervention being studied also precipitated other changes, such as increasing the number of foot or eye exams or increasing the use or testing of supplies or

*Much of the material in the remainder of this chapter has been adapted from work initially published in the *International Journal for Quality in Health Care* (Reiter KL, Kilpatrick KE, Greene SB, Lohr KN and Leatherman S. “How to Develop a Business Case for Quality.” *International Journal for Quality in Health Care*, 19(1), February 2007.)

medications, then the additional costs of these changes should be included to the extent that they are borne by the entity from whose perspective the analysis is being done. On the other hand, having personnel such as a *promotora* perform tasks formerly done by a physician or nurse may enhance patient care but reduce personnel costs on a per visit basis. Pharmacy costs represent a particularly challenging situation because any increases in drug costs may be covered by a pharmacy benefit carve-out or by the patients themselves. While these costs may be significant, unless they are a direct cost to the practice or insurer whose perspective is taken in the analysis, they are not relevant to the business case. However, they may be relevant to the economic or social case.

6. Reporting the Effects of Capacity Constraints

Because a business case study is typically conducted in the context of an existing organization, the physical facility configuration, staffing mix and levels, and existing equipment may significantly influence both the costs and outcomes of the intervention. An organization with ample capacity may encounter no new costs to accommodate the intervention, whereas an organization with tight capacity constraints may have to add new staff and expand facilities or equipment. Capacity constraints may also dictate whether an intervention is wholly developed and offered within the organization or contracted to a third party, which will affect the cost analysis by requiring that it include the contract costs. Business case analyses should make clear where the organization is operating with respect to its capacity constraints so that replication of the results in another setting can be properly assessed.

7. Selecting a Measure of Return on Investment

ROI should be measured in a way that will resonate with financing departments or budget offices. Three standard ROI measures are available: net present value (NPV), benefit/cost ratio and rate of return. Of the three measures, NPV is superior.

NPV measures the discounted aggregate effect of cash inflows and outflows accruing to an organization as a result of a QEI. Cash flows are discounted at an organization's opportunity cost of capital (e.g., the current borrowing rate) and summed to get a single dollar amount of the financial consequences of investing in a QEI. NPV is the best measure of ROI because it is straightforward and consistent. Regardless of the pattern of cash flows (i.e., inflows vs. outflows) or the classification of cash flows as returns versus costs, NPV will provide a single, easily interpretable result. If the NPV is positive, the QEI adds financial value to the organization. If the NPV is negative, the QEI consumes resources in excess of what are returned. NPV can also be reliably compared with other similarly calculated NPVs to rank multiple projects available to an organization.

The benefit/cost ratio is calculated by dividing returns by costs. Thus, it provides a measure of the financial return that can be expected per monetary unit invested in the QEI. If cash flows are discounted, the benefit/cost ratio is simply a variation on NPV. However, when compared with NPV, the benefit/cost ratio has two weaknesses. First, it allows for discretion in the definition of the numerator and denominator. For example, the costs that are included in "investment" costs (the denominator) may vary from one organization to another. In some benefit/cost ratios, investment costs will reflect only costs to implement a QEI, and operating costs will be subtracted from the savings (the numerator). In others, investment costs may be more comprehensively defined to

include both implementation and operating costs. Because the benefit/cost ratio is a ratio, the final result critically depends on this definition.

Second, in comparisons of multiple projects, the benefit/cost ratio may provide an incorrect ranking. For example, business case analyses of two QEIs may result in benefit/cost ratios of 2.0 and 1.5. However, the NPVs of the two projects might be \$15,000 and \$500,000. The benefit/cost ratio alone would suggest that the first QEI had the best business case, yet the second QEI would create the most value for the investing organization.

By varying the discount rate, an analyst can find the internal rate of return (IRR) — the rate that yields an NPV of zero for any given QEI project. In contrast to NPV and the benefit/cost ratio, a rate of return provides an intuitive way of looking at the magnitude of returns relative to costs and can be compared to a target rate of return, or “hurdle rate,” to determine whether a QEI satisfies an organization’s desired rate of return on its investments. However, calculating an IRR can be challenging. If the pattern of cash flow shows alternating inflows and outflows, the IRR may have multiple solutions. Moreover, organizations may find the identification of an appropriate hurdle rate for process innovations to be difficult.

In light of the weaknesses of the benefit/cost ratio and the IRR, we recommend the use of NPV to measure ROI. In combination with quality information, NPV allows organizations to communicate with finance and budget personnel about the financial consequences of a QEI for the organization. In our experience, financial officers must be convinced that taking on the risk of investing in a QEI is in the organization’s best interests. Making the case for quality investments requires knowledge of both immediate budgetary impact and longer-term payoffs that consider the opportunity cost of the investment.

8. Determining the Time Horizon

In industrial practice of ROI analysis, the time horizon is usually determined by the useful life of

the technology being evaluated. If, for example, we wished to evaluate the ROI for replacing existing manufacturing equipment, we would choose a time horizon over which we reasonably believed the new equipment would be used. For QEI analyses, the choice of project time horizon is often less clear. Process innovations are much less concrete than investments in equipment. Moreover, a significant time lag may occur between exposure to the QEI and the benefits it creates. Patients affected by QEIs may not remain in the care of the investing organization long enough for the organization to realize the benefits.

Because the returns from process innovations such as SMS for diabetes may occur long after the patient is affected by the QEI, business case analyses based on short time horizons may underestimate ROI. However, short time horizons are often required because patients move in and out of programs of care or in and out of a geographic region where a particular intervention is used. The simplest solution may be to set the time horizon to the average time that patients might be affected by the intervention. Alternatives include the exposure time for a given patient cohort, a weighted average to account for actual length of time exposed for all patients, or the average time over which exposed patients are affiliated with the investing organization. Everything else being equal, the conservative approach is to select the shortest reasonable time horizon consistent with the technology and the setting of the intervention being evaluated.

9. Determining the “Right” Discount Rate

Choosing a discount rate is a challenge in any setting. In theory, the discount rate should reflect the risk-adjusted opportunity cost of investing funds in a QEI. That is, it indicates the return given up by not investing the funds in another, equally risky project. In practice, however, organizations may not know either the opportunity cost or the project’s risk. For example, one common measure of opportunity cost is the organization’s cost of borrowing. But organizations funded by governmental

entities may not engage in their own borrowing. Furthermore, public organizations unaccustomed to thinking in terms of return to investors may not be aware of expected returns on alternative investment opportunities. Finally, methods for determining health-related project risk are complicated,¹² and the cost of engaging in such analyses likely outweighs the benefits for the business case.

If the time horizon for a business case analysis is short, the choice of discount rate is inconsequential. Still, organizations engaging in business case analyses should at a minimum acknowledge that some opportunity cost exists to investing in quality and give some reasonable consideration to what that cost might be. Failing to require a reasonable ROI over the long term will result in the eventual depletion of the organization's funds.

Economists can endlessly debate the appropriate discount factor. In practice, because the time period of a business case analysis will likely not extend beyond several years, a discount factor in a reasonable range (e.g., 3 percent to 10 percent) will not likely affect the conclusion.

10. Adjusting Costs and Savings for Inflation

In the absence of a control group, organizations may choose to look at costs and savings from a QEI in real terms — that is, in monetary units indexed to a base year to adjust for the effects of inflation. Analyzing cash flows in real terms separates changes in utilization from changes in price. In a market undergoing rapid price increases, if costs and savings are not brought back to a common base year, the analysis runs the risk of significantly underestimating the monetary savings from the intervention.

In practice, however, adjusting for inflation is a challenging process, because a general medical price index is unlikely to apply to all elements of the cash flows. For example, prices paid for specific services such as hospital stays or physician visits may increase at rates far different from cost elements such as staff wages. Thus, cost elements

must be separated and appropriate deflators applied to each element. Furthermore, if cash flows are inflation adjusted, discount rates reflecting opportunity cost must also be stated in real terms (i.e., inflation adjusted). Over a short time horizon, organizations may want to consider nominal cash flows.

Determining Organizational Readiness for Business Case Development

In our experience with a variety of interventions in both public and private health care delivery systems, we have found that organizations need to ensure that certain conditions are met to accomplish a useful business case analysis:

- Organizational leadership must be committed to the project and the evaluation.
- The intervention must be discrete and definable. Some interventions have value but are so diffuse and idiosyncratic that they have no well-defined starting point and replication elsewhere cannot be reasonably expected.
- Organizations should establish safeguards to ensure that they conduct the business case analysis with integrity and that biases and conflicts of interest do not influence the results.

Table 1-1 lays out some typical antecedents for a successful business case analysis and should prompt more detailed exploration of the feasibility of doing a business case analysis in your own organization. Not all the elements listed are hard and fast requirements. Working around some of the elements is possible. Nonetheless, as pointed out here and in the subsequent chapters of this handbook, designing and conducting a valid business case analysis requires administrative and clinical commitment, thorough preparation, adequate data collection and information technology resources.

Table 1-1: Readiness for the Business Case Check List

1. Do you have a well-defined, evidence-based project that has a specific starting date? A general goal, such as developing a greater focus on family-centered care, is not a project. A project will consist of identifiable tasks to be completed and will typically require additional resources to carry it out. The care delivered after the project is implemented will differ from the care delivered at baseline in definable, measurable ways.
2. Can your organization identify the patients — as a cohort — who will be exposed to the intervention? Can you track them over time? Knowing when a patient is enrolled in the intervention will help establish the “dose effect” of the intervention on that patient.
3. Do you have a system in place — or can you create one — that can quantify what it costs the organization to develop the intervention (e.g., staff time, materials development, information technology system redesign, etc.)? This may require working with a business manager who may not be a member of the project team.
4. Do you have a system in place — or can you create one — that can quantify what the intervention costs to operate over time? This would be the additional operating costs attributable to the intervention, over and above the cost of providing usual care.
5. Can you measure changes in the cost of care or the utilization of services resulting from the intervention? Determining the changes will require that you are able to estimate baseline levels of cost or utilization for the relevant patient cohort.
6. Do you have a system in place — or can you create one — to capture revenue increases resulting from the intervention?
7. Can you identify a quality bonus that can wholly or partially be attributed to the existence of this project?
8. Can you identify additional revenues from offering services that had not been offered prior to the initiation of this intervention (e.g., group visits) or from more comprehensive services being billed at a higher level?
9. Can you measure changes in the quality of care resulting from the intervention? Are those changes in processes of care or outcomes of care? Determining the changes will require that you are able to identify and measure specific quality indicators that you expect the intervention to affect.
10. Do you have a system in place — or can you create one — to capture indirect benefits from the intervention, such as improvements in your organization’s sustainability?
11. Can you measure decreases in days lost from work or days lost from school that could reasonably be attributed to improvements in the quality of care?
12. Can you quantify other economic or social impacts of the improved care?

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Chapter 2

Beyond Return on Investment: Other Financial and Nonfinancial Business Cases for Self-Management Support in Diabetes Care

As a counterpoint to Chapter 1, this chapter discusses measures other than ROI that could compel an organization to implement an SMS system for diabetes care. All organizations, even those with a strong profit motive, recognize that other financial measures of organizational performance are useful and that financial measures alone are not sufficient for long-term organizational survival. This is the line of reasoning that Kaplan and Norton¹ have developed in their “balanced scorecard” approach to the measurement of organizational performance.

