USING PAY FOR SUCCESS TO EXTEND DIABETES PREVENTION

Type II diabetes creates a tremendous burden on society; we know how to prevent it; and yet we dramatically underfund prevention. The disease causes more deaths than AIDS and breast cancer combined.[1] It reaches nearly 30 million Americans. Remediation is wildly expensive: the American Diabetes Association's most recent estimate of the total annual cost of diagnosed diabetes in 2012 was $245 billion per year.[2] Meanwhile, prevention is conceptually straightforward: it's about eating better and exercising more. Good interventions—tested in high-quality scientific studies worldwide—have existed now for 15 years.

Yet few of these interventions have reached a scale worthy of the challenge. The overwhelming burden of the disease has spurred both eager innovation and particularly uneven action. Strong programs are created, tested, but then rarely replicated with fidelity. Instead, the nation's diabetes prevention efforts resemble a patchwork of loosely related program models and methodologies.

Why the lack of progress if good interventions exist? While prevention may be conceptually straightforward, diabetes itself is terrifically complex. It strikes slowly and progresses unpredictably, with possible complications covering a broad landscape from blood clots to renal failure, glaucoma to degenerative nerve disorder.[3] Negative outcomes span decades and are hard to forecast, with different patients following very different disease pathways; their costs are dispersed across payors and systems. This complexity challenges our ability to make reliable claims of long-term impact from today's interventions and their near-term outcomes, and it obscures much of the value created by prevention.

Nevertheless, we at Social Finance US—following in the footsteps of our colleagues in Israel[4]—believe there is an opportunity to scale high-quality diabetes prevention via Pay for Success (PFS), creating significant short- and long-term value for both payors and beneficiaries. Pay for Success has been used to fund over 60 projects worldwide, from early childhood home visiting expansion in South Carolina to 'social prescribing' for lifestyle management of chronic diseases in Newcastle, UK. Following a critical review of intervention evidence, and drawing on recent additions to the field in estimating the value of prevention, we believe that lifestyle interventions in the model of the Diabetes Prevention Program can improve health and save money—and that Pay for Success can be a useful tool to help scale these programs up, preventing one of the most deadly and costly diseases in America.

Jake Segal, Director, Advisory Services, Social Finance *with generous support from the Humana Foundation*

Prevention Tools That Work

The US is home to hundreds of diabetes prevention interventions, offered by both nonprofits and for-profits, in clinics and in homes, by highly trained and by lay health workers. In the process of this study, we reviewed many of them.[5] We found a great deal of innovation, and a much more limited bedrock of strong experimental evidence.

WHAT IS PAY FOR SUCCESS?

Pay for Success is an innovative funding model that uses private investment to drive society's resources toward effective social programs. PFS transactions involve three key stakeholders: top-tier nonprofit service providers, whose evidence of impact is typically demonstrated via high-quality evaluations; private funders—often a mix of philanthropies and financial institutions or high-net-worth individuals—who are seeking both financial and social return; and outcomes payors, institutions—often governmental—who stand to benefit from improving the outcomes of their constituents.

PFS connects these actors. Funders support nonprofits with working capital for their programs. If those programs generate agreed-to outcomes, as determined by a third-party evaluator, then payors agree to share the savings they accrue—repaying funders, often with a modest return.

Any investigation of the diabetes prevention landscape in the US hinges on the field's landmark Diabetes Prevention Program (DPP) study. The large, multicenter 2002 study matched participants with one-on-one support from a well-qualified lifestyle coach, based in the clinic, to improve nutrition and physical activity.

DPP—and other, similar programs, tested in randomized controlled trials around the world[6]—was wildly successful. It demonstrated a 58% reduction in diabetes incidence over nearly 3 years versus a randomized control group. It was so successful that researchers, following the initial window, broke randomization, providing a modified version of the intervention to those in the control group. Nevertheless, the impact of those first three years persisted: after 10 years, DPP continued to reduce the incidence of diabetes by 34% versus the original control group.

In the years since, numerous programs have attempted to translate the DPP into lower-cost, often lower-intensity programs.[7] These translations, we found, have a mixed record. While based on the DPP, few had performed rigorous evaluations in their own right; those that did often found significantly less impact than the original study.

Only one translation in our review transcended that finding. The Healthy Living Partnerships to Prevent Diabetes (HELP PD) employs the DPP curriculum and methods, and delivers them using registered dieticians and community health workers to groups of participants in community settings. HELP PD is shorter and less costly than DPP, but, in a randomized controlled trial conducted in Winston-Salem, North Carolina, demonstrated similar effects on blood glucose, weight, and diabetes incidence.[8]

