

VIEWPOINT

INNOVATIONS IN HEALTH CARE DELIVERY

A Patient-Designed Do-It-Yourself Mobile Technology System for Diabetes

Promise and Challenges for a New Era in Medicine

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The US health care system has typically embraced a top-down model of health production, in which large-scale organizations, such as pharmaceutical or medical device companies or academic health centers, produce the tools and technologies for improving health. The underlying assumption is that physicians, researchers, and industry professionals are health experts rather than the patients. However, in 2014, the Nightscout Project, an innovative do-it-yourself mobile technology system for type 1 diabetes, was created by patients for patients and was rapidly scaled to a US and global population within a relatively short period. This bottom-up, patient-driven approach to health production has important lessons for a new era of medicine powered by patient engagement, mobile technology, cloud computing, and social media. This Viewpoint describes the Nightscout Project, including the challenges it poses for the current health care system, and the opportunities yielded from this new form of health production.

The Nightscout Project

The origins of the Nightscout Project began in February 2013 when the parents of a 4-year-old boy with newly diagnosed type 1 diabetes began using a continuous glucose monitoring system (CGMS) approved by the US Food and Drug Administration (FDA) that would provide interstitial glucose readings every 5 minutes.¹ The information was invaluable to the family, but the patient's parents could not monitor the child's blood glucose levels while he was at school because there were no commercially available mobile technology solutions to access the data in real time. The father (who is a software programmer) began developing a computer code that would enable him to access the blood glucose readings from the CGMS receiver to the computing cloud through a smartphone. With the data in the cloud, the blood glucose levels could be viewed by the parents from anywhere to provide a continuous monitoring solution.

When the father successfully transmitted his son's blood glucose data to the cloud, he sent a tweet of his achievement through the social media platform Twitter that was noticed by other caregivers and patients with type 1 diabetes. Those who had technical programming expertise reached out to the father. He shared the computer code with these individuals, and as a group they began using, adapting, and creating new code to generate novel and personalized mobile technology solutions, including displays of glucose values that served as care portals to allow caregivers to input additional data (insulin

doses, carbohydrates), smartphone applications with alerts for high or low levels of blood glucose, and real-time views of blood glucose levels on wearable computing devices like programmable wristwatches.

The group decided to make the computer code open source, which included the smartphone application for transferring data from the CGMS to the cloud, the web application to display values stored by the CGMS, and the watch face for a wearable device that displays the values open source (eFigure in the Supplement). The group created a website that hosted the code and do-it-yourself written instructions and informational videos for setting up the system.² The group also opened a private Facebook group called CGM in the Cloud that became a community forum where members could learn more about the system and ask for and receive technological advice and troubleshooting.

Although the majority of support occurs virtually through online interactions, individuals can also connect through the Facebook group to set up local in-person install sessions to provide and receive system support. At its inception, the Facebook group had approximately 40 members but rapidly increased to more than 15 000 members in the United States within 18 months, and has expanded to include more than 4000 members in a number of other countries.

New Approach in the Production of Health

The Nightscout Project represents an important development in the health care landscape for 3 reasons. First, it reflects the increasing autonomy of patients and caregivers in the context of a computing revolution. Mobile telephones, the Internet, and cloud-based computing have empowered patients to design and create their own technology systems for health without the need for assistance from industry or health care professionals. Second, it reflects a new type of large-scale health production created through human cooperation and collaboration facilitated by social media. Third, Nightscout was created through the virtual collaboration of a global community of patients and caregivers with diabetes, sharing their knowledge, computer code, and personal time.

Challenges

The Nightscout Project is an example of a patient-designed, technology-driven collaborative health innovation. However a number of important legal, regulatory, and cultural challenges must be addressed by patients, caregivers, and the health care ecosystem.