All organizations, even those with a strong profit motive, recognize that other financial measures of organizational performance are useful and that financial measures alone are not sufficient for long-term organizational survival.

As previously noted, many health care delivery organizations face considerable headwind when attempting to establish an ROI-focused financial business case. This may be the result of misaligned

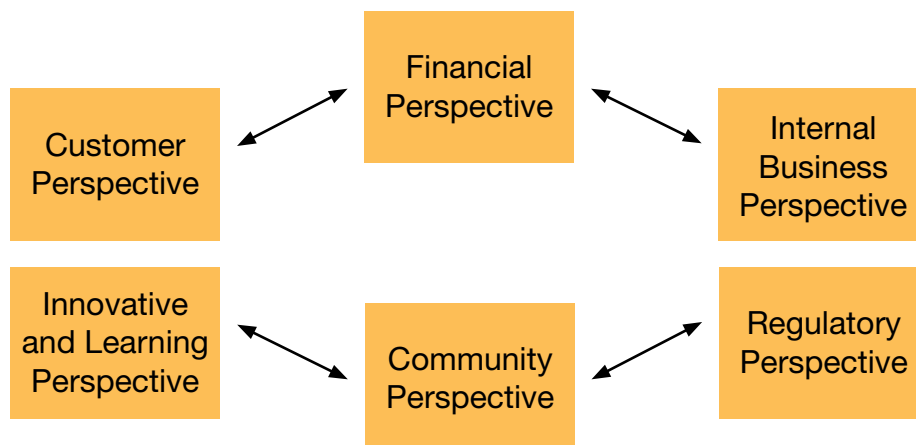
incentives in a fragmented health care system in which savings to one entity may result in reductions in revenue to another entity. We also noted that although the framework for a business case is conceptually straightforward, actually quantifying the costs, savings and revenue consequences of an intervention may exceed the capacity of an organization’s cost accounting and information technology systems. These concerns extend to even the most sophisticated of service delivery organizations or health insurers, whose accounting systems are designed to create or pay bills, not to evaluate health services interventions.

Although some of these impediments to the development of a financial business case are now becoming more generally recognized and slowly being reduced, even if the data barriers to developing an ROI were to be resolved completely, business case arguments other than ROI must be carefully considered.

An Expanded Framework for the Business Case

Norton and Kaplan organized their performance measures by four perspectives: financial, customer,

Business Case Perspectives



internal business, and innovation and learning. They argued that strength in all four perspectives and balance among them are essential for organizational growth and long-term survival. In the current context, we add two additional perspectives: regulatory and community. Each perspective contains measures beyond ROI that should be considered in making a business case for SMS.

Financial Perspective

As noted in Chapter 1, ROI is a compelling approach to establishing a business case because it ties all present and future expenditures required for a given quality intervention to all the present and future savings or revenue increases generated by the intervention and discounts them back to present dollars. Thus, a properly computed ROI encompasses the total picture of the real cash flows for the organization at risk. To be truly convincing, the costs, savings and revenue increases used in the ROI calculation must also be compared to those of a control group so that financial and quality changes can be attributed confidently to the intervention and not to factors that have affected all similar patients regardless of the care process.

So what can an organization do if it wants to justify the implementation of a program financially but does not have all the data required for a full ROI calculation? Several alternatives are possible. We highlight three: achieve budget neutrality, compute the “bang for the buck” and deal with displaced benefits.

One of the most appealing financial measures in the current climate of constrained resources is budget neutrality. If by implementing supports for self management an organization can simultaneously show increases in quality of care and improve the efficiency of the care delivery process by other means (e.g., implementing group visits, assigning tasks to volunteers or lower-paid personnel), then increased quality can be demonstrated at no increase in cost (i.e., budget neutrality). Although budget neutrality by definition results in a zero ROI, arguing against implementing a project that

improves care at no overall increase in cost would be difficult, unless accomplishing it would divert resources from positive ROI interventions.

If budget neutrality cannot be achieved because the implementation of SMS costs more than the previous system, then an argument may be made that SMS gives more “bang for the buck” than alternative uses of the organization’s financial resources. In other words, the measurable increases in quality are worth the increased expenditure of resources because no other intervention is likely to improve care as much as SMS. This approach is usually called cost-effectiveness analysis. It requires that the organization gather two essential kinds of information.

First, the organization will need to know the costs of implementing and operating the new program. These costs include personnel, educational materials, equipment and supplies, any new space required, and a share of the organization’s indirect or overhead costs. (The spreadsheet templates in Chapter 3 may be helpful in this exercise.)

Second, careful measurements of the changes in quality that occurred as a result of the new program must be collected. These include process measures such as increases in the percentage of patients receiving tests for HbA1c, retinal exams and nephropathy screenings; patient physiological measures such as HbA1c levels, low-density lipoprotein, blood pressure and body mass index; measures related to patient satisfaction and quality of life; and measures of staff satisfaction. Identification of the desired process and outcome measures, the design of data-gathering instruments and processes, and the means of analyzing and reporting these data will clearly need to be developed and in place before the intervention begins.

With both the cost and outcomes data in hand, an assessment can be made of the incremental increase in cost for the observed level of quality improvement. The business case argument from the perspective of the implementing organization then becomes that the measurable level of quality

enhancement for SMS exceeds or equals the level of quality enhancement that could be achieved through alternative uses of the organization's resources. (Incidentally, this process of quantifying costs and outcomes will force the advocates of other alternative treatments, such as using new medications, to justify their claims for quality enhancement with similar objective data, which is good organizational discipline.) This example assumes that comparisons are being made between alternative care processes for similar patients. If potential quality enhancements for different types of patients are being compared, the analysis becomes more complicated. If, for example, an organization wished to compare the costs and quality gains from SMS for adult patients with diabetes to the costs and quality gains resulting from enhanced prenatal services, then some common quality metric — such as quality-adjusted life-years — must be used for both groups of patients. Unfortunately, in the real world of financial management, quality-adjusted life-years do not resonate strongly with the chief financial officers of organizations. Hard data on increased cash flows or reduced operating costs resulting from an intervention are likely to be more persuasive.

Making a financial business case becomes more complicated when the benefits accrue to organizations other than the entity making the investment in the QEI. An example of displaced benefits was discussed in Chapter 1, in which the costs of the QEI were borne by a primary care practice but the reductions in utilization of the ED and in inpatient hospitalization were realized by an affiliated hospital. In this case, the ultimate beneficiary of the savings would be the health insurer for the affected patients. If benefits are displaced, the task for the organization that delivers the improved care is to leverage the downstream benefits to extract gain-sharing payments from the organization that receives the benefit. Enlightened health insurers have provided quality bonuses or incentive payments to individual group practices and

health plans that implement QEIs designed to maintain glycemic control and enhance health status in patients with diabetes.

Mercy Clinics, a large, multispecialty group practice in Des Moines, Iowa, successfully implemented a patient SMS system for adult diabetes care and also created a strong business model to sustain these quality interventions over time. Mercy Clinics was able to leverage its successful quality enhancements into additional payments for patient education from Wellmark, which covers 25 percent of its patients and is its largest insurer. These are billed at the same time as an evaluation and management service.²

When Wellmark was looking for a delivery organization to do innovation work to improve outcomes in diabetes for the state of Iowa, it was ready to explore QEIs. Mercy Clinics had been tracking data on adult diabetes care in two practices, and it had data on the percentage of patients whose testing was completed and the percentage who were meeting their goals. Wellmark wanted to test a pay-for-performance (P4P) system for meeting guidelines, and Mercy Clinics had the disease registry in place that could provide the required data. Recently, the P4P arrangement between Mercy Clinics and Wellmark generated the maximal total payment of several hundred thousand dollars for all 25 providers involved. Wellmark believes that quality initiatives such as SMS and outcomes tracking and reporting reduce its costs by reducing complications as well as ED and hospital visits. These P4P payments — along with increased billings for group visits, proper coding for enhanced visits and increased revenues from internal laboratory services — provided a positive business case for the clinic's expanded SMS services for adults with diabetes.

David Swieskowski, vice president for quality at Mercy Clinics, summarized the experience:²

[Physicians] have the power to make all the changes they need to deliver excellent care and still make money. They must look for new ways to deliver care, work in

teams, and have trained folks around them to help. With a registry, planned or group visits, and SMS, physicians can deliver excellent care in a way that is financially sustainable.

Another example of P4P is provided by the Monroe Plan for Medical Care in Rochester, New York. (JA Stankaitis, 2004, personal communication) The Monroe Plan is a managed care organization serving low-income individuals and the working poor with a mission to improve the health status of enrollees and their families. Excellus BlueCross BlueShield in New York state contracts with the New York State Department of Health (NYSDOH) to provide health care services to the Medicaid population on a per-member per-month (PMPM) capitation basis. Excellus, in turn, contracts with Monroe by providing a PMPM capitation payment that places Monroe at full risk for providing the contracted health care services.

NYSDOH assesses plan performance against its quality assurance reporting requirements and has recognized Monroe as one of the consistently best Medicaid managed care entities in the state by awarding it a full 1 percent increase in premium revenue — the maximum award — as part of NYSDOH's Quality Incentive Program. This added revenue has amounted to approximately \$1 million annually in recent years. A proportional share of this added revenue can be attributed to the plan's diabetes initiative. The Quality Incentive Program was initiated to encourage the provision of high-quality health care, which the state expects will lower the total cost of Medicaid services.

Aetna announced in May 2007³ that it has incorporated Bridges to Excellence (BTE) into its P4P programs for its contracted family practice and internal medicine physicians in the state of Washington. BTE is a physician recognition program designed by the National Committee for Quality Assurance (NCQA) and its partners — the American Diabetes Association, American Heart Association and American Stroke Association. The

program “encourages high-quality health care by providing financial incentives to health care providers who demonstrate safe, timely, effective, efficient, equitable, and patient-centered care.”

In the Washington state market, Aetna provides health benefits to approximately 280,000 members, who have access to a network of 90 hospitals, almost 4,000 primary care physicians and more than 7,700 specialists. Internal medicine and family practice physicians who are recognized by BTE are eligible for incentive payments of \$100 per year per diabetic patient and \$100 per year per heart/stroke patient. Those payments are in addition to what physicians receive for professional services provided to those patients.

A current summary of P4P initiatives is maintained on the Healthcare Financial Management Association Web site.⁴ Although the impact of P4P on health care quality has been mixed,⁵ these examples indicate that health care insurers, Medicaid and Medicare are experimenting with financial incentives to reward interventions they believe will improve the quality of care for their members and beneficiaries and ultimately lower the costs of care for targeted patient populations.

