

**Novel Sensing Technology  
for Non-Invasive Continuous Glucose Monitoring  
based on nano-, bio-, information technology and cognitive science**

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## **PREAMBLE**

While almost 100% of the people, not just in US but also across the world, Europe and Asia, all agree that a solution for Noninvasive Continuous Glucose Monitoring sure will have one of the greatest impact on modern mankind, most of advisors to small start-up recommend not to mention anything about Noninvasive Continuous Glucose Monitoring to investors or even funding agencies for a simple reason. Too many efforts, too much money over 20 years have been poured into then claimed promising solutions without any success, resulting in wide spread cynicism over any new effort. This proves it involves widely recognized high-risk of failure. Since the continuous monitoring is the key for the diabetes management while this national diabetes problem is growing bigger with increasing numbers of diabetes, its complication and its related cost, and more risk associated with aging population than ever, it proves that a successful Non-invasive Continuous Glucose Monitoring solution for easy and convenient management will bring the long waited high-return impact nationally and even globally.

Now is the time we could and we should develop a real reliable solution using all great advances in many different technology fields, not only bio technology, but also information technology, nanotechnology and even cognitive science. This is why Noninvasive Continuous Glucose Monitoring based on nano-, bio-, information technology and cognitive science, is proposed as one of the most Critical National Needs that government, especially NIST TIP program, needs to pay attention, since the program pursues to fund selectively high-risk, high-reward researches.

## **AN AREA OF CRITICAL NATIONAL NEED**

The area proposed as a Critical National Need(CNN) is “Novel Sensing Technology for Non-Invasive Continuous Glucose Monitoring”. The desired output of work funded through NIST TIP program is a reliable, usable and accurate sensing technologies, components and system for the Non-Invasive Continuous Glucose Monitoring, at an ultra compact size and low cost for an affordable personal wearable/mobile devices. Current sensing technologies are basically painful lancing solutions which require pin pricking three or four times a day all year long. It is commercially locked because the current solution vendors generate recurring sales by selling strips for one time use. Current sensing technology is not an effective continuous monitoring solution at all because it relies fully on the patient attention and most likely a typical patient pinpricks only when she or he feels already not normal.

The novel sensing technology and solution will requires not only transformative approach but also a quantum leap in technological philosophy. It will requires multi-disciplinary fusion technology, rather than relying on a single domain of expertise. The novel sensing technology and solution will continuously monitor every minutes without patient attention and interruption, and the accuracy will match the current lancing device’s accuracy. The sensing device will be battery operated with short battery charging time. The monitored data is so reliable that the patient and the networked doctor or hospital will be alarmed before the measured result reaches any critical result. The sensing device will be wirelessly connected to internet. Lastly the sensing device cost should be low enough for patients and insurers without recurring cost.

The need for the proposed novel sensing technology is *national* because already 17 million Americans across country are suffering from diabetes and undergoing the painful monitoring procedures everyday. The need is *critical* not only because the total estimated cost of diabetes is close to \$200 billion, but also because the diabetes population is growing ever fast with aging population, without any effective low cost continuous monitoring solutions.

## **MAGNITUDE OF THE PROBLEM**

The magnitude of the problem is well summarized in the recent report, *Diabetes Care* 31:596–615, 2008. The prevalence of diabetes continues to grow, with the number of people in the U.S. with diagnosed diabetes now reaching 17.9 million and 5.7 million people unaware that they have the disease. (Total 23.6 million, 7.8% of population)[American Diabetes Association]. The total estimated cost of diabetes in 2007 is \$174 billion, including \$116 billion in excess medical expenditures and \$58 billion in reduced national productivity.

Medical costs attributed to diabetes include \$27 billion for care to directly treat diabetes, \$58 billion to treat the portion of diabetes-related chronic complications that are attributed to diabetes, and \$31 billion in excess general medical costs. The largest components of medical expenditures attributed to diabetes are hospital inpatient care (50% of total cost), diabetes medication and supplies (12%), retail prescriptions to treat complications of diabetes (11%), and physician office visits (9%). People with diagnosed diabetes incur average expenditures of \$11,744 per year, of which \$6,649 is attributed to diabetes. People with diagnosed diabetes, on average, have medical expenditures that are 2.3 times higher than what expenditures would be in the absence of diabetes. For the cost categories analyzed, \$1 in \$5 health care dollars in the U.S. is spent caring for someone with diagnosed diabetes, while \$1 in \$10 health care dollars is attributed to diabetes. Indirect costs include increased absenteeism (\$2.6 billion) and reduced productivity while at work (\$20.0 billion) for the employed population, reduced productivity for those not in the labor force (\$0.8 billion), unemployment from disease-related disability (\$7.9 billion), and lost productive capacity due to early mortality (\$26.9 billion).