Other translations, while lacking in the same rigorous evaluations as those underlying DPP or HELP PD, have also demonstrated promise. Perhaps the most exciting is the YMCA's Diabetes Prevention Program (YDPP). YDPP delivers an updated DPP curriculum to groups of participants via a lifestyle coach at the Y. At one year long, it is the briefest of the three interventions we prioritized, but in a small 2008 analysis demonstrated a promising 4% greater average weight loss for a lifestyle group in one site versus a control site, suggesting important impact on diabetes prevention.[9,10] Further programmatic data suggest that impact on weight loss is replicable across the nation. We and other analysts believe it likely that YDPP has an important positive impact on blood glucose and diabetes incidence at a fraction of the cost of other interventions, and see its national network as a crucial opportunity for building scale.[11] Indeed, in March 2016, the Office of the Actuary in the Centers for Medicare & Medicaid Services (CMS) certified that YDPP and programs like it would reduce overall healthcare spending, and therefore has proposed reimbursing for the program via Medicare; if the proposed CMS rule changes are finalized, expanded coverage will take effect January 1, 2018.[12]

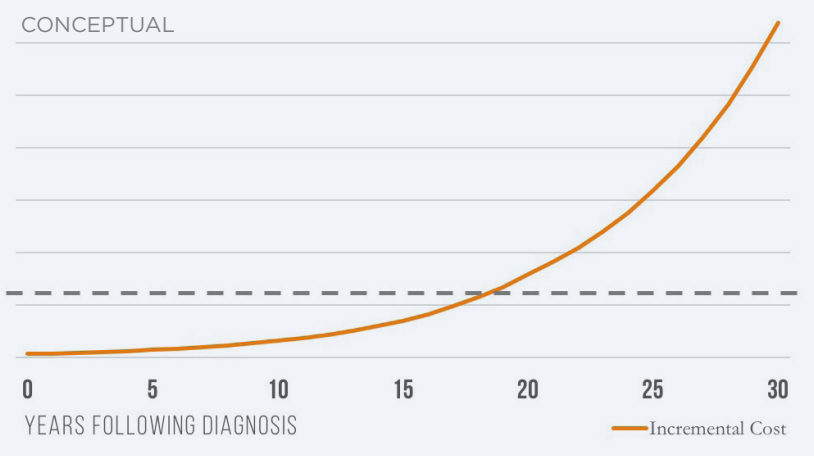
Despite the positive consensus, we are cautious in our expectations for HELP PD and YDPP. While HELP PD approximates DPP's initial 2-year findings, it does so for a relatively narrow study population, who were recruited to the study in a very different manner—both of which may influence the program's measured impact. We do not yet understand the trajectory of its long-term effects, which may dilute faster than DPP's. (Indeed, it may be that the very act of ongoing DPP evaluation is driving its effect; lacking the longitudinal follow-up, HELP PD may also have more limited long-term adherence.)

The YDPP, for its part, has not yet been subject to a rigorous outcomes evaluation, suggesting greater uncertainty still—both in its short- and long-term outcomes. Meanwhile, analysts have made a variety of assumptions about the relative effectiveness of the Y's program. For example, in a 2014 analysis conducted for the ADA and the YMCA, Avalere Health assumed that YDPP would be 50% as effective as DPP over 10 years.[13] The CMS actuarial report followed suit, estimating that YDPP would be 50% as effective in year one, with a 5% reduction in effectiveness each year through year seven (and a constant 20% effectiveness rate thereafter). Researchers at the CDC and the RTI-UNC Center of Excellence in Health Promotion Economics made slightly different assumptions still, estimating a 50% relative reduction during the first two years, and then assuming a constant 15% effect thereafter.[14] These assumptions are critical to modeling expected cost benefit; while consensus around the positive impact of YDPP exists, there is significant variation on the set of assumptions and analyses underlying that consensus.

The Value of Prevention

Even with powerful tools at hand, making the case for prevention requires us to estimate the social and economic value of these interventions, along with how that value accrues to different stakeholders. And estimating the value of diabetes prevention poses particularly intricate challenges.

For one thing, it's easy to misinterpret data about the value of prevention. Too often, analysts conflate the value of prevention with the cost of illness. As is often cited, diabetic patients cost, on average, $7,888 more than nondiabetics. But those costs do not appear as soon as a patient is diagnosed. The greatest cost burdens accrue in the later stages of the disease; significant divergence in costs between those who get diabetes and those who don't takes time.[15] Understanding the progression of diabetes is essential to understanding the value of prevention, because cost differences in the short term are much smaller than those later on.[16]



Unfortunately, it's hard to predict disease progression and cost for a given patient. Diabetes development and complication rates vary by age, gender, and race.[17] Importantly, prediabetics represent a relatively wide band of risk and impaired glucose tolerance. Costs, too, vary significantly across patient populations: patients diagnosed early (e.g., at age 40), for example, have greater lifetime costs—and their costs go up more quickly than patients diagnosed later in life.[18]

