Economic Benefits of Improved Insulin Stability In Insulin Pumps

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ABSTRACT

Purpose: Insulin pump users discard unused medication and infusion sets according to labeling and manufacturer's instructions. The stability labeling for insulin aspart [rDNA origin] (Novolog) was increased from two days to six. The associated savings was modeled from the perspective of a hypothetical one-million member health plan and the total United States population.

Design: The discarded insulin volume and the number of infusion sets used under a two-day stability scenario versus six were modeled.

Methods: A mix of insulin pumps of various reservoir capacities with a range of daily insulin dosages was used. Average daily insulin dose was 65 units ranging from 10 to 150 units. Costs of discarded insulin aspart [rDNA origin] were calculated using WAC (Average Wholesale Price minus 16.67%). The cost of pump supplies was computed for the two-day scenario assuming a complete infusion set change, including reservoirs, every two days. Under the six-day scenario complete infusion sets were discarded every six days while cannulas at the insertion site were changed midway between complete changes. AWP of least expensive supplies was used to compute their costs.

Principal findings: For the hypothetical health plan (1,182 pump users) the annual reduction in discarded insulin volume between scenarios was 19.8 million units. The corresponding cost reduction for the plan due to drug and supply savings was $3.4 million. From the U.S. population perspective, savings of over $1 billion were estimated.

Conclusions: Using insulin that is stable for six days in pump reservoirs can yield substantial savings to health plans and other payers, including patients.

Disclosures

Funding for this study was provided to Managed Solutions by Novo Nordisk Inc., the manufacturer of Novolog. An honorarium was provided to Derek van Amerongen, MD, MS, for his contributions.

Richard C. Weiss had primary responsibility for concept and design with assistance from van Amerongen and Gary Bazalo. The manuscript was drafted primarily by Weiss and van Amerongen with input from Bazalo.

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INTRODUCTION

Diabetes continues to be a critical health issue, both medically and financially. Its incidence in the United States has grown significantly, rising in tandem with the increase in the obesity rate (CDC 2010, Flegel 2010). Currently, almost 18 million people have diabetes in the United States; of these, 90 to 95 percent have type 2 (CDC 2010, American Diabetes Association 2010). As a result, diabetes is a major contributor to morbidity and mortality, driving increased use of a wide variety of medical services. The annual direct medical and pharmacy costs of diabetes, estimated at $116 billion in 2007, are substantial and are expected to continue to rise as the population of patients with diabetes expands (CDC 2010, American Diabetes Association 2010). These costs are largely borne by payers, including private carriers, employers, federal and state governments, and ultimately taxpayers and consumers. This article presents a method with potential to reduce the costs of insulin for individual payers and across the U.S. health care system.

> Appropriate patients for insulin therapy include patients with type 1 diabetes and individuals with type 2 diabetes who are unable to be controlled with other medications. Type 1 is an autoimmune disease in which the ability of the pancreas to make insulin has been destroyed. In type 2 diabetes, either the pancreas does not produce enough insulin or the body's cells are resistant to the action of insulin. (AHRQ)

The U.S. Agency for Healthcare Research and Quality (AHRQ) recognized that diabetes is a difficult and complex disease to manage. AHRQ has identified that intensive therapy and a team approach results in improved care of patients with diabetes. Specifically, the agency recommends the following:

- More frequent use of 2 oral medications (a hypoglycemic agent and an antihyperglycemic agent) or 1 oral medication plus insulin
- Greater likelihood of 3 or more daily injections for insulin recipients

- Four or more visits per year for many patients
- Visits with both physicians and nurse practitioners alternating with visits with a nurse practitioner
- Direct telephone availability of nurse practitioners
- Dietitian visits with patients
- Screening for complications
- Self-monitoring

Using these guidelines, the mean glycosylated hemoglobin (HbA_{1c}) for type 1 patients was 7.1 percent, and the mean for type 2 patients was 6.9 percent (AHRQ).

An important subset of the diabetic population consists of users of insulin pumps, estimated to be over 360,000 pump users in the United States (JMP Securities, 2009). Insulin pumps offer the advantages of being readily available and may simplify the diabetes treatment regimen.