The actual national burden of diabetes is likely to exceed the \$174 billion estimate because it omits the social cost of intangibles such as pain and suffering, care provided by nonpaid caregivers, excess medical costs associated with undiagnosed diabetes, and other diabetes-attributed costs for health care expenditures such as health care system administrative costs, over-the-counter medications, clinician training programs, and research and infrastructure development. The burden of diabetes is imposed on all sectors of society— higher insurance premiums paid by employees and employers, reduced earnings through productivity loss, and reduced overall quality of life for people with diabetes and their families and friends. [Diabetes Care 31:596–615, 2008]

## **SOCIETAL CHALLENGES**

### *Continuous monitoring*

Among others, one single most important and widely recognized challenge about diabetes is the continuous monitoring(24/7) to manage the disease effectively at all stages. However with current monitoring solutions, it is not easy, practically very difficult to monitor the

glucose level continuously.

Modern lancing devices have improved further, and most now feature adjustments to control depth of penetration of the needle (stoneworkers will need a deeper puncture to find blood than people who don't work with their hands). Needles are smaller and sharper, and recent devices have been approved for "alternate site testing," (obtaining blood from the forearm, upper arm, back of the hand, thigh or calf) but anyone who test their blood glucose will say that it still sometimes hurts and can cause bruising. If we add the natural dislike of needles to the actual pain produced, to the social unacceptability of droplets of blood and bloody test strips and meters (and concerns about blood-borne diseases), and it's easy to understand why people have long looked for a measurement that doesn't involve blood. [The Pursuit of Noninvasive Glucose: "Hunting the Deceitful Turkey", John L. Smith]

Simply because current invasive solutions and minimally invasive solutions are not convenient at all, it is not easy for patients to keep monitoring their blood glucose level at necessary frequency. There are also non-invasive solutions approved by FDA, but they all failed to pass the market acceptance due to either inconvenience or lack of accuracy.

In the blood glucose monitoring industry, it is well accepted that there are three "C" terms that drive people's willingness to test: Cost, Comfort and Convenience. The comfort (pain) advantage of a noninvasive technology is easily understood, and since very few proposed noninvasive approaches need a test strip that is consumed every time a test is performed, there should be a clear cost advantage to both customers and insurance companies alike. The cost of meters, however, would most likely increase with a successful noninvasive approach - the projected cost for common noninvasive approaches varies from several hundred to several thousand dollars. Convenience includes such issues as how long a test takes, how obtrusive or visible the apparatus is, and whether a visible drop of blood is required to perform the test. This issue is more subjective and deals with the comfort level people have to testing in public, letting everyone know they have diabetes, and concerns about the sight of blood. [The Pursuit of Noninvasive Glucose: "Hunting the Deceitful Turkey", John L. Smith].

Without this successful Non-Invasive Continuous Glucose Monitoring solution, this national critical problem will continue to stay and get worse.

## **TRANSFORMATIONAL RESULT**

*Significant reduction in total national medical expenses and great improvement in quality of life for diabetes patients and their families, employers, and medical care providers through Preventive, Patient-centered, and Remote/Mobile/Wireless solutions.*

The global healthcare industry is facing the convergence of three forces that will transform the whole landscape of the industry in the next few years: *disruptive demographics* that are straining healthcare systems to the breaking point; *disruptive economics* that will render today's model of medical care unsustainable; and emerging *disruptive technologies*, which will enable an entirely new paradigm of care.[Source: Forrester Research]

At the same time, as a rapid development of information technology brings forth a ubiquitous network system such as the Internet and all kinds of wireless networks, there has been no

such precedent powerful infrastructure of information and communication in any previous history. These technological trends with the social trends of aging population bring enormous transformation to the value chain of healthcare industry/ market, creating a new concept of u-Health or healthcare unbound, composed of mainly four major market segments. The novel sensing technology developed under this TIP will play a critical role for these coming eras, as a preventive, personalized and remote solution. This sensing technology is a must to have, not a good to have one, and there is no time for delay for any reason.

## **MAPPING TO NATIONAL OBJECTIVES**

Having a National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) within government organizations clearly shows that it is a national objective to manage the diabetes from a long term national perspective.

Griffin P. Rodgers, M.D., M.A.C.P., Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) provides, on the NIDDK web site, five key factors about diabetes to help people with diabetes better understand how to manage the disease. Among them here are top two.