IT'S EASY TO MISINTERPRET DATA ABOUT THE VALUE OF PREVENTION

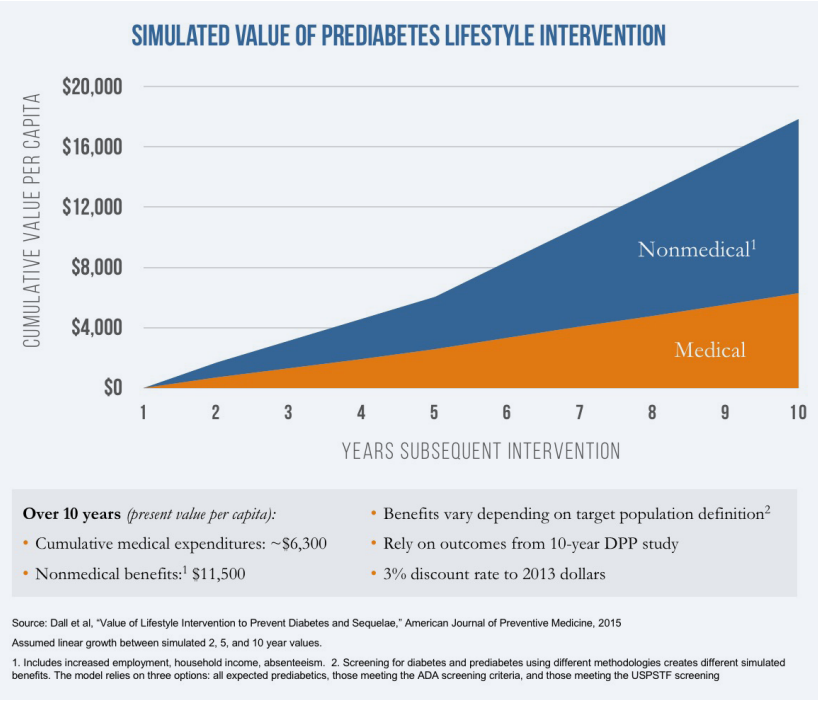
Even to the extent that learning from the past can guide cost projections, there's the abiding challenge that the future of diabetes costs just might not reflect that past. Because many costs occur decades after intervention, the counterfactual is murky: future diabetes treatment costs may change, subject to both improved medical technologies and increased longevity, and thereby erode—or, less optimistically, improve—the value of prevention.[19]

Prevention modeling, then, is a tricky business.

An elite set of health economists have taken on these challenges. In the past decade, at least 10 high-quality diabetes simulation models have been developed around the world.[20] They typically employ data from dozens of evaluations to extrapolate results across longer time periods and across alternative populations.[21] As opposed to large "cost-of-illness" studies, simulation models are intended to describe the value of a new intervention within a population—going beyond the results of tightly-controlled clinical trials. They are complex, recursive models that predict the interaction of multiple comorbidities over time.[22]

The most recent entry into this space comes from Tim Dall et al. at IHS Global Research Life Sciences.[23] Their model, the Disease Prevention Microsimulation Model (DPMM), estimates the health and economic benefits of a Diabetes Prevention Program lifestyle intervention oriented toward prediabetics over the course of 10 years. Outcomes are compared between a simulated intervention, based on the Diabetes Prevention Program (discussed above), and a simulated natural disease progression.

This allows the DPMM to do some important things—like predict the true value of diabetes prevention, absent the problematic distortions of individual studies like the DPP. Ultimately, the model suggests that "the simulated economic benefits of treating prediabetes via lifestyle intervention appear to far outweigh intervention costs over the analyzed 10-year period." Lifestyle intervention reduces 10-year cumulative per-capita medical costs by $6,300, and creates nonmedical benefits— like increased employment rates, greater household income, and lower absenteeism—of $11,500.[24]



The DPMM is only one of a number of sophisticated, and sometimes conflicting, simulation models. Judging the quality of such models is a highly technical pursuit. And they are only as good as the research existing in the field today, including studies and models created from non-US-based populations, and some that compare diabetic populations to non-diabetics. While the DPMM has been tested for validity against other clinical trials, it does not always match longitudinal outcomes from the Diabetes Prevention Program, the largest US-based experimental prevention study. It parts ways most notably in its ultimate conclusions around the positive economics of lifestyle interventions.[25]

Despite appearing more economically positive than the 10-year DPP observations, the model may still be overly conservative. Because the DPMM only models diabetes and "recognized sequelae," it underestimates the total cost aversion produced from weight loss.[26]

On the whole, the DPMM is a thorough and well-informed effort to look past the challenges in prospective disease modeling, stripping away the DPP's own methodological questions and presenting a useful estimate of the value of prevention. At a high level, we can use its results to impute the value of HELP PD and YDPP as well. Doing so requires navigating crucial assumptions underlying the long-term effectiveness of these interventions, which—as we describe above—vary considerably.

Comparative Cost-Benefit

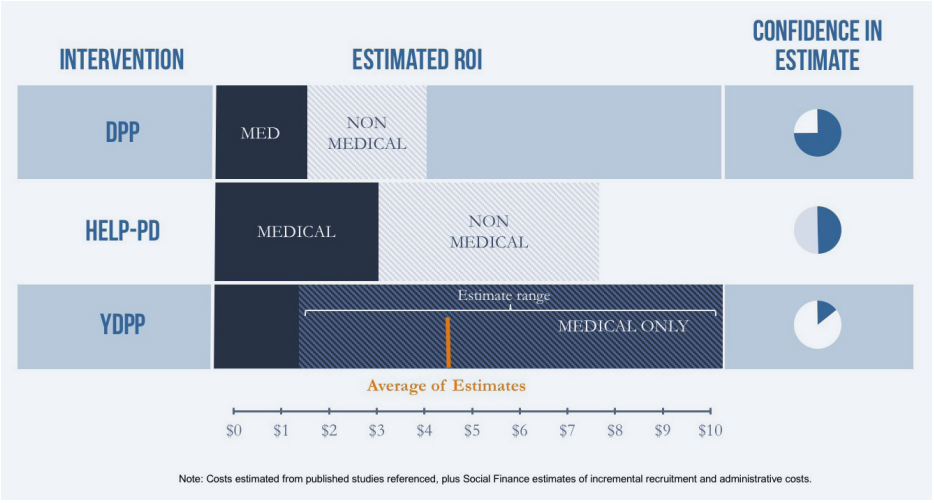
In order to prioritize among these interventions, we next sought to compare various estimates of intervention benefit against their costs.[27]

