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EDITORIAL

Future of Diabetes-Technology: Certificate of Competency for Insulin Pumps and Continuous Glucose Monitors

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Introduction

Imagine that you are a health insurance company executive whose task is to decide whether to reimburse the costs for a new diabetes technology. Unlike other chronic diseases, diabetes requires multiple daily decisions by the client to maintain a path between the twin chasms of hypoglycemia and hyperglycemia that can lead to unwanted and costly consequences for your company. The manufacturer of the new product has generated a colorful and convincing PowerPoint presentation that highlights its product's advantages, summarizes key aspects of the clinical studies performed during the development process, as well as reports from patients stating how much they benefit from the product. The presentation may also contain figures showing savings on certain aspects of patient care when the device is used regularly. So, what will your decision be?

Position of Randomized Controlled Trials

In view of the ever-increasing cost of health care insurance, your shareholders demand that nothing should be reimbursed without good evidence for a proven benefit. You will carefully check the quality of the randomized controlled trials (RCTs) that are performed during the clinical development process to evaluate the safety and efficacy (however these are defined) of the new product.

Randomized controlled trial studies are often designed to show benefit. Therefore, even if economic aspects are addressed adequately, you realize that these studies have not tested the "effectiveness" of the product in daily life. The subjects recruited into a RTC have to fulfill rigid inclusion and exclusion criteria to be eligible for such studies and may not represent the typical patient seen in a busy diabetes practice. Pump, continuous glucose monitor (CGM), and meter studies are handicapped in that it is usually not possible to do a single-blind—much less a double-blind—study.

In RTCs, there is often a study effect over a certain period of time that has a positive influence on outcome parameters. Even when an RCT shows positive results, a number of other factors often come into play in daily life that can hamper the usage or efficacy of a given product.

Outcome Research

We have had CGMs on the market for more than 10 years, with a number of RCTs showing evidence that regular usage of CGM systems is associated with improvements in metabolic control. Meta-analyses have shown benefits for CGMs, yet a Cochrane Review (*http://summaries.cochrane.org/CD008101/continuous-glucose-monitoring-systems-for-*

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Abbreviations: (A1C) hemoglobin A1c, (CGM) continuous glucose monitor, (RCT) randomized controlled trial

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type-1-diabetes-mellitus) was more critical of the available evidence, "There is limited evidence for the effectiveness of real-time continuous glucose monitoring (CGM) use in children, adults and patients with poorly controlled diabetes." Despite their obvious benefits for individual patients, CGMs have shown only modest benefits for glucose stability and reductions in hemoglobin A1c (A1C) and hypoglycemia if you accept the point of view of the Cochrane reviewer. Furthermore, we do not have a good understanding of why patients in RTCs are reluctant to use CGMs. Under study conditions with paid sensors, many patients do not use such systems as often as one would expect.

Evaluation of the patient acceptance in adequately designed outcome research studies might help device companies and the scientific community to understand at an early stage why patients are willing to use (and probably pay) for this development and not for the other one. What researchers and device engineers regard as a medical need might differ considerably from the patients' real needs. Do patients really use new technical devices in ways that allow them to get the best out of the products offered to them? For example, a surprising number of diabetes athletes who participate in endurance events will use full pump suspension (or removal) or pre-event hyperglycemia to manage their glucose, without having considered use of a temporary basal reduction, a much better solution to varying insulin need during events.

In summary, as a health insurance company executive, you would be reluctant to approve a new device to help patients with a chronic disease if they cannot use it in the manner the developer intended or if your investment will not generate the benefits promised.

Certificate of Competency

To get out of this tricky situation, patients who want to have device reimbursement might be asked to make a deal with your health insurance company to demonstrate that in their individual case, such an investment makes sense. For example, a patient who is interested in reimbursement for glucose test strips, an insulin pump, or a CGM system might be asked to attend a training course and pass a competency exam to receive a certificate of use as a first step. These courses would be paid for but not organized by the device manufacturer for obvious reasons.

The insurance companies would be responsible for payments for the device (perhaps delayed payments) and ongoing supplies once the user demonstrates some clinical benefits. Patients require a clear and thorough introduction on how the device relates to their diabetes over at least two or three sessions, with repetition of the necessary information and demonstration by the patient.