Internal Business Perspective

Kaplan and Norton¹ characterized the internal business perspective as identifying customer needs, translating those needs into products, improving the production and delivery processes, and following up with customers after product delivery. These elements can also be considered in our current context. Moreover, it is useful to step back and consider how a proposed intervention such as patient SMS fits with the mission of the organization and whether the implementation of the intervention will likely be facilitated or impeded by the internal organizational culture. (Other examples on these points have been provided by Bailit and Dyer.⁶)

Even if an intervention cannot be shown to have a viable financial business case, an organization

may still pursue the intervention if it is consistent with its mission and goals. However, the “it’s our mission” argument does not relieve the organization of its obligation to know what the intervention costs and what changes in quality it produces. Rather, when the actual or projected costs and outcomes are available, the organization can make an informed decision that the level of increase in quality is sufficiently large that it should be undertaken as long as the drain on financial resources does not threaten the organization’s long-term survival.

An example of this line of reasoning was reported by the Group Health Cooperative (GHC) in Seattle.⁷ A detailed analysis of GHC’s smoking cessation program, Free & Clear, was one of seven case studies for The Commonwealth Fund’s business case for quality project. GHC achieved 25 percent to 30 percent quit rates measured after one year — a high percentage for this type of program. Despite the fact that smokers are estimated to have \$1,041 more in medical costs per year than non-smokers, GHC was unable to demonstrate a convincing ROI for Free & Clear, either for its own enrollees or for enrollees of other plans to which it sold the program. Part of the difficulty in making the ROI case was that many of the applicable program costs were difficult to measure accurately. More importantly, participants in the smoking cessation program were known to cost GHC more while undergoing treatment, and the cost savings were estimated not to occur until at least three years in the future. In that time, the successful quitter may be employed elsewhere or participate in another health plan. Furthermore, the health care costs of former smokers are still greater than those who have never smoked, thereby attenuating the potential savings from the program.

Tim McAfee, MD, chair of the Tobacco Use Subcommittee of the Committee on Prevention at GHC, related the smoking cessation program to GHC’s core mission:⁷

We are in the business of helping people preserve and improve their health. There

is demonstrably no cheaper, more effective way to do this than helping people to quit smoking (with the possible exception of childhood immunizations). If you don’t step up to the plate on this, then you aren’t really in the business of helping people preserve, restore, and improve their health; you are just in the business of trying to make money by lowering costs.

From the perspective of the leadership at GHC, the smoking cessation program was continued even in the absence of a positive ROI because it was consistent with the core mission of the organization. Of note, however, is that GHC had other business lines that were sufficiently profitable to carry the smoking cessation program.

Closely akin to implementing an intervention because it is consistent with the organization’s mission is the decision to support an intervention because it sends a message that the organization is committed to quality care. Being known for a culture of quality can have both internal and external benefits for an organization. The internal benefits can include a higher level of staff satisfaction (which can increase staff retention and lower recruitment and retraining costs), increased productivity and higher profitability. By definition, a culture of quality provides benefits to the patients that, in addition to improving patient care, are reflected in patient satisfaction scores.

Stubblefield⁸ discussed how he and his team developed a culture of quality at Baptist Health System. Baptist achieved a competitive advantage by transforming an organization that was performing poorly on virtually every measure of patient and staff satisfaction into one that is now considered among the best health care systems in the country. Stubblefield notes that improving Baptist’s corporate culture and patient satisfaction has led to increased employee loyalty and workforce stability, higher levels of productivity and greater profitability.

At CHRISTUS Health, researchers also found statistical evidence that good quality enhances

long-term profitability.⁹ In addition, Stelfox et al.¹⁰ found a correlation between low patient satisfaction scores and higher recorded complaints from patients, more risk management episodes, and higher rates of malpractice lawsuits. Thus, a culture of quality does more than simply make the staff feel good about their organization, it makes good financial sense as well.

Measures of performance from an internal business perspective also include process measures such as patient throughput time, efficient use of staff and other scarce resources, and patient waiting time. A comprehensive summary of tools and techniques available to produce a business case for process efficiency can be found in work done for the Health Resources and Services Administration (HRSA) as part of its Finance and Redesign Pilot Collaborative.¹¹ With the approaches outlined in this handbook, an organization can make efficiency improvements that can free the resources needed to improve quality and expand the scope of its services. Making these internal improvements is fully consistent with the budget neutrality goal previously discussed. A note of caution is in order, however. Do not confuse the business case that results from implementing the QEI itself with the business case for improving efficiency at the operational level. Improving efficiency is always a desirable goal, but improved efficiency does not necessarily result in improved quality.

Regulatory Perspective

All health care providers must meet federal and state regulatory requirements. To obtain commercial contracts, providers must also meet the conditions of participation of Medicare, Medicaid and, increasingly, commercial third-party payers. Although governmental conditions of participation at one time addressed only basic health and safety standards, current requirements frequently specify that quality assessment and performance improvement systems be in place as well. States have also designed their own requirements for Medicaid providers to participate in quality improvement

projects or risk sanctions or unfavorable press. Thus, a compelling business case can be made for complying with all conditions of participation or the organization risks the loss of revenues from government and private payers.

Organizations accredited by the Joint Commission are deemed by the Centers for Medicare and Medicaid Services (CMS) to have standards that equal or exceed the standards set forth in the federal Conditions of Participation and Conditions for Coverage. The Joint Commission accreditation process provides a formal link to a private organization making a determination that affects the Medicare and Medicaid certification of a provider. Thus, if the Joint Commission strengthens its requirements for patient safety or health care quality, an immediate business case is made for providers subject to Joint Commission accreditation to collect and report the required quality measure data and initiate the required quality improvement programs.

NCQA accreditation of health plans is voluntary but nonetheless quasiregulatory from the perspective of the plans. The federal Medicare Advantage program recognizes NCQA accreditation as meeting many of its central quality standards for managed care organizations and preferred provider organizations (PPOs). The U.S. Office of Personnel Management requires its fee-for-service plans offering PPOs through the Federal Employee Health Benefits Program to collect and report quality performance measures. Furthermore, several states now recognize NCQA accreditation as a mechanism to assist its health plans to meet state managed care requirements.

A health plan may need NCQA accreditation to compete successfully for state Medicaid or commercial contracts. Bailit and Dyer⁶ discussed the situation of HealthNet in California, which let its NCQA accreditation lapse in October 2000. Immediately thereafter, the Pacific Business Group on Health (PBGH) “issued a strong press statement against the plan’s intention, and some PBGH purchasers froze enrollment in HealthNet,

communicated the plan's lack of NCQA accreditation to its employers and the importance of accreditation and offered additional 2001 health plan options from NCQA accredited plans." By July 2001, HealthNet was successfully reaccredited by NCQA and announced its strong endorsement of the NCQA accreditation process. So, although NCQA had no official standing as a regulatory agency, it took on a quasiregulatory role in this instance.

The National Quality Forum, the Hospital Quality Alliance, and the Agency for Healthcare Research and Quality (through its National Quality Measures Clearinghouse), among others, all provide guidance on quality measures and benchmarks that providers should meet. At present, these standards are voluntary, but nothing currently prevents a state Medicaid agency or commercial insurer from adopting these standards or others as minimal requirements for participation.

Under these conditions, an organization having a well-developed quality improvement program and a high profile as a quality health care provider could be seen as meeting a *de facto* regulatory requirement.

Community Perspective

The community perspective encompasses a broad spectrum of stakeholders and interests. An organization delivering health care services seeks to shape its image in the community in ways that will maximize its competitive advantage and long-term survivability. Similarly, the community will attempt to mold the health care delivery organization to meet its needs, which sometimes are in direct conflict with the business objectives of the organization. This is especially true for delivery organizations such as community health centers, which are established by the community to meet needs not being met by other area providers.

Providers that must generate revenues to achieve their financial objectives may find that a business case can be made for creating an image as a quality provider. Enhancing a provider's reputation

for quality may generate greater patient volumes, expand market share and permit the provider to target product lines consonant with its business objectives. For example, a community hospital may seek to enhance its image as a quality provider of obstetrical services with the intent of attracting patients to its women's health and pediatric services, which typically have higher contribution margins than obstetrics.

A delivery organization can improve its reputation for quality through some of the formal regulatory or quasiregulatory means discussed above. Accreditation at the highest status levels confers bragging rights that can be exploited in advertising or in campaigns to attract third-party contracts. In some states, Medicaid uses its power of autoassignment to reward providers that have distinguished themselves as high-quality providers. Whatever mechanism is used, the organization's goal is to expand market share and enhance cash flow.

Public release of provider quality data through such programs as the Joint Commission's Quality Check system (www.qualitycheck.org) or CMS' Hospital Compare system (www.cms.hhs.gov/HealthCareConInit), which provides comparative data on selected quality measures for a set of hospitals the user selects, is beginning to alter the landscape regarding the kinds of information on quality available to consumers. Although it is currently rudimentary, CMS provider quality data systems will eventually provide explicit quality ratings for hospitals, nursing homes, physicians and other providers. Patient satisfaction and surgical complications data are projected to be added within the next year,¹² and later the system is expected to include quality of care information for hospital outpatient settings. CMS intends to integrate other data from a variety of public and private sources.

Although not yet available, CMS plans to have comprehensive data on quality and cost so that consumers can search for providers offering diabetes care in their area and see how they rate.

CMS says that “this tool could show results sorted by the name and location of the provider (location), the provider’s quality of care, and the cost of the services overall and to the patient (using insurance information).” As public data on quality become more readily available and more usable, the business case for creating a reputation as a quality provider will become better defined and communicated, and more urgently demanding of providers’ attention.

Perhaps the most arduous route to enhancing an organization’s image as a quality provider is to compete for recognition from external organizations such as the Malcolm Baldrige National Quality Program (www.quality.nist.gov). Baldrige pushes an organization beyond the requirements of accreditation to become consumer focused, quality oriented and data driven.⁸ The enhancement in brand identity and image that results from achiev-

An organization’s effectiveness in the short term and sustainability in the long term depend on the investment it makes in its people, production processes and information systems.

ing Baldrige recognition is considered to be worth the investment in resources required to compete successfully for the award.

Community stakeholders can also shape the mission of a community provider in ways that constrain the organization’s flexibility and viability. If, for example, an organization is developed with the express purpose of providing health services to migrant workers, the notions of revenue generation and enhancing cash flow are not likely to be viewed as particularly central to its mission by officials who oversee its budget. If the budget is provided by the government or foundations, the principal financial objective of the organization is to provide services of acceptable quality to the maximum number of patients. The business case from the community’s perspective is made by reducing lost

days of work or school for the patients; reducing the impact of this population on other community health, education and social services; and enhancing the welfare of the community as a whole. From the funders’ perspective, a business case would typically mean that the organization did not exceed its budget and expended the resources in the categories of activities for which the resources were provided. When looked at from the perspective of those community entities providing the resources, the expectations for quality health care are much broader and much more challenging than simply achieving good care processes and health outcomes for a specific cohort of patients.

Innovation and Learning Perspective

An organization’s effectiveness in the short term and sustainability in the long term depend on the investment it makes in its people, production processes and information systems. These investments are treated as accounting costs and directly reduce profitability or cash retention in the current period. However, the business case for an organization to invest in innovation and learning is so persuasive that its merits are rarely debated.