Of the three programs, we feel most confident about our ability to estimate the long-term cost and benefit of the DPP, and increasingly less confident in our ability to do so for HELP

PD and YDPP.[28] Our confidence is a factor of the information at our disposal, and we have more and better information about those interventions tested with rigorous evaluations; translational programs may be less impactful than the soup-to-nuts DPP described in the 2002 publication, and the duration of their impact may be shorter lived.

Using best-available published impact estimates, we tried to compare the likely ten-year cost-benefit ratios of the three programs. In the case of HELP PD, our estimate likely inflates the ROI, as it assumes a similar impact trajectory to DPP over time. In the case of YDPP, we found a wide range of published long-term impact estimates, creating a large possible ROI band from which we took a simple average.

On the whole, these estimates underscore the reality that, while translational programs may create somewhat less impact than the original DPP, they do so at dramatically reduced costs—making both HELP PD and YDPP better value-per-outcome propositions than DPP. Between the two, only a highly conservative estimate of YDPP effectiveness and a highly optimistic estimate of HELP PD effectiveness would suggest that HELP PD is the better bet; more likely, the low-cost YDPP intervention produces the best preventative bang for our public health investors' collective buck.



THE LOW-COST YDPP INTERVENTION PRODUCES THE BEST PREVENTATIVE BANG FOR OUR PUBLIC HEALTH INVESTORS' COLLECTIVE BUCK

Nevertheless, it's worth reiterating that the evidentiary landscape and our still-limited understanding of diabetes prevention make it complex terrain. A Pay for Success project in diabetes would benefit greatly from further simulation modeling from expert economists, helping to set a neutral third-party definition of the expected value-per-outcome.

Path Forward

For too long, policymakers have been paralyzed by the discomfiting complexity of diabetes prevention. Prediabetics move across the borders of our gerrymandered healthcare system, and the benefits of prevention are parceled out among payors—too little to catalyze action for any one player, too great to ignore in the aggregate.

Using the tools of Pay for Success, we believe that diabetes prevention gains a new luster, allowing innovative financing to subtly shift the balance of risk and return to suit our multipayor system. We could envision doing so in a numbers of ways.

Expand the Diabetes Prevention Program using Pay for Success. Fifteen years ago, the DPP—expensive, intensive, based in the clinic and run by highly qualified providers—

demonstrated tremendous effects on diabetes prevention. Recent simulated analysis of DPP suggests that, contrary to the surprising findings in the DPP Outcomes Study, prevention is cost effective.[29] Armed with this new information, we see expansion of the "fully-loaded" DPP as a low-risk—though relatively expensive, and hence, lower return—method of expanding diabetes prevention, which distinctly improves upon the status quo.[30]

Strengthen the evidence for promising models. Translations of DPP may be able to deliver similar results at a lower cost. HELP PD has a single, high-quality randomized controlled trial (RCT) to date; a second, confirmatory evaluation—conducted in a different geography, with a more economically and racially diverse population—could vault HELP PD into the top tiers of evidence-based practice.[31] A Pay for Success model could be designed to experiment with the intervention in a new geography, building on the program's initial evaluation while running an RCT on the program's new implementation.[32]

Evaluation, of course, can be—and historically has been—accomplished independently of Pay for Success. We believe that governments and philanthropy should continue to proactively evaluate promising community translations, including both HELP PD and YDPP, to build knowledge about what works. Pay for Success may be used as a catalyst for this knowledge building.

Scale our most promising prevention program, the YMCA's Diabetes Prevention Program. The appeal of YDPP is undeniable: it is inexpensive to deliver; it draws on the national infrastructure and reputation of the YMCA; it has been recognized by the Centers for Disease Control and Prevention; and it has been certified as cost-saving by the Center for Medicare & Medicaid (CMS).

Perhaps more than other analysts, we see its risks as substantial. The evidence underlying YDPP's effectiveness is less robust than that of DPP or HELP PD; its evaluated outcomes (in a relatively small 2008 analysis) demonstrated no effect on HbA1c, and its program data—which are focused on weight loss, rather than diabetes per se—suggest somewhat lower effect sizes than its higher-cost peers.

Despite these risks, however, the evidence strongly suggests that YDPP creates positive impact for prediabetics, and that this impact creates disproportionate public value.[33] This impact is likely to be bolstered further—as in the Israeli social impact bond model targeting type II diabetes—by the application of new health technology, from physical activity monitors and health bracelets to online support tools.