The insulin pump has changed diabetes management but has added new complexities to diabetes care. Patients must fill the pump reservoirs, whose capacities differ by pump product, with insulin, discarding unused insulin that has passed the in-use expiration date, as well as changing the needle and the tubing on a regular basis. The insulin and the other disposable parts constitute a significant portion of the pump care costs. Extending the expiration period for insulin potentially decreases drug wastage and reduces the frequency of changing infusion sets. This could lead to lower costs for payers and patients, as well as simplifying the regimen for patients.

Recently, the labeling for Novolog (insulin aspart [rDNA origin] Injection) has changed to reflect the improved stability in insulin pump reservoirs from two days to six days in three insulin pump devices (Novolog prescribing information). In this study, we used a population-based model to project the potential impact on medical and pharmacy costs, from the payer point of view. We also examined care management issues related to pump use for insulin pump–dependent patients with diabetes. Some of these care management issues included complexity of treatment regimen, patient dosing requirements, and frequency of changing insulin in reservoir and infusion sets.

METHODS

The cohort of insulin pump users under each scenario ("two-day" and "six-day") was distributed among a mix of the three insulin pumps with various reservoir capacities (Minimed Report). These pumps have been evaluated for use with insulin aspart [rDNA origin] and are listed in the insulin aspart product label. Table 1 summarizes reservoir capacity, cost of consumable pump components, and the approximate U.S. market share of three insulin pump types.

In the two-day scenario, the entire infusion set, including the reservoir, is discarded at the end of each two-day period. In the six-day scenario, the needle and cannula are changed at the infusion site at day 3 (as per pump manufacturer recommendation) and the entire infusion set is discarded at the end of each six-day period. We calculated the total cost of discarded pump components for each two-day period for the "two-day scenario" and each six-day period for the "six-day scenario" based on AWP prices derived from the MediSpan database for December 2009.

The daily insulin doses assumed to be taken by the pump user cohort were based on the distribution shown in Figure 1, which is derived from a large sample of U.S. diabetes patients (IMS LifeLink). All patients are assumed to be using insulin aspart [rDNA origin] 10-mg vials, as this would appear to be the most convenient method for transferring insulin into pump reservoirs.

We calculated the amount of discarded insulin remaining in the reservoir at the end of the two-day and six-day period, assuming the pump reservoir is filled at the start of the two-day or six-day period and is filled whenever the reservoir is emptied during the period. We also included in our calculations any unused insulin remaining in the vial 28 days after opening. The cost of the discarded insulin in each two-day and six-day period was based on the wholesale acquisition cost (WAC) of insulin aspart [rDNA origin] 10-ml vials *(Red Book)*.

Finally, the difference in total cost of all discarded insulin and all pump components consumed over a one-year period for the six-day scenario was compared with the two-day scenario.

The two population cohorts used in the model were based upon 1) a one-million member health plan and 2) total estimated pump users in the U.S. (360,000 U.S. pump users correspond to a prevalence of 0.118 percent or 1,182 pump users in a one-million member plan) (JMP Securities). These

TABLE 1
Characteristics and market share of top three pumps in market

Pump	Reservoir size in units	AWP of full infusion set with reservoir	AWP of needle and cannula	Patient mix
Accu-Chek Spirit	315	$12.80	$5.75	10.0%
MiniMed 522	180	$13.80	$5.75	45.0%
MiniMed 722	300	$13.80	$5.75	45.0%