First is the issue of safety. At the start of the project, there were many potential points of technical failure in the hardware and software systems, including breakage of the CGMS-receiver USB port, difficulties with data transfer to the smartphone, and loss of glucose readings in the wearable, mobile, or desktop applications. If individuals solely relied on the readings or alarms from a separate device to make medical decisions, hypoglycemic or hyperglycemic trends could be missed in the event of technical failure.

In October 2014, leading members of the Nightscout Project contacted the FDA to discuss safety concerns, which is of paramount importance to the community. The FDA emphasized the need for a single entity, even if the entity is nontraditional, to be responsible for ensuring the safety and effectiveness of the project, which includes the reviewing and testing of code before public release, monitoring safety, detailing how quickly problems are identified and addressed in the system, tracking the code updates, and identifying the responsible party for these updates. The group has embarked on this process, but to date, there is no systematic measurement or monitoring of these events inside the community except for the unstructured information being shared by the Facebook group.

Second, there is the issue of legal liability. The Nightscout code is publicly available with the following disclaimers: "Highly experimental. Not intended for therapy. Use at your own risk. Intended only as an investigational and educational tool to learn about this technology." Despite the disclaimers, the risk of personal liability from system failures or adverse events is possible. Liability may be particularly important and relevant with an increasing number of non-technical users. Many of its initial users were computer programmers or engineers who were aware of its technical limitations and the possible points of failure, which would inform their interpretations of the data. In the future, liability may be a key issue as more people use the system. Given that a large number of individuals from a global community contributed both to the original codebase and provided technical suggestions to individual users, it is unclear who would be liable. A foundation was created by the community to help protect the volunteer developers and contributors; however, ownership of code when created by many is still a new phenomenon that would be challenging in a legal scenario.

Third, there are regulatory challenges. Software that reads data from a medical device is technically regulated by the FDA, but only if it is being sold as a commercial product.³ This is not the case for the Nightscout system, which has been distributed for free via a do-it-yourself model of dissemination, and to date, there has been no action by the FDA to prevent sharing of the code.

Fourth, there are issues of access. The system is predicated on having access to a CGMS; however, a recent study of a type 1 diabetes cohort reported that just 11% of individuals use a CGMS.⁴ Compared with nonusers, users of a CGMS have a higher educational level, higher household income level, and are more likely to have private health insurance.⁵ However, a CGMS is not universally covered by all insurance plans; therefore, many individuals who may benefit from a CGMS and the Nightscout system may not have access to the technology.

Although commercially available FDA-approved mobile technology solutions now exist for viewing blood glucose levels from the CGMS on mobile telephones (eg, Dexcom G4 Platinum Share), the number of individuals in the Nightscout Facebook group continues to increase. The project has led to increased innovation within the diabetes community, with community members now combining elements of a commercial CGMS system with the Nightscout system as well as creating novel solutions for blood glucose prediction and management, including developing their own hardware solutions for glucose monitoring,² and closed-loop artificial pancreas technology.⁶ These components, however, are not part of the general Nightscout package.

The Nightscout Project is changing current definitions of health production and patient engagement. Some critics may raise questions about the project such as: Should patients even be doing this type of activity? Is distributing the code dangerous? Should the code be regulated by the FDA? Should the FDA shut down the Facebook group?

However, a different set of questions may be more relevant such as: How might the current health care delivery system integrate patients and caregivers more fully into the design of health systems, tools, and technologies? How might open-source coding and large-scale collaborative communities be used for solving problems in health? How might health care stakeholders leverage technologies like social media to scale the communication and dissemination of innovations in health?

The Nightscout community leadership has engaged with the FDA on a regular basis with the hope of receiving approval for Nightscout for monitoring purposes, which would reflect an important milestone for patient-driven design. In addition, a collaborative approach to patient-driven research is being explored jointly by the community with researchers.⁷ As the Nightscout Project continues to develop and unfold, the questions it raises should lead to greater opportunities for patients and their families to help drive innovation in the health care delivery system.

ARTICLE INFORMATION

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