Growth through Pay for Success would allow YDPP to expand its reach. Building on the example of CMS, other public payors—particularly States and Counties looking at healthcare for their own employees—could use Pay for Success to expand YDPP to their beneficiaries, paying only for quality implementation (aligned against the CDC's guidelines) and near-term obesity outcomes. Public-sector employees are older; nearly 50% more likely to be diabetic;

and have longer tenure (and hence, allow preventive programs to capture greater long-term value) than private-sector employees.[33] With the support of sophisticated simulation modeling, we believe that a PFS project to expand YDPP for public employees could make a compelling case for medium-term (~5 year) positive return on investment—and dramatic long-term returns. Ultimately, we believe that YDPP represents a low-cost, scalable solution to one of our nation's largest public health challenges, and that Pay for Success can help finance the program as it expands.

The burden of diabetes demands new approaches toward funding and scaling prevention. We know, based on the strength of recent modeling efforts, that prevention is dramatically less expensive than remediation. What we lack is the bridge between preventative efforts today and benefits in the future—a way of ensuring that interventions are on track toward producing long-term rewards. Based on our analysis of the field's literature, and encouraged by the pace of progress exhibited by our colleagues in Israel, we believe that Pay for Success can help to overcome the capital challenge facing diabetes prevention and reach more of those in need.

1. Diabetes Research Institute Foundation. "What Is Diabetes?" 2014. Web. 27 Oct. 2015. <www.diabetesresearch.org/what-is-diabetes>.

2. Ibid.

3. The American Diabetes Association lists over 100 potential comorbidities. See Wenya Yang et al., "Economic Costs of Diabetes in the U.S. in 2012: Supplementary Data," American Diabetes Association, 2013.

4. Tava Cohen, "Israel Launches First Social Impact Bond To Prevent Diabetes," Reuters, 14 March 2014, <uk.reuters.com/article/israel-diabetes-bonds-idUKL5N16M3NH>

5. The process used for this scan and prioritization are described in more depth in other Social Finance publications, particularly our "How-To Guide for Nonprofit Diligence," 2016. In short, we deprioritized programs without rigorously defined control groups, those with unreliable study designs or methods, and those that did not track relevant outcomes. (Outcomes included type 2 diabetes incidence, HbA1c, or weight loss. Diabetes incidence was defined by the rate of patients diagnosed as diabetic, generally defined by those with HbA1c <6.5%.) We also deprioritized interventions demonstrating small or no effect. Ultimately, our review process suggested a shorter list of top-priority

interventions in both diabetes prevention and management. In support of this process, Social Finance spoke with national experts—thought leaders, diabetes researchers, health economists, public-sector officials, potential payors—and reviewed a wide selection of published diabetes intervention and cost-benefit literature from regional resources (such as the University of Texas Health Science Center), national best practices (such as the Centers for Disease Control and Prevention, the American Diabetes Association, the National Institute of Diabetes and Digestive and Kidney Diseases, and the American Pharmacists Association), and clearinghouses of top-tier social interventions (such as the Coalition for Evidence-Based Policy).

6. Similar results have been obtained in studies in China (1986), Sweden (1991), Finland, (2003), and India (2006).

7. They have also sought to update the DPP's two-decade-old curriculum, which has since been influencing by changing dietary and activity recommendations.

8. Katula JA, et al., "The Healthy Living Partnerships to Prevent Diabetes Study: 2-year Outcomes of a Randomized Controlled Trial," American Journal Preventative Medicine. 2013 April; 44(4 Suppl 4): S324–S332. The study was not large enough to detect statistically significant difference (at $p<0.05$) in diabetes incidence between the treatment group and a control group. However, at $p<0.1$, the raw data show a reduction in diabetes incidence of 70% at the end of year 1. This equates to a 90% chance that HELP PD generated a meaningful change in diabetes incidence. See also: Blackwell CS, et al., "Healthy Living Partnerships to Prevent Diabetes: recruitment and baseline characteristics," Contemporary Clinical Trials. 2011 Jan; 32(1): 40–49; Katula JA, et al., "Healthy Living Partnerships to Prevent Diabetes (HELP PD): design and methods. Contemporary Clinical Trials. 2011 Jan; 32(1): 40–49; Katula JA, et al., "Healthy Living Partnerships to Prevent Diabetes (HELP PD): design and methods. Contemporary Clinical Trials. 2010;31:71–81; Lawlor MS, et al., "Cost of a group translation of the Diabetes Prevention Program: Healthy Living Partnerships to Prevent Diabetes," American Journal Preventative Medicine. 2013 April; 44(4 Suppl 4): S381–S389.

9. At the end of the follow-up period, the lifestyle intervention group showed a 6% average weight loss (versus 2% average weight loss for control group), with no effect on HbA1C levels. Ackermann RT, et al., "Translating the Diabetes Prevention Program into the Community: the DEPLOY Pilot study," American Journal of Preventative Medicine. 2008 Oct; 35(4): 357–363.