A parallel business case can be made for investment in QEIs such as SMS for diabetes. As previously noted, investment in quality can increase employee satisfaction, productivity and retention. A quote from Cheryl Scott, CEO of GHC at the time of the case study,⁷ underscores this point:

In a world where there are employee shortages, tobacco cessation and chronic care are incredible tools for persuading people to work for Group Health rather than somewhere else. They give employees pride about what they are doing. Programs like these have a huge intangible benefit in the kind of people we recruit, the kind of organization you have, the spirit of the place, and the kind of consumers who

choose you. These programs are fundamentally important and should never be discounted because they become the stories of the organization, building its culture and giving the organization meaning.

Furthermore, investment in SMS requires improvements in the processes of care, the measurement of process improvements and health outcomes, and the enhancement of information systems to track progress. Whether the change is a new disease registry to identify and track patients, a new quality-of-life measurement instrument, or a group visit model, changes made to implement SMS in diabetes permeate the organization, positively affect other service lines and send tangible messages to reinforce a culture of quality in the organization.

The degree to which changes in processes and information systems affect employee satisfaction, retention and productivity can be measured and tracked. If coupled with other approaches to empowering employees, such as expanding the rewards for employee suggestions for improvement, the SMS program in diabetes can serve as a catalyst for innovation and learning throughout the organization. The business case resulting from this shift in culture can be substantially more powerful than a short-term financial business case.

Customer Perspective

When we think of customers in a health care context, our immediate association is with patients or clients. The patient is clearly the most important customer and the one from whose perspective the performance of the system of care must ultimately be judged. But, as anyone who works in health care can attest, other customers must be satisfied for an organization to remain viable. These include governmental and commercial payers; local, state and federal agencies and foundations that provide either direct or indirect financial support; and a host of regulatory and licensing bodies without whose approval the organization could not function.

Successfully making a business case for SMS in diabetes means identifying the customer and presenting the business case from that perspective. Every entity in the system should be interested in documented process improvements, improvements in intermediate or ultimate health outcomes, and measures of patient satisfaction and health-related quality of life. Other customers may have specific interests beyond clinical quality of care that, if properly addressed, could garner their support for the intervention. For example, in addition to the patient-focused measures mentioned, a state Medicaid agency may be interested in decreases in lost days of work or school for the population targeted by the SMS intervention. Although not directly related to either the mission of the health care provider or the Medicaid program, measurable improvements in these social measures can help the Medicaid program sell its budget to the state legislature. If your program makes your payer or funding organization look good, then future support from these sources is more likely to be forthcoming.

Kaplan and Norton¹ identified five core measures related to customers: market share, customer acquisition, customer retention, customer satisfaction and customer profitability. In our current context, a useful exercise is to identify principal customers and determine measures that relate to that customer for each of these dimensions. It has been our purpose in this chapter to suggest customer perspectives and measures that may not have come readily to mind previously and to suggest how a business case might be made from these new perspectives.

Summary

Making a business case for quality involves more than computing ROI. Other perspectives, including the internal business perspective, the regulatory perspective, the community perspective, the innovation and learning perspective, and the customer perspective, are all vital. Each perspective

suggests relevant measures on which to build a business case for SMS. The perspective that is most persuasive depends on the context and the audience. The core message of this chapter is that the ROI business case is not the only business case that can be made and, in some circumstances, may not be the most powerful. Health care delivery organizations and their community partners are complex and multifaceted; the effective business case must be multifaceted as well.

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Chapter 3

Spreadsheet Models for Computing Return on Investment for Self-Management Support

The heart of this chapter is the Excel spreadsheet models that can be found on the CD that accompanies this handbook.* The instructions for their use are included in Appendix A. An example of the use of the models is provided on the CD and in Appendix B.

As discussed in Chapter 1, creating a financial business case analysis requires the collection of three types of data:

1. The costs incurred to develop the intervention
2. The continuing costs of operating the intervention over time
3. The effect on revenues and other quantifiable financial benefits or costs that accrue to the organization implementing the intervention

There is a separate spreadsheet (tab) for entry of each of these types of data. Each spreadsheet displays categories of expense or revenue (cells) for the user to fill in. Once the input data are complete, the program will compute the ROI for the intervention. In essence, two analysis options are available to the user:

1. Before-after analysis
2. Before-after analysis compared with a control or comparison group

To affect the analysis compared with a control or comparison group (option 2), the user must have revenue and/or cost data for the control or comparison group in exactly the same format as for the intervention group. If a control or comparison group is not available, the results of the intervention will be compared with a baseline period before the intervention (option 1).

Two ROI spreadsheets are available: one without the control or comparison group and one with the control or comparison group. The ROI computations are automatically completed and

displayed by the program by linking the investment, operating and revenue data to the ROI spreadsheets.

The ROI spreadsheets provide alternative measures of ROI as discussed in Chapter 1:

1. Undiscounted values of the net cash flows by year beginning with the baseline or pre-implementation year
2. Discounted NPV of all cash flows
3. Cumulative ROI by year
4. Internal rate of return

Positive values of these measures indicate that the project has a positive ROI. Negative values indicate that the project does not pay for itself in the time period used in the analysis (set at three years in the spreadsheets). As discussed in Chapter 1, each measure of ROI has its uses. Financial analysts typically look at the discounted cash flows as the primary indicator of return, but other measures are useful as well. Some accountants prefer to see the undiscounted cash flows. When the discount rate is low, little difference exists between the undiscounted cash flows and the discounted cash flows in any case.

Also displayed is the cumulative rate of return of each project year. For a project that returns more in revenues and cost savings than it costs in operational costs, the cumulative rate of return would typically increase each year. If, for example, the cumulative rate of return at the end of three years of operation is 3.0, the ratio of cumulative discounted gains divided by the discounted investment and operational costs at the end of three years is 3:1. A ratio of 1:1 is a break-even situation at the discount rate selected. A ratio less than 1:1 indicates that the project is losing money.

Finally, also displayed is the internal rate of return, which will be positive for a project returning

*The spreadsheet models and the accompanying Appendix A have been adapted from work done in connection with grants to the University of North Carolina supported by The Commonwealth Fund and the Center for Health Care Strategies.

more than it costs. The higher the internal rate of return, the better. As discussed in Chapter 2, however, there may be other reasons to continue the project even in the face of negative ROI.

With this brief background, you may now want to open the spreadsheet models themselves for a tour or turn to Appendix B for a case study example.

Appendix A

The Business Case for Self-Management Support

Using the Return on Investment Template

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Acknowledgements

Earlier versions of the return on investment template and the related supplemental instructional manual were developed at the University of North Carolina and supported by a grant from The Commonwealth Fund and through collaboration with the Center for Health Care Strategies.

Tab 1. Instructions for Using the Return on Investment Template

Proposed Use

The ROI template was designed to allow organizations to analyze retrospectively the ROI on QEIs. The ROI model seeks to determine whether revenues or cost savings by the QEI study population will increase sufficiently after the implementation of the QEI to justify the additional expenditures necessary for its implementation and operation.

Design of the ROI Template

The ROI template is a Microsoft Excel model consisting of three required data entry spreadsheets, one optional data entry spreadsheet and three output spreadsheets. Each of the output spreadsheets is linked to the data entry spreadsheets so that information flows directly to the ROI calculations. Cells in the spreadsheets are color coded so that users can identify places where data must be input by the user and places where calculations are automatic. The color-coding scheme is described below and in Tab 1 (Instructions) of the Excel handbook.

Green cells are input cells that allow direct data input by users



Yellow cells are intermediate calculations (*These cells contain formulas and should not be edited.*)



Gray cells are key outputs (*These cells contain formulas and should not be edited.*)



Data Entry Spreadsheets

Tab 2. Investment Cost Data

General Information

The first spreadsheet in the model captures the personnel and nonpersonnel costs required to develop the QEI and bring it to the point of implementation. **A central principle for determining what costs to include is that the investment cost should reflect any cost that the organization incurred to get the QEI implemented that**

it would not have incurred in the absence of the QEI. Thus, in cases in which the activities necessary for developing the QEI were also used for other projects or reflect ongoing business practices, only include the portion of the costs that would not have been incurred if the QEI had not been developed. This requirement does not, however, preclude the recognition of opportunity costs. For example, a portion of the chief financial officer's (CFO) time might be devoted to QEI development. The CFO's salary would be paid regardless of whether the QEI was developed, yet you may wish to recognize that, in the absence of the QEI, the CFO could have devoted time to another project.

Cost categories have been provided as examples of the types of costs that might be incurred in QEI development and implementation. Broad categories include personnel, contracted services, office operations, equipment, and construction or renovation. However, individual line items may need to be tailored to reflect your specific circumstances. Data do not have to be entered into every cell. A column for personnel names and/or notes is provided for your convenience.

Data Requirements and Calculations

Specific instructions for entering data and descriptions of spreadsheet calculations are provided below.

Line 9. Reporting period: Enter the beginning and ending date for the period over which the data are reported.

Column C. FTE%: Enter the full-time equivalent percent effort devoted to the QEI by each individual involved in QEI development. For dedicated personnel (new hires or existing hires devoted entirely to the QEI) the percent effort will be 100 percent. For existing personnel who devote a portion of their time to QEI development, a rational allocation system should be used to determine percent effort. For example, the individual could submit timesheets tracking time spent on different projects.

Column D. Salary and fringe: Enter the salary plus fringe benefits for the relevant reporting period for all key personnel. For example, if the preimplementation period (the investment period) is one year, enter the annual salary plus fringe benefits. If the investment period spans multiple years, enter a weighted average of the relevant annual salaries.

Column E. Cost: The spreadsheet will automatically calculate personnel costs by using the formula $[FTE\% \times \text{Salary and fringe}]$. Other costs must be input by the user. For each relevant cost category in lines 43 through 58, enter the direct costs (costs incurred that are directly attributable to the QEI) for the designated reporting period. The organization's general ledger (from the accounting system) should contain detailed transactions (dates and amounts) affecting revenue, expense and capital (property, plant and equipment) accounts. However, note that costs may not be tracked by project in the accounting system and may need to be allocated by using source documents (e.g., telephone bills, project copy codes) or another rational allocation system.

Line 59. Subtotal, direct costs, initial investment: The spreadsheet will automatically calculate the subtotal by summing all personnel and nonpersonnel costs.

Line 60. Indirect cost %: Indirect costs are costs that cannot be directly traced to the QEI, such as rental expense for space, utility costs and costs of support departments such as payroll. Although these costs would be incurred regardless of whether the QEI was developed, a portion of indirect costs may be allocated to the QEI to reflect the opportunity cost (e.g., resources such as space devoted to the QEI that could have been used for something else). Because these costs are not directly traceable to the QEI, they must be allocated in a rational and defensible manner. Many organizations choose to allocate indirect costs as a

percentage of direct costs. If you choose this method, enter your organization's established rate (if there is one) or a reasonable percentage of direct costs.

Line 61. Indirect costs, initial investment: If you entered a percentage in the previous cell, the spreadsheet will automatically calculate indirect costs by using the formula [Direct costs x Indirect cost %]. If you choose to allocate indirect costs in another way, enter the actual indirect costs here and document the method of allocation.

Line 63. Total costs, initial investment: This cell reflects the sum of direct and indirect costs. The amount shown in this cell flows to Tab 7, ROI Analysis, and Tab 8, Incremental ROI Analysis, where it appears as initial investment costs in the preimplementation period (line 14).