Source: MediSpan 2009

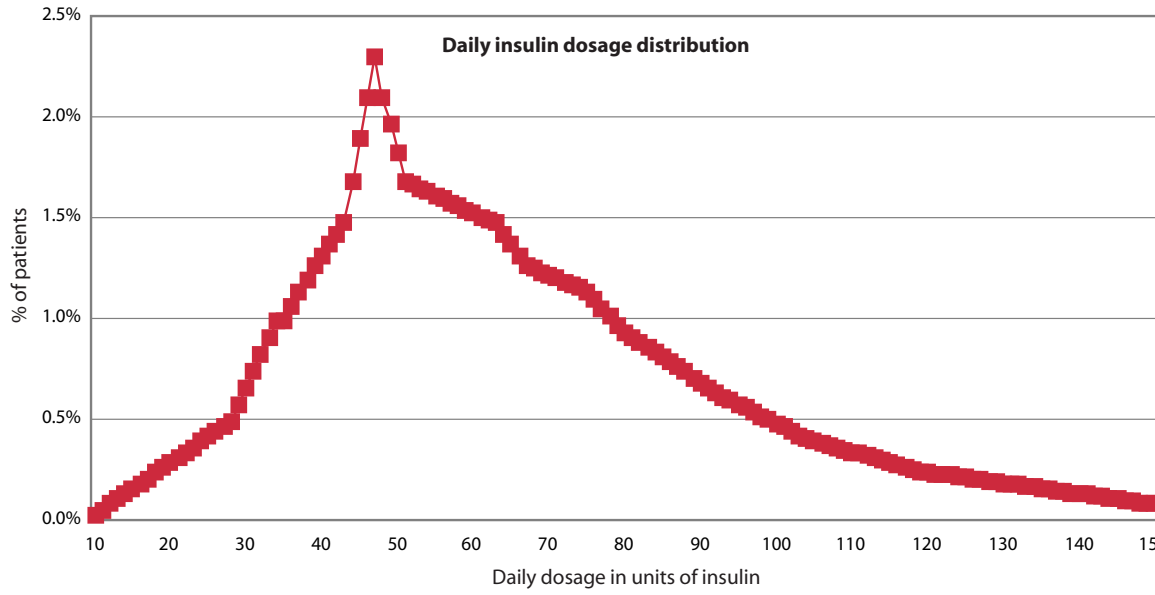

FIGURE 1
Distribution of insulin utilization

Based on daily consumption (quantity dispensed/divided by days between refills) of pump users. (IMS LifeLink data.) Time period, 2000–2008. Includes prescriptions of NovoLog and insulin lispro [rDNA origin] (Humalog) in vials among 6,868 patients using pumps. (Total number of patients with diabetes in 2008 was 803,404).

cohorts were selected as they represent common planning scenarios used by payers and epidemiologists.

RESULTS

Table 2 shows the breakout of cost savings on a per-patient basis, which are independent of total population. On average, a typical health plan of any size can expect total annual savings in drug and supply costs for each pump patient to average $2,873, assuming that patients follow the six-day scenario regimen.

Table 3 shows the breakout of savings associated with each of the studied populations. For the one-million member health plan, the model estimates that there will be 1,182 insulin pump users with prescribed insulin amounting to 28 million units of insulin aspart [rDNA origin] at a WAC of $2.6 million each year. The reduction in discarded insulin in the "six-day scenario" compared to the "two-day scenario" is estimated at 19.8 million units, saving $1.84 million. The reduction in pump supply costs yields a further $1.55 million in savings. The overall annual savings associated with all 1,182 pump users is $3.39 million.

Based on U.S. census data for July 2009, the population is estimated to be just over 307 million people. (U.S. Census Bureau) The model estimates 362,746 pump users with prescribed insulin, amounting to 8.6 billion units at a WAC of just under $800 million annually. The reduction in discarded insulin in the six-day scenario, compared with the two-day scenario, for the total U. S. cohort of pump users is estimated at 6.1 billion units, saving $564 million. The reduction in pump supply costs yields a further $478 million in savings. The overall annual savings associated with the entire U.S. cohort of pump users is just over $1 billion.

TABLE 2
Per-person average annual cost savings for a six-day versus a two-day scenario

Source of annual per-person savings	Estimated average annual per-patient savings
Reduction in discarded insulin (WAC)	$1,556
Reduction in supplies (AWP)	$1,317
Total savings	$2,873

DISCUSSION

The potential clinical impact of uncontrolled diabetes to patients is well established as is the economic burden to both the patient and society. Patients utilizing insulin pumps

TABLE 3
Population-based savings for a six-day versus a two-day scenario

	Health plan scenario (annual)	Health plan scenario PMPM	U.S. population scenario (annual)
Population	1 million		307 million
Estimated insulin pump users	1,182		362,746
Insulin units prescribed (avg. 65 units per day)	28 million		8.6 billion
WAC of prescribed insulin	$2.6 million		$798 million
Reduction in discarded insulin (units)	19.8 million		6.1 billion
Reduction in discarded insulin (WAC)	$1.84 million	$.15	$564 million
Reduction in supplies (AWP)	$1.55 million	$.13	$478 million
Total annual savings	$3.39 million	$.28	$1.04 billion

have the additional costs and inconvenience of periodically having to replace both their insulin medication and infusion sets. Our results demonstrate that there is an opportunity to provide patients using an insulin pump with a six-day stability with a less complicated, cost-saving treatment regimen that is likely to increase patient and provider satisfaction with therapy.