10. Most diabetes prevention studies and researchers use weight loss as a proxy for diabetes. There is a strong correlation between weight loss and diabetes incidence. This relationship is typically defined by the DPP; in that study, researchers found that, adjusted for changes in diet and activity, "for every kilogram of weight loss, there was a 16% reduction in risk [of diabetes incidence]." Richard F. Hamman, et al., "Effect of Weight Loss With Lifestyle Intervention on Risk of Diabetes," Diabetes Care. 2006 Sep; 29(9): 2102–2107. The Finnish Diabetes Prevention Study supported these findings. The large, multicenter Look-AHEAD trial, which tested the long-term impact of lifestyle interventions for overweight or obese patients, found that weight changes were significantly correlated with modest HbA1c reductions. After one year, each higher category of weight loss (2-5%, 5-10%, 10-15%) was associated with a decrease in HbA1c (of ~0.2% per category). Wing RR, et al., "Benefits of Modest Weight Loss in Improving Cardiovascular Risk Factors in Overweight and Obese Individuals With Type 2 Diabetes," Diabetes Care. 2011 July; 34(7): 1481-1486.

However, our research suggests that, while there is a strong relationship between weight loss and diabetes, it is complex, culturally reliant, and may change as the disease progresses. (It should be noted as well that obesity creates comorbidities beyond diabetes.) Other studies beyond DPP—including major evaluations in India and China, smaller translational studies in the US, and earlier weight loss research—suggest that the relationship between weight loss and blood glucose is unpredictable and nonlinear. Across dozens of interviews with diabetes researchers and clinicians, the use of weight loss as a proxy was described as "fraught," "tenuous," and "complex." According to one researcher, "it's not perfect—but for most practical studies, it's the best we've got."

Weight is only one important risk factor for diabetes. According to the National Institute of Diabetes and Digestive and Kidney Diseases, genetic susceptibility plays an important role as well, as does physical activity, high blood pressure, cholesterol levels, and cardiovascular disease. National Institute of Diabetes and Digestive and Kidney Diseases, "Causes of Diabetes," Web. 2015 Oct. < http://www.niddk.nih.gov/health-information/health-topics/Diabetes/causes-diabetes/Pages/index.aspx> Marion J. Franz, writing in the American Diabetes Association's Diabetes Spectrum, points outs that—despite the "modest association" between DPP's weight loss and HbA1c reductions—"in several studies, weight loss was not associated with improvement in glycemia." Franz MJ, et al., "The Dilemma of Weight Loss in Diabetes," Diabetes Spectrum. 2007 July; 20(3): 133-136.

Total energy intake, rather than weight loss, may be the key underlying driver in incidence reduction. Unlike DPP, the 1986 Diabetes Study in Da Qing, China, which used a randomized cluster analysis to test nutrition and exercise strategies in preventing diabetes, found decreases in diabetes incidence despite only very modest (<1 kg) weight reductions. According to Tuomilehto et al., "this indicates that body weight alone may not be the most critical issue in the prevention of type 2 diabetes." Tuomilehto J, et al., "Long-Term Benefits From Lifestyle Interventions for Type 2 Diabetes Prevention," Diabetes Care. 2011 May; 34 (Supplement 2): S210-S214. A randomized controlled trial in India showed a smaller, but still strong, relative reduction of diabetes incidence versus the control (~26-28% for different arms of the study). However, according to Ramachandran et al., "weight reduction and change in plasma glucose were not significantly correlated in any of the intervention groups." Ramachandran A, et al., "The Indian Diabetes Prevention Programme shows that lifestyle modification and metformin prevent type 2 diabetes in Asian Indian subjects with impaired glucose tolerance (IDPP-1)," Diabetologia (2006) 49: 289–297.

In the US, two earlier weight studies produced inverse results. A 1998 study of weight loss strategies by R.M. Manning et al. tested a 3-month course of a since-withdrawn appetite suppressant on diabetic patients. After 4 years, they found that the drug had long-term impacts on weight loss, but did not result in improved glycemic control. Manning RM, et al., "The comparison of four weight reduction strategies aimed at overweight patients with diabetes mellitus: four-year follow-up," Diabetes Medicine. 1995 May; 15: 497–502. Another 1990 study concluded that, "in contrast to conventional teaching, many patients with non-insulin-dependent diabetes mellitus will

not have any improvement in plasma glucose levels after a 9.1-kg weight loss." Watts NB, et al., "Prediction of glucose response to weight loss in patients with non-insulin-dependent diabetes mellitus," Arch Intern Medicine. 1990 Apr; 150(4): 803-806.

More recent studies similarly raise questions about the clear relationship between weight loss and blood glucose. In the DPP community translations we reviewed, for example, three tracked HbA1c change—but only one of those three had an impact on HbA1c.

On the whole, diabetes and weight appear to be deeply related, and certainly weight loss is a less cumbersome metric to track, presenting fewer barriers to enrollment, lower costs of delivery, and fewer challenges to storing and communicating secure health information. However, our literature review suggests that it is worth being cautious about this relationship.