Tab 3. Operating Cost Data

General Information

The second spreadsheet in the model is identical to Tab 2, Investment Cost Data, except for the time period covered. The operating cost data worksheet captures personnel and nonpersonnel costs required to operate the QEI over time, *after it has been implemented*. The same inclusion principle applies: **Operating costs should reflect any costs that the organization incurred to operate the QEI that it would not have incurred in the absence of the QEI.** The reporting periods entered on line 10 under the headings Year 1, Year 2 and Year 3 should reflect years of operation for the QEI and should mirror the reporting periods for the revenue data entered on Tab 4, Revenues: Intervention. Three years of operating cost data collection are allowed but not required. The key outputs from this worksheet are found in the gray cells on Line 62, Total costs, operating. The amounts shown in these cells flow to Tab 7, ROI Analysis, and Tab 8, Incremental ROI Analysis, where they appear as

operating costs in intervention years 1, 2 and 3 (line 15).

Tab 4. Revenues: Intervention

General Information

The third spreadsheet in the model captures the revenue increases or cost savings to the organization resulting from the investment in the QEI. The worksheet is designed to measure changes during the intervention years compared with a baseline period *for the group affected by the intervention*.

The results produced in this worksheet reflect a simple pre-post analysis. No control is used for inflation effects or regression to the mean.

Revenues or cost savings are broken down into broad categories, including inpatient care, long-term care, outpatient care, office-based care, emergency department (ED) care, ambulance and emergency transportation, home health care, pharmacy, laboratory, other, and quality bonus payments or pay-for-performance (P4P) payments on a per-patient basis. A typical organization delivering care to diabetic patients will not require this many categories of patient activity. Simply leave blank the categories that do not apply to your organization. Alternatively, you may want to replace some of these categories with revenue sources specific to your organization. For example, you may want to indicate revenues from patient education or group visits.

Most organizations will need to calculate the increases in revenues or the cost savings offline and then enter these values into the spreadsheets. Revenue increases and cost savings may depend on case mix or other factors. In some cases, an analyst may wish to enter data that represent the best available estimates. Remember that these ROI analyses are being developed from a particular organization's perspective. For example, if a physicians' group practice is the organization that implemented SMS for diabetes, only revenue increases and cost savings at the level of the group

practice are relevant to the analysis. Do not include savings accrued to other entities, such as decreases in ED visits, unless the ROI analysis will encompass the broader perspective that includes the ED's revenues and costs.

Data Requirements and Calculations

Specific instructions for entering data and descriptions of spreadsheet calculations are provided below.

Column B, lines 12-22. Baseline per-patient per-month (PPPM): Enter per-patient per-month revenues or cost savings, by category, for the period (typically a year) immediately before the implementation of the QEI. These data serve as a baseline against which revenues or cost savings in the intervention years will be measured.

The use of PPPM revenues and costs may at first appear artificial in a fee-for-service environment, where revenues typically are presented on a per-visit basis. We have chosen to use PPPM revenues and costs because we are interested in the total gains and losses generated by a cohort of patients affected by the intervention over the course of many months or several years. Revenues and costs on a PPPM basis can be computed from average per-visit values by multiplying by the average total number of patient visits per year and then dividing by the average number of patients in the cohort multiplied by the number of months during which the intervention was active during the year. For some type of revenues, such as capitation or P4P revenues on a PPPM basis, no conversion is necessary.

Columns C to E, lines 12-22. Intervention Yr 1-3: Enter PPPM revenues or cost savings, by category, for the years the intervention was operational. The reporting periods should mirror the reporting periods for operating costs in Tab 3, Operating Cost Data. If desired, revenues or costs may be adjusted for price increases in each of the categories before entering the data on the worksheet.

Columns C to E, lines 32-42. Intervention Yr 1-3 (yellow): These cells calculate changes in

revenues or cost savings by category by using the data entered in lines 12 to 22 and the formula [Baseline – Intervention year]. So, for example, if revenues increase in intervention year 2 relative to baseline, the amounts shown in column D, lines 32 to 42, will be positive, indicating gains. If revenues or cost savings decrease over baseline, the amounts shown in lines 32 to 42 will be negative. Data may be entered for up to three intervention years, but three years of data are not required.

Line 43. Total Estimated PPPM Revenue Increase (Decrease): The worksheet will automatically calculate this value as the sum of the amounts in lines 32 to 42.

Line 44. Average Monthly Patients in Cohort for QEI: Enter the average monthly number of patients affected by the intervention. Some judgment may be required for this entry. If a patient is new to the intervention and has not yet been exposed to the full intervention, you may decide not to include that patient this month but to include the patient next month, after they have had an opportunity to benefit from the intervention. We implicitly assume that patients entering or leaving the cohort are similar to those already in the cohort. If you are uncomfortable with this assumption, you may adjust the number of patients in the cohort number accordingly.

Line 45. Total Estimated Monthly Gains (Losses): The worksheet will automatically calculate this value by using the formula [Total estimated PPPM gains (losses) x Average monthly patients for QEI].

Line 46. Number of Months QEI Was Operational During Year: Enter the number of months the QEI was operating in a given year.

Line 48. Total Estimated Gains (Losses): The worksheet will automatically calculate this value by using the formula [Total estimated monthly gains (losses) x Number of months QEI was operational

during year]. The amounts in these cells flow to Tab 7, ROI Analysis, where they appear as estimated gains or losses for Intervention Years 1, 2 and 3 (lines 21 and 22).

Tab 5. Revenues: Control (Optional)

General Information

The fourth spreadsheet in the model is optional. Tab 5 is identical to Tab 4, Revenues: Intervention, except that it captures data for a comparison or control group. These data are used in Tab 6, Revenues: Incremental, to calculate incremental changes in revenues or cost savings [Intervention group – Control group] over the intervention years and may provide some assurance that results are not solely from regression to the mean or secular changes affecting all patients whether in the intervention or not.

Output Spreadsheets

Tab 6. Revenues: Incremental

General Information

The fifth spreadsheet in the model is an output spreadsheet and requires no data entry. **The information in Tab 6 will be identical to Tab 4 unless you choose to enter data for a comparison or control group.** Lines 32 to 42 on Tab 6 calculate incremental changes in revenues or cost savings from the baseline year to each intervention year by subtracting changes in the control group (Tab 5) from changes in the intervention group (Tab 4). This calculation may adjust for (1) trends (e.g., if revenues increase in the intervention group but remain flat in the control group, the incremental results will reflect a gain for the intervention group) or (2) regression to the mean (e.g., if revenues or cost savings increase equally for intervention and control groups, the incremental results will reflect zero gains or losses). The amounts in the gray cells on Line 48, Total Esti-

mated Incremental Gains (Losses), flow to Tab 8. Incremental ROI Analysis, where they are shown as Estimated Incremental Gains or Losses for intervention years 1, 2 and 3 (lines 21 and 22).

Tab 7. ROI Analysis

General Information

The sixth spreadsheet in the model is primarily an output spreadsheet with one optional field for data entry. **This spreadsheet calculates the ROI based on data for the intervention group only.** Tab 7 displays multiple ROI metrics, including a cumulative benefit/cost ratio, NPV and IRR.

Data Requirements and Calculations

Line 9. Discount rate: This field is optional. Enter the organizational opportunity cost of capital. Cash flows may be discounted to reflect the fact that money has different values at different points in time. Because an amount of money in hand can be earning interest or put to work in other ways, it is not equivalent to the same amount of money received in the future. For example, if you can invest \$1 at 5 percent, you should be indifferent to having \$1 now or \$1.05 a year from today. The model allows for the entry of a discount rate to reflect the opportunity cost associated with waiting for savings to occur over the intervention years.

Lines 14-15 and 21-22: Display a summary of the cash flows calculated in Tabs 2 to 4.

Lines 17 and 24. Present value factors: The spreadsheet automatically calculates present value factors on the basis of the discount rate entered in line 9. Present value factors are calculated by using the formula $[1/(1 + \text{Discount rate})^N]$, where ^ means “to the power of.”

Lines 18 and 25. Total discounted annual investment costs and total discounted annual gains (losses): Discounted annual investment costs and

discounted annual gains (losses) are automatically calculated by multiplying lines 16 and 23 by the present value factors. Annual values are presented in Columns B to E. Column F presents the sum over all years (preimplementation and all intervention years).

Line 28. Undiscounted annual net cash flows: Line 28 sums the undiscounted cash flows in lines 14, 15, 21 and 22 to provide information about the net cash inflow or outflow to the organization in any given year resulting from the QEI.

Line 29. Cumulative ROI: The spreadsheet calculates a benefit/cost ratio in each intervention year by using the formula [Sum of (Σ) cash flows in line 25 through the intervention year/ Σ cash flows in line 18 through the intervention year]. The value shown in Column F, line 29, is the overall ROI (benefit/cost ratio) for the QEI. The benefit/cost ratio will be negative if decreases rather than increases occur in revenues or savings relative to the baseline. The benefit/cost ratio will be positive but less than 1:1 if, for each dollar invested, the QEI returns less than the original dollar. The benefit/cost ratio will be positive and greater than 1:1 if, for each dollar invested, the QEI returns the original dollar plus some positive amount.

Line 30. Net present value: NPV reflects the cash gain (loss) to the organization resulting from the QEI, accounting for the opportunity cost of capital if a positive discount rate is entered on line 9. The NPV is calculated as [Column F, line 25 – Column F, line 18] and reflects the following formula [NPV = Sum of discounted annual net savings – Sum of discounted annual investment costs]. If the benefit/cost ratio is negative, or positive but less than 1:1, the NPV will be negative. A negative NPV means the organization lost money on the QEI.

Line 31. Internal rate of return: The IRR is the discount rate at which the NPV would exactly

equal zero. In general, a higher IRR is better. The spreadsheet automatically calculates IRR.

Tab 8. Incremental ROI Analysis

General Information

Tab 8 is identical to Tab 7, ROI Analysis, except that the ROI metrics are calculated on the basis of incremental revenues or cost savings data (adjusted for the control or comparison group) from Tab 6 instead of intervention group-only data from Tab 4.

The results in Tab 8 will be identical to the results in Tab 7 unless you choose to enter data for a control or comparison group in Tab 5.

An illustration of the use of the ROI template can be found in Appendix B.

The following example illustrates the use of the ROI template.

Appendix B

Sample Business Case Analysis

Care of Adult Diabetics in a Physicians' Group Practice

Background

The Ruth Clinics, located in a Midwestern state (disguised name and data, but based on a real organization) is a large, multispecialty group practice that successfully implemented a patient self-management support (SMS) system for adult diabetes care and also created a strong business model to sustain this quality intervention over time. Ruth Clinics has 25 clinics and had 800,000 patient visits last year. It is entirely fee for service and operates almost as a private practice, with all revenues and expenses tracked back to an individual physician.

The medical director of the clinics was initially skeptical that an SMS system would be feasible in this setting. Although SMS looked helpful, he calculated that it would take seven extra minutes per visit to implement, and physicians did not even have two extra minutes for health education. It appeared to be another task that would take physician time without any additional reimbursement. He reasoned that the only way SMS would work would be to assign the counseling, goal setting and results tracking to other staff and find ways to get them paid to do SMS.