*Fact #1: Diabetes is a serious disease. It can lead to serious complications such as heart attack, stroke, blindness, kidney failure, and lower limb amputations. People with diabetes can take steps to manage it and lower their risk for complications. Make healthy food choices, be physically active, and stay at a healthy weight. Good diabetes care includes managing the ABCs of diabetes – as measured by the A1C test, blood pressure, and cholesterol – to help avoid having a heart attack, stroke, or other problems.*

*Fact #2: The only way to know for sure what your levels are is to check your blood glucose. The absence of symptoms of high blood glucose is an unreliable guide for judging glucose control, since symptoms do not occur until blood glucose reaches high levels. Diabetes is often called a “silent disease” because it can cause serious complications even before you have symptoms. Set your blood glucose targets with your diabetes care team. Ask your health care team to show you how to self-monitor your blood glucose. Keep a record of your results, and share them with your team. Also, know your A1C goal and keep a record of your test results, which reflect your average blood glucose levels over the past three months. It is the best way to know how well your blood glucose is controlled overall.*

Considering the first fact is about the serious disease itself, fact #2 is the top priority to manage the diabetes, and monitoring the blood glucose level is actually the only way to know about the status of diabetes. Therefore most convenient, easy, reliable and low cost solution to monitor glucose level continuously, is the key technology to be developed to manage the disease best.

Sensing technologies also directly correspond to NIST’s areas of technical competence of measurement science, and NIST historically has funded ATP funding into a few glucose sensing related technologies.

## **ESSENTIALS FOR TIP FUNDING**

Noninvasive glucose sensing is one of the most well known problems for decades without a clear reliable solution. It is not, perhaps, as difficult or fraught with problems as time travel or the absolute, final cure for cancer, but it is the more tantalizing because it has seemed for decades that the solution was always “just around the corner,” or at most, “just over the horizon.” One of the most disturbing aspects of this field has been the perennial announcements by fledgling companies that the problem has been solved, and that people with diabetes will no longer have to stick their fingers. Without exception, these have been premature and often were meant to generate “hype” in order to increase awareness of a company that is trying to raise money, and equally frequently, they raise false hopes in people who need the product.[ The Pursuit of Noninvasive Glucose: “Hunting the Deceitful Turkey”John L. Smith, 2006]

Given the scale and importance of the problem of our nation’s diabete, it is not surprising that there are other agencies that have been working on challenges associated with this topic such as National Institute of Diabetes and Digestive and Kidney Diseases(NIDDK), National Science Foundation(NSF) and American Diabetes Association(ADA). For ADA grant, fund sizes vary from \$50,000 to \$115,000. NIDDK has much bigger size, \$1.25 million annual fundings available but only for establishing diabete centers. Research on sensing technology might be a part of it, but then again only about 10% of the budget could be allocated. Fundings from NSF have been available through SBIR projects whose sizes are \$100,000 for phase I and \$500,000 for phase II. While those fundings are necessary for wider scope of diabetes research, those are far from being focused on the specific research and development for non-invasive continuous glucose sensing technology and the fund sizes are far from being appropriate for the task.

This sensing technology is positioned in a gray area between science/engineering and bio/medical fields, it might be not easy for any side to fund significant amount for real high risk project. It is a right area for TIP to take a role to fund this gray area project to integrate advances in sciences and technologies and bio-medical fields to meet one of the most waited national critical needs. It is a right time. As an example, recently, after a desicive feasibility study, Korean government issued a RFP for a sensing technology research and development (5 year, \$5 million) for Continuous Glucose Monitoring. They might try minimally invasive solutions first and then will move on to non-invasive solution. They see the urgent needs and feasibility as well. Since most of the prior efforts to develop non-invasive glucose sensing have been done in U.S., TIP program should help a final reliable solution for non-invasive glucose monitoring to be developed first in U.S.

Also the research and development of novel sensing technology by bringing together multidisciplinary sciences and technologies will also open up new application opportunities in the convergence areas of IT (information technology), BT (biotechnology) and NT (nanotech nology) and cognitive science. The sensing technology to be developed under this program will be applicable directly to other noninvasive health monitoring or vital sign monitoring as well, such as hemoglobin level, heart rate, respiration rate and blood pressure etc. for further chronic disease management.

### **Potential competition**

Since the history of developing the noninvasive glucose monitoring is more than 20 years and there are still many active small companies and research groups everywhere across countries, of course with less attention these days, there will be extremely high competition if RFP is issued for this proposed CNN; Individual inventors, small companies, researchers at

Universities and Diabetes Centers from many different organizations. All could participate in the competition in some allowed entity format.

**The tentative joint proposal team**

NanoLambda : Nano-optic based spectrum sensor development

Carnegie Mellon University (Robotics Institute): Pattern identification and recognition

University of Pittsburgh Medical Center (Diabetes Institute): Diabetes data analysis, comparison and Pilot test

Penn State University: Nanofabrication

One system device companies: Optical interfaces and proto system integration

**CONCLUSION**

Sensing technology for noninvasive continuous glucose monitoring is one of the most well known problems for decades without a clear reliable solution. By looking at all other advances in other technology and science fields, it is uncomfortably felt that it should be now to have such a long waited CNN solution. TIP program is the only program which can initiate and fund these forgotten efforts again in full scale. Of course it's risky, but the rewards will be enormous nationally and globally as well, with huge impact on one of the most difficult disease management issues.