It is important to consider the major stakeholders in any decision to implement a broad-based program to migrate patients to a new regimen. These include the payer, provider, and patient. Insulin and pump supplies for patients covered under traditional multi-tier pharmacy benefit plans with typical medical benefit coverage for durable medical equipment cost substantially less for the six-day regimen compared to the two-day regimen. Each patient utilizing daily doses of insulin ranging from 10 to 150 units, with a mean of 65 units saved, on average, $2,873 ($1,556 insulin and $1,317 supplies) annually (IMS LifeLink). These savings are greater than the total cost at WAC ($2,199) of the prescribed insulin for a patient taking the average daily dose of 65 units. For a one-million member health plan, overall savings are estimated to be almost $3.4 million, equating to 28¢ per member per month (PMPM) savings.

The implications of this level of savings to a health plan are dramatic, because there is a substantial difference in cost and profit compared with two-day regimen. Assuming that a health plan is operating on a 3 percent margin, to achieve $3.4 million in bottom-line profit, it would have to acquire $113 million in incremental revenue from new sources. In 2009, the average cost of health care premiums was $13,375 (Kaiser Family Foundation 2009); therefore, it takes new employer groups with 8,460 employees to yield an equivalent amount. The costs of health care premiums are likely to go up and therefore the implementation of this new regimen may help slow some of these increases.

Another aspect that is important to health plans is for patients to maintain glycemic control through adherence to their treatment regimens. This is important to health plans, because members with diabetes utilize more health care services than members without the illness. One study found in a privately insured patient population that adults with type 2 diabetes and 24 months of continuous health plan enrollment had 2.4 times the adjusted health care costs of matched controlled non-diabetic patients (Durden 2009).

It is important to recognize that managed care organizations make decisions by committee; therefore, a change in protocol is likely to require P&T or even medical technology committee approvals. As a result, like any other systematic change, an internal champion must emerge to make the case and handle any objections that may arise. Based on the impact of the cost savings involved, it seems likely that either a pharmacy director or medical director with pharmacy budget responsibility will take the lead.

Although these estimated cost savings from reduced wastage are impressive for private health plans, the cost implication also applies to the significant portion of the diabetic population covered by government sponsored plans such as Medicare, Medicaid, Tricare and the Veterans Affairs Department. The result is to further magnify the positive impact on both costs and patient outcomes at a societal level.

Diabetes is a complex disease requiring patients to demonstrate excellent care management over their lifetimes in order to successfully keep their HbA_{1c} levels within target range. It has been shown that medication adherence rates for patients with type 1 and type 2 diabetes who use a self-monitoring blood glucose regimen are 70 percent and 64 percent, respectively (Delamater 2006). Complex treatment regimens are a barrier to successful glucose control, result-

ing in increased morbidity and mortality as well as economic consequences. The Diabetes Control and Complications Trial proved that intense management of patients with respect to glycemic control resulted in dramatic reductions in the rate of development and progression of retinopathy, neuropathy, and nephropathy. In turn, tighter glycemic control yielded lower long-term medical costs from reduced hospitalization and fewer medical services (Zinman 1997).

Lower adherence rates have been correlated with chronic conditions, asymptomatic, or varying symptomatology during disease progression, and complex treatment regimens, especially those requiring lifestyle changes (Delamater 2006). All of these are associated with diabetes and can represent a challenge to patients and health care professionals. From the payer perspective, tighter control represents a significant medical cost savings opportunity.

Patients who make pharmacy copayments for drugs and have out-of-pocket coinsurance for some supplies under more traditional pharmacy and medical benefit plans have much to gain by converting to a six-day regimen. In 2007, Kaiser Family Foundation reported average copayments for generics, preferred brands, and non-preferred brands were $11, $25, and $43, respectively (Kaiser Family Foundation 2011). Under a six-day scenario, we assume that doctors will continue to prescribe the same number of insulin units per prescription; however, patients will refill them less frequently because of the changed label of insulin aspart, which allows for 6 days' use in a pump, and the reduction in discarded insulin. Furthermore, patients save on the infusion sets because of the reduced number required throughout the year. Based on the six-day regimen, patients will refill 3 to 4 fewer prescriptions per year, resulting in $75 to $172 in annual savings, depending on whether the six-day insulin is reimbursed as a preferred or non-preferred brand.