All practical hands-on aspects should be trained several times. Patients need to understand how to "drive" their insulin pump and how to respond to meter and CGM data amidst the requirements imposed on them in daily life. Passing the examination guarantees that patients are, in principle, able to use the given device in a manner that enables them to optimize their metabolic control.

If there is no improvement in A1C results, standard deviation, mean amplitude of glycemic excursions, or average glucose, or if no reduction in hypoglycemia is shown after a defined period of time, such as 90 days, the patient's insurance company can ask for retraining and eventually stop paying for the device if it has no proven benefit.

For different reasons, attending such courses might be an eye-opener for the developers of new devices and the managers of health care insurance companies. Device developers can receive user feedback from those who fail to manage the device and from those who succeed. They will probably better understand the demands of patients in daily life, while insurers will see how complex diabetes care can be for patients who live a normal life with all its requirements.

Consequences of a Certificate

Having a certificate similar to a driver's license for a medical device would give some rights to the patient, but it would also apply some pressure to use the technology in a thoughtful manner. Ongoing documentation regarding the frequency of use and outcomes achieved can be done automatically, due to the progress made with data communication.

Also, an insurance executive would have to be very cautious not to discriminate against certain patients or patient groups. For example, patients that have intellectual issues or prior compliance issues should not be automatically blocked from getting access. It is not always clear which patients will benefit from an expensive technology until they are given a chance to try it. Until patients have access to an artificial pancreas system that works ideally in each and every patient to optimize blood glucose, the use of glucose monitoring and insulin

delivery systems will require a certain amount of abstract thinking, understanding of how therapeutic interventions are helpful to optimize metabolic control, or consistent medical follow-up from a competent clinician.

Current Teaching Programs

You might think that this is fully covered by the currently available teaching programs for patients with diabetes and that an additional course is not necessary. To the best of our knowledge, optimal usage of medical devices is only one of the many topics that are covered in conventional teaching programs. Primary care physicians and endocrinologists commonly see patients who monitor their glucose and wear a pump but do not understand how to change their settings to improve their control. Depending on the technical interest and skills of the diabetes nurse giving such programs, training may not include all the details of using an insulin pump with all the different options. Each pump company, to varying degrees, provides training to the pump wearer, but it is not mandatory to participate in a teaching course and demonstrate skills before you can get an insulin pump prescribed. Unfortunately, clinical outcomes so far have been marginal.

Without a thorough understanding of diabetes and how to treat it, a modern high-tech device cannot be of real help. A device course has to cover the basics of diabetes as well as specifics for the medical device you are planning to use. Investing in a technical device without investing in adequate training is a great plan for failure. Unless the time of a health care professional is paid for to review a patient's 24-h glucose profiles, it is doubtful that covering these monitoring costs will be a smart investment.

It would be interesting to compare teaching approaches and successes between different countries and between states in the United States with each other. We are unaware of a thorough economic evaluation of these different teaching activities. Because diabetes has a lifetime of health care costs, clearly, an analysis would be needed for the proposed competency certificate regarding multiple and lifestyle endpoints.

Summary

There are numerous questions and significant issues to overcome before we will have a system in place that requires a competency certificate and outcomes data of each patient. Only then would health care insurance companies be willing to reimburse and continue reimbursing a medical device.

Concerns that this would raise include whether the requirements will be the same for insulin vs noninsulin users, how to track the outcome of usage of the device without generating high additional costs, and how to monetize the patients' efforts. It might also be that some patients are incapable of passing a competence examination but that their health care professional may be very competent at using the results they bring to the clinic. Another key concern is finding good trainers for such courses who have skills as diabetes educators and training by the device company. These clinician/trainers have the best teaching background and know best how to motivate patients.

As with each and every system that we create, there are pros and cons in our proposal. We have to carefully watch that it is not predominantly used to restrict the access of patients to innovative technology that can help them ease and improve their daily life with a demanding disease. Even so, implementation of competency certificates might be a way forward into the future of diabetes technology.

P.S. We acknowledge that this editorial is the result of a nice afternoon sitting outside on a deck in San Diego, CA, on December 31, 2011, enjoying a wonderful glass of California wine. However, it summarizes many discussions, talks, observations we have had about this topic in the last few years. As we tried to indicate, we are aware of numerous critical aspects, but also believe that there is a pressing need for such an initiative and for further discussion of this situation.