11. See, for example, American Diabetes Association and the National Council of Young Men's Christian Association, "Estimated Federal Impact of the Medicare Diabetes Prevention Act H.R. 962/ S. 452," February 2014; Xiaohui Zhuo, et al., "A Nationwide Community-Based Lifestyle Program Could Delay Or Prevent Type 2 Diabetes Cases And Save $5.7 Billion In 25 Years," Health Affairs. 2012 Jan; 31(1): 50-60; Hamman RF, et al., "Effect of weight loss with lifestyle intervention on risk of diabetes," Diabetes Care. 2006 Sep; 29(9): 2102–2107.

12. "Independent experts confirm that diabetes prevention model supported by the Affordable Care Act saves money and improves health," March 23, 2016 < http://www.hhs.gov/about/news/2016/03/23/independent-experts-confirm-diabetes-prevention-model-supported-affordable-care-act-saves-money.html>

13. Avalere Health, American Diabetes Association and the National Council of Young Men's Christian Association, "Estimated Federal Impact of the Medicare Diabetes Prevention Act," February 12, 2014, pg. 6.

14. Xiaohui Zhuo, Ping Zhang, Edward W. Gregg, Lawrence Barker, Thomas J. Hoerger, Tony Pearson-Clarke and Ann Albright, "A Nationwide Community-Based Lifestyle Program Could Delay Or Prevent Type 2: Diabetes Cases And Save $5.7 Billion In 25 Years," Health Affairs, 31, no.1 (2012):50-60.

15. It is worth noting that preventative efforts are not prevention, per se; while in some cases they may entirely avert the disease for some patients, more often these programs slow increases in HbA1c, delay onset, and thereby mitigate some of the disease's worst complications. Even patients who never become diabetic (for whom the disease has been "prevented") may still have elevated HbA1c within the prediabetic range and suffer long-term health consequences. Thus, models risk overstating the incremental cost of diabetes by comparing diabetics against non-diabetics. Such models may accurately achieve their objectives—describing the total social and economic costs of diabetes—but we should be careful not to use these estimates to describe the value of preventative efforts.

16. Over the long term, the effect of prevention on lifetime healthcare utilization is a more nuanced picture, because increased life expectancy mutes some of the preventative savings.

17. Note that while prevention helps to defray treatment costs, it also may extend life expectancy and therefore increase total lifetime medical spending. Of course, when viewed through a cost-per-QALY lens, these challenges can be mitigated. Xiaohui Zhuo, et al. (2014)

18. Xiaohui Zhuo, et al., "The Lifetime Cost of Diabetes and Its Implications for Diabetes Prevention," Diabetes Care. 2014 Sep; 37(9): 2557–2564.

19. Ibid.

20. This estimate is based on the participants in the Seventh Mt. Hood Challenge, June 2014, with the addition of IHS Global.

21. Palmer AJ, et al., "Computer Modeling of Diabetes and Its Complications: A Report on the Fifth Mount Hood Challenge Meeting," Value in Health. 2013 June; 16(4): 670–685.

22. Such models are typically Markov-based—recursive mathematical structures that describe disease progression as probabilistic transitions between a fixed number of states. Such models can account for the complexity of diabetes progression by annually recalculating the risk, for a given sub-population, of developing a given morbidity. In this way, they hope to model the future health and costs of a set of diabetic patients.

23. Dall TM, et al., "Value of Lifestyle Intervention to Prevent Diabetes and Sequelae," American Journal Preventative Medicine. 2014 Dec; 48(3): 271–280.

24. 2013 dollars, using 3% discount rate.

25. When comparing the 10-year costs of lifestyle intervention to metformin and placebo groups, the Diabetes Prevention Program Outcomes Study (DPPOS) found that "the cumulative, combined total direct medical costs were greatest for lifestyle and least for metformin ($31,382 lifestyle vs. $29,665 metformin vs. $29,759 placebo)." That is, after 10 years, the lifestyle intervention was "cost effective"—in that it produced significant health benefit for relatively limited costs—but was not cost saving. However, the authors introduce an important methodological caveat. DPPOS compared a lifestyle intervention against a control only for the first 2.8 of its 10 years of study. Following the nearly three years of the DPP intervention, the placebo group was un-blinded and offered a less-intense version of the DPP intervention. Over half of the placebo group participated in at least one such session—therefore receiving more than 'usual care.' "Thus," wrote the DPPOS authors, "if real-world usual care was used for comparison, the difference between lifestyle and placebo might have been greater." In addition to this challenge, the DPPOS authors report that "the costs of medical care outside the interventions appear[ed] low compared with those reported in the literature for people with diabetes." While the DPPOS measured significant effect sizes between the control and experimental populations, these effects did not translate into cost savings as expected. The Diabetes Prevention Program Research Group, "The 10-Year Cost-Effectiveness of Lifestyle Intervention or Metformin for Diabetes Prevention: An intent-to-treat analysis of the DPP/DPPOS," Diabetes Care. 2012 April; 35(4): 723-730.

26. Weight loss may reduce comorbidities beyond diabetes, such as (for example) cancer or respiratory problems, which would not fall within the model's scope. "Consequently," note the authors, "estimates of the health and economic benefits of lifestyle intervention…are likely conservative with respect to the benefits of weight loss associated with these omitted morbidities." Dall TM, et al., "Value of Lifestyle Intervention to Prevent Diabetes and Sequelae – Technical Appendix," American Journal Preventative Medicine. 2014 Dec; 48(S): 9.