When a major payer in the state was looking for a team to do innovation work to improve outcomes in diabetes, Ruth Clinics was ready to explore quality interventions to improve care. Ruth Clinics had been tracking data on adult diabetes care in two practices. It had data on the percentage of patients whose testing was completed and the percentage of those meeting their goals. This was valuable for the insurer and for Ruth Clinics. The insurer wanted to test enhanced payment for meeting guidelines, and Ruth Clinics knew it could do it because it had the data to show where it stood.

With encouragement from the major insurer, Ruth Clinics moved forward to use planned care visits and group visits to improve access and efficiency in its facilities. It found that using a diabetes registry and preparing for the visits with a previsit review freed up valuable time for the physicians. In 2005, Ruth Clinics hired registered nurses to serve as “health coaches.” The health coaches oversaw the disease registry, made sure that the data were properly entered into the registry, contacted patients who were not meeting their goals, and developed performance reports for the individual physicians. This relieved the physicians of clerical burdens and freed up time for them to assess the clinical status of patients and develop plans with patients to address their needs.

Group visits were added at the same time. This improved access and self-management because of the exposure to other patients with diabetes. The physicians facilitated discussion in the group visits and offered clinical information when needed but limited the number of suggestions they made. The group discussion worked well to help patients identify goals and problem-solve around barriers they might encounter. Group visits allowed physicians to work with patients in this way in an economically feasible manner. These visits made better use of the physicians' time and were preferred by the patients.

Results at Ruth Clinics

Ruth Clinics began implementing the Chronic Care Model for diabetes care in two clinics in 2005. A disease registry was used to track all patients, and health coaches were identified in each clinic (a total of 1.6 full-time equivalents).

Business Case for Self Management Support
Return on Investment Analysis

Adult Diabetes SMS
Ruth Clinics
Upper Midwest

	Intervention Year			Total
	1	2	3	(All Years)
Pre-implementation Investment in QEI				
Initial Investment Costs	\$ 44,873.25			
Operating Costs	147,122.54	149,036.32	154,467.25	
Total Annual Investment Costs	44,873.25	147,122.54	149,036.32	154,467.25
x Present Value Factors	1.00	0.95	0.91	0.86
Total Discounted Annual Investment Costs	\$ 44,873.25	140,116.70	135,180.33	133,434.62
				453,604.91
Gains (Losses) from QEI				
Estimated Losses	\$ -	-	-	
Estimated Gains	158,670.00	177,485.04	190,561.20	
Total Annual Gains (Losses)	158,670.00	177,485.04	190,561.20	
x Present Value Factors	0.95	0.91	0.86	
Total Discounted Annual Gains (Losses)	\$ 151,114.29	160,984.16	164,613.93	476,712.38
Return on Investment Summary				
Undiscounted Annual Net Cash Flows	\$ 44,873	11,547	28,449	36,094
Cumulative ROI		0.82	0.97	1.05
Net Present Value				23,107.47
Internal Rate of Return				26%

The duties of the health coach were to:

1. Enter data from each visit into the disease registry
2. Place an up-to-date diabetes flow sheet on each chart before a patient visit
3. Review charts before visits to order all laboratory tests per the standing diabetes orders
4. Create lists of patients overdue for care or not meeting goals and contact them to come in for a visit

Because of the prework done by the health coaches, the use of standing orders and the use of a diabetes

office visit form (a checklist format to make sure all care was done and easily documented), providers were able to bill a higher level of service without requiring more provider time. An analysis of diabetes visit evaluation and management (EM) coding showed that EM level 4 visits went from 35 percent to 74 percent of the billings. The impact of this was to increase the average net revenue from diabetes by \$12.29 per visit.

In addition to the increased EM coding revenue, Ruth Clinics is seeing other financial benefits from the Chronic Care Model implementation. Ruth Clinics has internal laboratories and

has increased lab revenue system wide. Urine microalbumin testing went from essentially zero to more than 11,000 tests per year, which yielded a profit of approximately \$90,000 per year. Ruth Clinics also performs HbA1c tests in the office, with a comparable increase in the number of tests and revenue.

Group visit revenue exceeds expenses by a large margin, but these visits are currently done in only two clinics. Transcription and filing costs have been reduced. The diabetes office visit form requires little or no dictation, saving physician time and transcription costs.

Ruth Clinics now receives P4P payments from its major insurer and has received the maximum payment for all providers involved in diabetes care.

During the same period, providers achieved consistently favorable quality results. Providers track the percentage of patients getting HbA1c, low-density lipoprotein (LDL) and systolic blood pressure (SBP) tests in the last six months. These percentages range from 93 percent to 100 percent, depending on the provider. Microalbumin test percentages range from 74 percent to 100 percent. Outcome goals include percent HbA1c greater than 8 mg/dL, percent HbA1c less than 7 mg/dL, percent LDL less than 130 mg/dL, percent LDL less than 100 mg/dL, percent SBP less than 140 mm hg and percent SBP less than 130 mm hg. Although these measures vary by physician, averaged over all providers Ruth Clinics has consistently been better than the Healthcare Effectiveness Data and Information Set 90 percent level for all outcome measures.

Spreadsheet Analysis for Ruth Clinics

The entire spreadsheet for Ruth Clinics is provided on the CD as Return on Investment template sample — Ruth Clinics.xls. Outputs from the input sheets, although not reproduced in the text below, are discussed. Ruth Clinics did not have a control group, so all the results are shown relative to the baseline period of 2004. The intervention began in 2005 and continued through 2006 and 2007.

A discount rate of 5 percent was assumed in this analysis because this is a reasonable rate of return on fixed investments (e.g., certificates of deposit) in the current market. Because the time period for the analysis is short (three years), the discount rate is of less consequence in this case than it would be with a longer time horizon. In any case, the user can easily explore the changes in the results when alternative discount rates are used.

All cash values are discounted back to Year Zero (i.e., 2004). Thus, the analysis takes the point of view of the decision-maker looking forward from 2004. The initial investment costs of \$44,873.25 are carried forward from Tab 2. Details are provided there. Similarly, the operating costs are carried forward for each of the three intervention years from Tab 3, which provides the details.

For this example, we have quantified the gains from increased payments for diabetes visits, increased lab revenues and P4P payments received as a consequence of this intervention. We have not included grant funds, which typically would not continue beyond the duration of the grant. Reducing the investment and operating expenses by any grant funds received would be possible if they were used for this purpose. The results indicate a net undiscounted cash flow at the end of implementation Year 3 of \$31,217, indicating a positive cash flow.

Also at the end of Year 3, the cumulative ROI is 1.05, which is positive, indicating that the project pays for itself by the end of Year 3. In fact, the discounted NPV is \$23,107.47, which is the dollar return the project would have made had the initial investment and operating expenses unfolded as projected.

Finally, the internal rate of return is 26 percent, which indicates that the project is a very worthwhile expenditure of funds.

Chapter 4

Review of Evidence of Cost-Effectiveness of Self-Management Support in Diabetes

As outlined in Chapter 1, determining whether a business case exists requires that the accomplishments of a given program of SMS be known in terms of improvements in the patients' conditions, costs of the program to implement and operate, and cost savings from reductions in adverse consequences and the resultant reductions in health services utilization and costs. Therefore, we address four related questions:

1. What is the evidence of the efficacy of SMS?
That is, what is the evidence that SMS improves commonly captured physiological measures and quality of life for patients compared with usual care?
2. What does it cost to implement and operate an SMS program in a clinical or community setting?
3. What are the expected short- and long-term consequences of improvements in care in terms of prevention of adverse events, reduction of health services utilization and reduction of costs?
4. For a given intervention that has demonstrated specific levels of program costs and clinical improvements, how can the expected cost savings from prevented adverse consequences of diabetes be estimated?

Even a cursory review of the literature related to these questions reveals that the potential literature to access and review is vast. Fortunately, for Question 1, recent comprehensive systematic reviews and meta-analyses are available to serve as starting places. A small number of studies are pertinent to Question 2. Although we report the cost of intervention values here, most of the studies we found were vague on what precisely was included in the intervention cost estimates. For Question 3, the literature is diverse and widely scattered but can be synthesized with some effort.

For Question 4, literature is emerging regarding comprehensive modeling approaches for estimating the future cost consequences of improvements in care achieved through current interventions.

Evidence of Efficacy of Self-Management Support

A convenient starting place for a review of the evidence is the meta-analysis by Chodosh et al.¹ published in 2005. They included references to studies covered in earlier systematic reviews, such as those by Norris et al.²⁻⁴ and Shojania et al.⁵ To ensure that we have not left out any significant publications subsequent to the Chodosh paper, we searched Pub Med for the last three years. (Chodosh et al. concluded their search in September 2004.) With the key words “diabetes” and “self-management” and limits to “humans, English, age 19+, last three years, and article type: clinical trial, meta-analysis, randomized controlled trial or review,” we found 160 additional articles. We were particularly interested in locating systematic reviews or meta-analyses. We also included a review related to adolescents.^{6,7}

On the basis of our inclusion and exclusion criteria, seven articles were retained for further review.⁶⁻¹² Three of these were of particular interest. The Cochrane Review by Deakin et al.⁹ and the Glazier et al.¹² systematic review provided additional coverage of the literature to ensure that we had not missed important recent trials.

Five of the recent systematic reviews^{1,5,7,9,12} found significant improvements from the self-management interventions. Glazier listed the results but did not summarize them on a common scale. Chodosh presented the results in terms of their relative effect size using the Hedges' “g” statistic.¹³ The Deakin review is the easiest to interpret because the effects are summarized and presented in natural

units. Note, however, that the Deakin review studied group interventions relative to control patients who may have been receiving individual SMS or usual care that did not include SMS.

Of course, effects of the intervention can only be properly interpreted in the context of the characteristics of the patient population, the setting and the intervention protocol. Thus, the values provided here should only be viewed as generally indicative of the gains that can be made in other practice settings. Nonetheless, knowing the magnitude and directions of the reported gains is instructive.

In the abstract of their paper, Deakin et al.⁹ reported:

Fourteen publications describing 11 studies were included involving 1532 participants. The results of the meta-analyses in favour of group-based diabetes education programmes were reduced glycated haemoglobin at four to six months (1.4%; 95% confidence interval (CI) 0.8 to 1.9; $P < 0.00001$), at 12-14 months (0.8%; 95% CI 0.7 to 1.0; $P < 0.00001$) and two years (1.0%; 95% CI 0.5 to 1.4; $P < 0.00001$); reduced fasting blood glucose levels at 12 months (1.2 mmol/L; 95% CI 0.7 to 1.6; $P < 0.00001$); reduced body weight at 12-14 months (1.6 Kg; 95% CI 0.3 to 3.0; $P = 0.02$); improved diabetes knowledge at 12-14 months (SMD 1.0; 95% CI 0.7 to 1.2; $P < 0.00001$) and reduced systolic blood pressure at four to six months (5 mmHg; 95% CI 1 to 10; $P = 0.01$). There was also a reduced need for diabetes medication (odds ratio 11.8, 95% CI 5.2 to 26.9; $P < 0.00001$; RD = 0.2; NNT = 5). Therefore, for every five patients attending a group-based education programme, we could expect one patient to reduce diabetes medication.