Relative to insulin costs and pump supplies, greater savings to the patient are more likely to occur through the reduction of the number of full infusion sets required during the year. Under the two-day regimen, patients require 15 infusion sets per month, costing an estimated $2,500 annually. Conversely, a six-day regimen requires only five complete infusion sets per month, costing $833 per year and resulting in $1,667 in infusion set savings for the year.

There is, however, an additional cost of $350 to the six-day regimen associated with new needles and cannulas, which are required every three days. But even with this adjustment, the supply cost savings net at $1,317 per annum per patient. We would expect patients to realize additional savings from reduced medical costs, because adherence and glycemic control improves with the less complicated regimen.

Further potential benefits to diabetic patients result from the reduction of these supply cost savings. Many health plans impose a durable medical equipment cap for the year, typically $2,500. By lowering the supply costs associated with pump supplies, patients are less likely to reach their cap, or they can have more coverage for other durable medical equipment purposes.

In the United States, the number of individuals with high deductible health plans (HDHP) is increasing (AHIP 2009). According to a 2009 report from America's Health Insurance Plans Center for Policy and Research, HDHP coverage rose to 8 million in January 2009. This is an increase of 1.9 million from 6.1 million in January 2008. For patients with high deductible health plans the six-day regimen has an even greater favorable financial impact than for patients with more traditional coverage. For the former, 100 percent of their medical and pharmaceutical expenses are paid out of pocket until their high deductible is reached. For a member with a $5,000 deductible, a reduction in out-of-pocket expenses of $2,500 or more is quite considerable.

The change to the six-day regimen would be especially important for patients who are trying to stretch their health care out-of-pocket dollars. Perhaps these patients are not changing their insulin and infusion sets every two days as directed and therefore are at risk for less efficacious results because the insulin that they are using is outdated. Benefits of the six-day protocol include a reduction in frequency of changes.

The six-day protocol also has meaningful advantages for health care professionals trying to simplify the complex and costly treatment regimens. With the ever-increasing costs of health care, the new regimen enables the provider to offer a more economical option to patients. It provides yet another opportunity to educate patients on the need to follow the health care professional's guidance. It provides a much simpler method for patients to follow that could lead to better adherence, not only to the insulin pump dosing but to overall treatment.

LIMITATIONS

There are limitations to this analysis. The model assumes patients are currently adhering to the manufacturers' recommendations for changing the insulin reservoir every two-days, as per the FDA's indications or the pump instructions. In the real world, patients are not always compliant with their medication or with device instructions. If a patient continues to use the same insulin reservoir until it is empty, regardless of the two-day in-pump use limitation, this would diminish the savings projection. However, there may be clinical and economic consequences associated with adverse events caused

by the use of expired insulin. In addition, in an effort to reduce costs, there may be patients who currently do not fill their reservoir to capacity as instructed.

There will also be a certain level of noncompliance with proper insulin pump use, although this is likely to be less common with a pump-dependent group than with insulin-dependent diabetic patients in general, (Raccah 2011) because of the screening that typically occurs before a patient is started on the pump and because of the hyperglycemic risks associated with running out of insulin too soon. A reasonable amount of resources applied by health plans toward educating health care professionals and patients on the clinical and economic benefits of the six-day protocol should result in new pump users initiating therapy with the new regimen.

The model assumes typical distributions of patients and market shares of the three different insulin pumps. Individual health plans may, of course, have their own preferred insulin pump products and, therefore, have a different mix of pumps that will affect the outputs from the model.

Another assumption in the model is that patients will continue to obtain prescriptions for insulin from their doctors as they are currently written. For example, if a patient is currently prescribed 2,000 insulin units for a 30-day supply, the patient will continue to refill that prescription—only the time between refills will be less frequent (more than 30 days). The result is less cost to the patient and payer; however, the plan will collect fewer copayments during the year.

Overall, we believe that these limitations do not significantly change the impact of the savings that plans and patients are likely to experience.

CONCLUSION

Our model clearly demonstrates that significant costs savings can be achieved through the conversion of a two-day insulin regimen to a six-day regimen among insulin pump users. Pharmacy budgets can be expected to lower their insulin costs by $1,556 per patient and medical supply costs lowered by $1,317 per patient under the six-day regimen. Health plans with even small numbers of patients who use insulin pumps may find it useful to encourage the use of the six-day regimen. From a societal perspective, it appears that significant cost savings to the health care system might be achieved.

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