27. Costs and benefits were estimated over a 10-year time horizon. We lightly revised published costs of each prevention program to estimate their cost of delivery in non-experimental settings. (For example, we assumed that a future expansion of the DPP would not require the same dramatic marketing and recruitment effort exhibited in the original study; recruitment strategies for more recent translations bear this assumption out.) Further, we built upon our estimated cost of intensive intervention for DPP (3 years), HELP PD (2 years), and YDPP (1 year) to add the incremental cost of continued maintenance over 10 years. Doing so allows us to compare the relative cost effectiveness of each intervention under a standardized set of assumptions. However, we do not expect that, in a Pay for Success context, interventions would be structured over a 10-year basis; rather, we would expect the basis of a PFS project to cover the intensive intervention period only.

28. It is worth noting, however, that we have imperfect information on both sides of the cost-benefit equation. The evaluated costs of each program that we reviewed are not likely reflective of their true costs at scale. Costs of the DPP, for its part, are likely significantly inflated, particularly with regards to enrollment; a program-based costing model, even at the same level of intensity, could likely cut out significant costs. At the same time, the evaluated costs of HELP PD and YDPP may underestimate the costs of identifying and attracting adequate referrals. Our experience with and anecdotal information about like programs in the sector suggest that real resources are required to drive patient flow at scale. Our comparative cost-benefit approach, below, sought to account for this by building in small supplemental marketing and outreach funding for these two programs.

29. See earlier footnote for discussion of the methodology underlying DPPOS unblinding of control group participants. The DPMM attempts to reverse-engineer this decision. Using the DPP as a proxy for the effect of the less-intense version offered to placebo-group participants following un-blinding, the model simulates the plausible effect of a non-tainted control group. Ultimately, it suggests a conservative increase in the 10-year effect of DPP, at the upper end of the DPPOS 95% confidence interval: DPMM estimates a 37-39% reduction in diabetes incidence over 10 years, versus the DPPOS-observed 34% reduction. Rather than rely on the self-reported cost methodology used by DPPOS, the DPMM uses MEPS data to estimate costs. Dall TM, et al., "Value of Lifestyle Intervention to Prevent Diabetes and Sequelae," American Journal Preventative Medicine. 2014 Dec; 48(3): 271–280.

30. Note that this approach has been pursued by others in the space, including the State of New York, which chose the Primary Care Development Corporation and a coalition of partners to explore this issue following a 2014 Request for Proposals.

31. The evidence underlying HELP PD suggests two key risk factors. The first lies in the external validity of HELP PD's evidence. What proved true in a small experimental context, among a generally non-Hispanic population in North Carolina, may not hold true in other geographies or for other populations. The second lies in the assumption that HELP PD, based on its two-year results, will continue to replicate the effect of DPP in the years thereafter; a longitudinal evaluation will help to confirm this assumption.

32. Note that this kind of approach would mirror that taken by New York State's Pay for Success project with the Center for Employment Opportunities, in which a previous RCT suggested effectiveness in subgroup analysis and is being confirmed by a new implementation.

33. Whereas simulating the medical and nonmedical value of the DPP is complex and uncertain, doing so for programs without the architecture of research and rigor built around DPP is dramatically more challenging. Doing so requires estimating the effect durability over time, with and without maintenance intervention. Translations that draw on the DPP evidence base must contend with the challenges of DPPOS—estimating the impact of un-blinding the control group on the 10-year efficacy of the intervention. They must also estimate (or measure) how the program's effect changes with various alterations to the program model. Nevertheless, YDPP demonstrates tremendous promise. At ~15% the cost of DPP, it must create only a fraction of the DPP's effect size in order to compete on a cost-per-outcome basis—which, given that the YDPP is based on the DPP curriculum and replicates its impact on weight loss, seems highly plausible. Multiple analysts agree on this point. A grant from the Center for Medicare and Medicaid Innovation suggested that the program would produce a dramatic return on investment over six years. YMCA of the USA, "The Y Receives Innovation Grant to Test Cost Effectiveness of Diabetes Prevention Program Among Medicare Population," June 2012. http://www.ymca.net/news-releases/20120618-innovation-grant.html. See further discussion above on analysis from CDC and the RTI-UNC Center of Excellence in Health Promotion Economics, as well as Avalere Health. In 2015, the research team at IHS Global behind the DPMM released a paper describing the simulated morbidity and costs of obesity, which suggests that the YDPP's impact on this metric alone significantly overmatches its cost. Su W, et al., "Modeling the clinical and economic implications of obesity using microsimulation," Journal of Medical Economics. 2015 Nov; 18(11): 886-897.

33. Maria Schiff, "States Cracking the Code on Health Costs," presentation to the National Conference of State Legislatures, August 21, 2014. <pewtrusts.org/healthcarespending>.

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Social Finance US is a nonprofit that is dedicated to mobilizing capital to drive social progress. We believe that everyone deserves the opportunity to thrive, and that social impact financing can play a catalytic role in creating these opportunities. Jake Segal (jsegal@socialfinance.org) is a Director on the Advisory team.

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