Interestingly, Chodosh et al.¹ reported a pooled effect size from 20 SMS studies of -0.36, which

translates into a reduction in HbA1c of “about 0.81%” — precisely at the mean of the 12- to 14-month effect reported in Deakin et al. Chodosh et al. also reported that 17 comparisons from 14 studies showed no statistically significant difference in change of weight. Fourteen comparisons from 13 studies reported a pooled effect of -0.28 in fasting glucose outcomes compared with controls subjects, which equals a “decrease of 0.95 mmol/L,” again within the confidence limits of the Deakin paper results.

In an earlier review, Norris et al.² reported an average decrease of HbA1c by 0.76 percent compared with a control group immediately after the intervention. At one to three months after the intervention, the effect declined to 0.26 percent and stayed at a 0.26 percent decline at follow-up greater than four months. Again, the 0.76 percent reported decline in HbA1c is very close to the pooled results reported by Deakin et al. and Chodosh et al., despite of the variety of interventions reported.

The *Diabetes Initiative* of the Robert Wood Johnson Foundation (the sponsor of this handbook) was designed to demonstrate through 14 projects around the country that diabetes self-management programs could be effective in real-world settings.

An Agency for Healthcare Research and Quality review⁵ cited a mean improvement in HbA1c levels of 0.80 for 27 programs that included patient education, self-management or patient reminders. Although the programs varied in their approaches to self-management, the mean HbA1c reduction was again identical to that reported by Chodosh et al.

Gage et al.⁶ reported a systematic review of 62 studies of the impact of educational and psychosocial programs aimed at improving care for adolescents with diabetes. In a related study, Hampson et al.⁷ reported on a meta-analysis of 18 interventions

for which effect sizes could be calculated. They estimated a mean decrease of approximately one-half percentage point in HbA1c. But the authors cautioned that it would be more appropriate to evaluate the effectiveness of the behavioral intervention “in terms of the behaviors it is designed to impact.”

The *Diabetes Initiative* of the Robert Wood Johnson Foundation (the sponsor of this handbook) was designed to demonstrate through 14 projects around the country that diabetes self-management programs could be effective in real-world settings. The *Diabetes Initiative* selected the 14 sites from more than 300 applicants in September 2002. The 14 selected sites began a 15-month planning phase in February 2003 and initiated interventions that would last 30 months on May 1, 2004. Preliminary findings from some of the sites were published in a special supplement of *The Diabetes Educator* in June 2007. We report selected findings here. Further analysis of the post-intervention data is ongoing.

The Holyoke Health Center in Holyoke, Massachusetts, initiated self-management activities over the project period that were culturally relevant for their predominately urban, Hispanic population of Puerto Rican descent.¹⁴ Nearly half of all diabetic patients participated in self-management activities, with average HbA1c dropping from nearly 8.4 percent to about 7.5 percent; the percentage of patients with HbA1c levels <7 percent increasing from 29.9 percent to 46.2 percent; and the percentage of patients with HbA1c levels >10 percent falling from 18.2 percent to 10.8 percent. This intervention did not include a comparison group and did not report data on blood pressure, lipid management, tobacco use, weight control or physical activity.

In Laredo, Texas, the Gateway Community Health Center, which serves a predominantly Mexican-American Hispanic population, incorporated self-management services led by a *promotora* (community health worker) into the clinic structure and operations.¹⁵ The self-management course

completion rate exceeded 80 percent and, at the end of the course, most participants reported achieving their goals. Comparing outcome measures at 12 months following the program to baseline measures, Gateway found statistically significant improvements in HbA1c levels (8.0% to 7.3%), low-density lipoprotein (112.7 mg/dL to 93.4 mg/dL) and triglycerides (205.3 mg/dL to 183.1 mg/dL), as well as increases in foot examinations (24.1% to 56.3%). The results demonstrate a high retention rate among program participants and a persistence of program effects following the end of the formal course.

A *promotora* model was implemented in a primary care setting to provide diabetes self-management education to Mexican-American patients of La Clinica de La Raza in Oakland, California¹⁶ HbA1c showed a statistically significant drop (8.73% to 8.25%) at one year following the initiation of the intervention. Decreases were also seen in low-density lipoprotein (LDL) cholesterol, systolic blood pressure and diastolic blood pressure, but none was statistically significant. An interesting dose effect was observed with the number of contacts per week over a one-year period. Patients having four contacts per week during the first year of the program showed a decrease in HbA1c of 1.16 percent, whereas patients having one, two or three contacts per week showed decreases of 0.28 percent, 0.33 percent and 0.43 percent, respectively. While no formal comparison group was employed, the usual care patients in the clinic showed no decrease in HbA1c levels during the course of the study.

Positive outcomes were also reported by Campesinos Sin Fronteras for its community-based program targeting farmworkers along the U.S.-Mexico border.¹⁷ Statistically significant changes were reported after one year in HbA1c (-.58%), high-density lipoprotein cholesterol (+3.3 mg/dL) and systolic blood pressure (-5.8 mm Hg). For at-risk patients with HbA1c levels >6.9 percent, the reported changes were HbA1c -1.0 percent and LDL cholesterol -8.6 mg/dL. For these

patients, the decreases in blood pressure were not statistically significant. They also reported a dose effect, with the number of total contacts, support group contacts and advocacy contacts all positively correlated with decreases in HbA1c levels.

Although all these studies were done in real-world settings and were demonstration projects rather than controlled trials, the range of reported improvements is generally consistent with those summarized by the meta-analyses of the peer-reviewed literature. None of the *Diabetes Initiative* projects reported intervention costs, savings or revenue effects.

Costs of Developing and Operating a Self-Management Program

A review by Klonoff and Swartz¹⁸ summarized the costs and benefits of nine self-management programs for which costs were collected. The cost per patient ranged from \$100 (1985 dollars) to \$770 (1979 dollars). Ritzwoller et al.¹⁹ reported intervention costs of \$1,295 in 2001 dollars (approximately \$1,500 in current dollars). Their costs were similar to those found by the Diabetes Prevention Program Research Group,²⁰ which reported a first-year intervention direct medical cost of \$1,399 (in 2000 dollars). Keers et al.²¹ reported a per-capita cost of €1,327 for a multidisciplinary diabetes education program. Considering the diversity of settings and program content, these estimates cover a surprisingly small range.

Snyder et al.²² reported a cost of \$673 in 2001 dollars per participant per year for a commercial disease management program with members of the Teachers Health Trust in Clark County, Nevada, and Sidorov et al.²³ reported a cost of approximately \$985 per participant per year in 2000 dollars for an internal disease management program at Geisinger Health Plan.

Glasgow et al.²⁴ reported an intervention cost of \$14,755, or \$137 per participant (approximately \$19,384 in current dollars, or \$180 per participant), for a brief dietary intervention in a medical office. Lorig et al.²⁵ reported a program cost of \$200

(approximately \$240 in current dollars) per participant in a chronic disease self-management program (not diabetes specific) offered to Kaiser Permanente patients at 21 sites and Group Health Cooperative of Puget Sound patients at one site. The program cost included leaders training, program materials and administration. Banister et al.²⁶ reported a per-capita cost of \$279 (2001 dollars) for a community clinic diabetes self-management program. Huang et al.²⁷ reported costs of \$712 (2004 dollars) per patient in the first year of a general quality improvement collaborative, \$600 in the second year, \$472 in the third year and \$378 in the fourth year.

That these reported program costs span a broad range suggests that if a greater number of studies were to report their intervention costs, a relation could be developed between program intensity and intervention cost. This relation, coupled with findings on the dose effect of SMS on clinical outcomes, could, in turn, lead to an interesting line of cost-effectiveness analysis.

Kilpatrick et al.²⁸ speculated on the reasons for the relatively small number of studies that report their intervention costs:

First, investigators who conduct and publish studies of interventions meant to enhance health services quality are typically not trained to be concerned with the business case for the interventions. Historically, contributors to quality-of-care literature are clinicians, health services researchers, or quality-of-care professionals whose motivation to date has been driven largely by what they considered to be a compelling imperative to improve the process of care delivery and patient outcomes. This has been seen, explicitly or implicitly, to be a sufficient imperative, and often a focus on costs is taken by authors (or editors) to mean that quality of care was of secondary importance. Second, internal sponsors of QEIs (e.g., those within a hospital,

health plan or delivery system) may not be interested in implementation costs or may not require such information; the additional effort required to track such costs would thus be neither budgeted nor expended. Third, an external agency or foundation may have funded the QEI; in this situation, costs to the organization implementing the QEI may have been minimal, and thus investigators would likely not track or report them. Fourth, a series of technical or methods challenges may pose obstacles for this type of work; for example, better research methods to evaluate the financial impact of QEIs are needed, and current cost accounting systems of hospitals (let alone of private physician practices or community-based entities) may not be adequate to capture the required micro-cost and revenue data. Finally, academic journals and their readership have not required cost information as a requisite for publishing the article.

In their article, Ritzwoller et al.¹⁹ also called for inclusion of program cost estimates in reports of diabetes self-management studies:

First, for diabetes self-management education (DSME) programs to become more widely accepted and reimbursed at higher levels, it is important that at a minimum, DSME programs report intervention-related costs and, where feasible, include cost-effectiveness or other economic outcomes. Second, given the current obesogenic environment, the costs and cost-effectiveness of behavioural support, social support, and DSME programs, while considerable, especially for the intensive and ongoing long-term programs such as MLP [Mediterranean Lifestyle Program] that may be necessary to produce lasting behavior change in multiple behaviors are not large or unreasonable compared

to many alternative surgical procedures.

Third, when estimating and tracking costs, care should be taken to plan from the outset and collect data prospectively, to include all relevant costs, and to be clear what economic perspective is being used.

Gage et al.⁶ were unable to determine which programs offered the greatest return on expenditure to “inform resource allocation.” In the 62 studies they reviewed, they found that “investigators ignored the costs of providing programmes, and their longer-term health and service utilization implications, so few cost-effectiveness conclusions can be drawn about the provision of educational or psychosocial programmes for adolescents with diabetes from available evidence.” Although it may be possible, given the increasing weight of the evidence, to make some estimates of the likely range of impacts of DSME programs on clinical measures, it appears that program costs must be captured simultaneously with the intervention if they are to have any hope of reflecting the actual costs incurred in a given setting for a given style and intensity of intervention. As the field matures, guidelines regarding which costs to include may develop. In the meantime, the templates provided in Chapter 3 of this handbook can serve as a convenient guide for program cost analysis.

Economic Consequences of Clinical Improvements Resulting from Self-Management Support

Because much of what has been published on the cost-effectiveness of self-management interventions is from the perspective of countries with national health systems, a large payer such as Medicare or the Veterans Administration, or a health care plan at risk for downstream costs, we must keep in mind that an intervention that appears to be cost-effective from the perspective of a large payer may not be cost-effective from the perspective of a single medical group practice or community setting.

In the short term, patients with uncontrolled diabetes are likely to generate more visits to the ED, more inpatient admissions and resultant higher health care costs. In the long run, uncontrolled diabetes can lead to macrovascular complications (e.g., stroke, transient ischemic attack, myocardial infarction, angina) and various levels of progressive complications (e.g., nephropathy, retinopathy, neuropathy). Nephropathy can lead to end-stage renal disease; background retinopathy can lead to macular edema, proliferative diabetic retinopathy and eventually blindness; and peripheral neuropathy can lead to foot ulcers and eventually amputation. These long-term complications become increasingly more expensive to treat. (For an early description of the increased costs generated by members with diabetes in a managed care population, see Ramsey et al.²⁹) For a business case analysis, comparing the discounted costs of the complications with the cost of the intervention would not be sufficient, as it would if a societal perspective were taken. If we want to compute the ROI for an intervention that may reduce these long-term cost complications, it is critically important that we know which entity in the health care system bears the cost of the intervention, what the intervention cost is, what the cost savings from the intervention are likely to be and which entity is likely to save money if the long-term complications are prevented. Thus, if an intervention is shown to be cost-effective in a large health maintenance organization, that result may have no influence on the decision of, for example, a primary care practice that bears no financial risks for downstream costs to undertake a similar intervention unless it is directly paid to do so.

Klonoff and Swartz¹⁸ reviewed nine studies that published cost of intervention and savings in hospital costs the year after the intervention. The study years ranged from 1974 to 1990. Reported benefit/cost ratios ranged from 0 to 8.76. All nine studies were conducted from the perspective of a health insurer that would benefit from reduced hospitalization costs. Discounting was not performed

because of the short time frame used. On the basis of their review, Klonoff and Swartz concluded that “Flawed but consistent evidence suggests that diabetes self-management programs are possibly cost-effective.” They went on to call for studies using more rigorous methods that examine long-term costs and benefits.

Using Medline and other sources, we found 11 studies^{21-23, 27, 30-36} that address the cost-effectiveness of diabetes self management. We were liberal in our inclusion of disease management programs that included aspects of self management. We did not search for promotional literature from commercial diabetes disease management companies.

On the basis of the 11 studies summarized in Table 4-1, diabetes self management appears to be cost-effective from the perspective of a health insurer or health maintenance organization that was at financial risk for the increased costs generated by patients with diabetes. The same cautions raised by Klonoff and Swartz apply to the studies in Table 4-1. Because patients were not randomly assigned to intervention and control groups, many of these studies may suffer from regression to the mean effects. That is, patients who generate high costs in one year may have lower costs in the subsequent year because their costs tended toward the average rather than because of the beneficial effects of the treatment.

This is not to imply that disease management programs for diabetes save money in all cases. An interesting debate on this topic emerged in *Health Affairs*. Fireman et al.,³⁷ from the Permanente Medical Group, Division of Research, reported that from 1996 to 2002 disease management of chronic conditions, including diabetes, achieved significant clinical improvements but no absolute cost savings compared with the baseline period. They concluded that disease management programs may be cost-effective but not cost saving. That is, disease management programs improve the length and quality of life at a level of cost that is a good value for the gains achieved but still at a higher total cost than the comparison group. This is consistent with the simulation results of Huang et al.²⁷

Estimating the Cost-Effectiveness of a Current Intervention

The final question to be addressed is how to forecast what the future savings will be as a result of an effective intervention implemented now. Suppose a self-management intervention has been demonstrated to be effective in improving patient care and, furthermore, that the costs of the intervention are known or can be estimated with a reasonable degree of accuracy. How might investigators estimate the future savings from reduced complications? A major difficulty in answering this question arises because the significant averted health care costs — attributable to retinopathy, renal failure, cardiovascular complications or neuropathy, for example — would typically arise many years in the future. If we want to estimate the averted costs of these long-term complications, we would have to use a model to forecast both the clinical progression and health care utilization effects of the intervention of interest.

Fortunately, in the last several years researchers have developed computer simulation models specifically designed to estimate the health effects and costs of diabetes complications. An example of the use of these computer models is provided by Huang et al.,²⁷ who projected for community health centers the long-term health and cost consequences of documented improvements in care from the Health Disparities Collaborative. They incorporated their own input data into a computer simulation model developed and validated by Eastman et al.³⁸ The model simulates a cohort of patients with given initial conditions through time in one-year increments. The patients progress through microvascular complications, cardiovascular complications, and death or age 95 years, whichever occurs first. The model reflects the benefits of the intervention by predicting lower complication rates and lower health services utilization and costs for the intervention group compared with usual care. A convenient feature of the model is that it is programmed to run on a personal computer using Excel and @Risk for Windows.

Huang et al. used their results to argue that quality improvement (QI) programs in community health centers are cost-effective from the perspective of society, even if they generate financial losses for the health centers in the short term. This provides evidence for maintaining external funding to continue the QI initiatives. Without external financial support, Huang et al. are concerned that the QI programs will not be sustainable and the health benefits to patients and downstream cost savings will be lost.

Other researchers have developed simulation models with goals similar to the Eastman model. The models developed by Mueller et al.,³⁹ Palmer et al.,⁴⁰ Herman et al.,⁴¹ Zhou et al.⁴² and Jacobs-van der Bruggen et al.⁴³ are similar to the Eastman model in that they are discrete-event Markov simulations that move a simulated patient through time in annual steps. Transition probabilities depend on the status of the simulated patient at any given year in the progression. Eddy and Schlessinger^{44,45} have developed and validated a complex model of the anatomy, pathophysiology, tests, treatments and outcomes relevant to diabetes that can be used to make projections of the effects of a variety of clinical and administrative interventions. Their model, called Archimedes, is written in differential equations with object-oriented programming. Although much more complicated than the Markov models of the type used by Huang et al., Archimedes has predicted results of clinical trials never used to construct the model with a correlation of $r = .99$, which indicates that the model simulates reality with a high degree of accuracy. On the other hand, other researchers have found Archimedes to be less accessible and harder to explain to policy-makers than the Markov models.

Recognition of the benefits and risks of using computer models to predict the consequences of changes in practice prompted the American Diabetes Association to convene a Consensus Panel to develop guidelines for the use of computer models of diabetes and its complications.⁴⁶ The panel called for the models to be transparent,

meaning that their structures, inputs, equations, algorithms, data sources and assumptions should be available for others to review. Practically, this well-intentioned requirement can only be realized for the most simplistic of models. The panel also called for the models to be validated, preferably against data not used in their development. Because diabetes affects many organ systems and because the interactions between complications and other comorbidities are complex and may unfold over many years, the panel recommended that the models explicitly address these realities. Although transparency and complexity are contradictory criteria, the panel's emphasis on validation is important and could serve as a guide to model development in other fields as well. Ultimately, the model's results can be no more valid than the inputs they are given and the internal parameter estimates they use. Thus, the utility of models of this type is in estimating the relative impact of alternative interventions rather than the absolute outcomes of the interventions.

Summary

Substantial evidence shows that diabetes self-management programs are clinically effective. This is true of programs in community settings as well as more tightly constrained university settings. Although not as thoroughly documented, a number of published studies have reported the costs of the interventions. These costs range from approximately \$200 per participant for a brief clinical intervention to \$1,500 per participant for a year-long intensive intervention. The cost depends on the setting, content, structure, process and intensity of the intervention.

The literature on the cost-effectiveness of diabetes self-management programs is sparse and currently not robust. Unless a program is initiated by a payer or a managed care organization that is financially at risk for hospital and ED costs, short-term savings that will offset the cost of the intervention are unlikely. Nonetheless, any organization that delivers an intervention may estimate

the short- and long-term savings expected from the intervention through computer modeling. These computer modeling results can be useful in arguing for higher payments from private or government insurers, gain-sharing payments or quality bonuses. The emerging empirical evidence on the efficacy of SMS in community settings, combined with the power of newer computer models of long-term consequences and costs of untreated diabetes, can be an effective tool for resolving the misaligned incentives for the provision of quality diabetes care in a fragmented health care system.

Table 4-1 Cost-Effectiveness of SMS Interventions

Study	Perspective	Intervention	Cost of Intervention	Results
Huang et al., 2007	Society	Multiple process improvements or simulation	\$712 per participant for year 1, \$600 for year 2, \$472 for year 3, \$378 for year 4	Estimated lifetime costs increased by \$11,685 after intervention; QALY increased by 0.35 or \$33,386 per QALY
Wolf et al., 2007	Health plan	Lifestyle case management by registered dietitian	Lifestyle group = \$374.57 Usual care = \$46.23	Mean annual health care costs = \$7,295 for intervention group vs. \$11,406 for control subjects
Keers et al., 2005	Society	Education program	€1,327	€1,469 first-year reduction in health care costs for participants compared with baseline
Villagra and Ahmed, 2004	HMO or POS	Disease management program	Not given	Paid claims were \$417 PMPM for participants vs. \$554 PMPM for control subjects; pharmacy costs were \$9.02 PMPM lower and inpatient costs were \$17 PMPM lower; 30% fewer inpatient admissions among participants
Diabetes Prevention Program Research Group, 2003	Health system	Metformin and lifestyle interventions	\$2,919 for lifestyle, \$2,681 for metformin, \$218 for placebo — all over three years	\$51,600 per QALY for lifestyle and \$99,200 per QALY for metformin
Snyder et al., 2003	Health benefits plan	Commercial disease management program	\$673 per capita	Adjusted net savings in health care costs of \$1,598 per participant per year
Berg and Wadhwa, 2002	HMO or PPO	Commercial disease management program	Not given	Inpatient admissions decreased by 391 per 1,000 in intervention group; 4.34:1 return on investment claimed
Sidorov et al., 2002	HMO	Disease management program	\$985 per participant	Paid claims were \$395 PMPM for participants and \$502 for control subjects, mainly from lower inpatient and ED use
Albisser et al., 2001	Mixed model HMO	Education only (E alone), education with computer-assisted self-care management (E+caSM), education with self-management training (E+SMT), education with SMT and intensified therapy (DCCT)	E alone = 0 E+caSM = \$1.31 PMPM E+SMT = \$18 PMPM DCCT = \$9.70 PMPM without pump or \$14.06 PMPM with pump	E alone = no effect E+caSM = HbA1c decreased by 1.1% at 12 months E+SMT = HbA1c decreased by 1.1% at 12 months DCCT = HbA1c decreased by 2.5% at 12 months
Wagner et al., 2001	Staff/network HMO	Usual care/historical cohort study 1992–1997	Not applicable	Patients with improved HbA1c had lower total health care costs (\$685 vs. \$950), but these were significant only for patients with higher baseline measurements (10.0% vs. 7.7%)
Steffens, 2000	HMO	Disease management program	Not given	Total medical costs decreased from \$471 PMPM to \$415 PMPM in the treatment group

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Other resources

Diabetes at Work

www.cdc.gov/diabetes/pubs/factsheets/atwork.htm

The Business Community Takes on Diabetes

www.diabetesmonitor.com/b192.htm

Economic Impact of Diabetes (chapter 30) in *Diabetes in America*, 2nd Edition

diabetes.niddk.nih.gov/dm/pubs/america/contents.htm